



INDUSTRY
COMMISSION

THE PHARMACEUTICAL INDUSTRY

VOLUME 1: THE REPORT

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This Report comprises two volumes. Volume 1 contains the Overview and the body of the Report and is divided into two parts. Part A outlines the current industry position and policy environment. Part B outlines the key influences on the industry and options for reform. Volume 2 comprises supporting appendices.

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ABBREVIATIONS

ABS	Australian Bureau of Statistics
ADEC	Australian Drug Evaluation Committee
ADR	Adverse Drug Reaction
ADRAC	Adverse Drug Reactions Advisory Committee
AHIDF	Australian Health Industry Development Forum
AHMAC	Australian Health Ministers' Advisory Council
AIDS	Acquired Immune Deficiency Syndrome
AIHW	Australian Institute of Health and Welfare
AIPO	Australian Industrial Property Organisation
AMA	Australian Medical Association
ANAO	Australian National Audit Office
APA	Advance Pricing Agreement
APAC	Australian Pharmaceutical Advisory Council
APMA	Australian Pharmaceutical Manufacturers Association
ARC	Australian Research Corporation
ARTG	Australian Register of Therapeutic Goods
ATO	Australian Taxation Office
BIE	Bureau of Industry Economics
Blue Book	Doctor's copy of the Schedule of Pharmaceutical Benefits
BP	British Pharmacopoeia
BRRU	Business Regulation Review Unit
CBA	Cost Benefit Analysis
CEA	Cost Effectiveness Analysis
CGRD	Competitive Grants for Research and Development
CHF	Consumers' Health Forum
COAG	Council of Australian Governments
COPS	Centre of Policy Studies (Monash University)
CPI	Consumer Price Index
CPMP	Committee for Proprietary Medicinal Products (EU)
CRC	Cooperative Research Centre
CRG	Collaborative Research Grant
CSIRO	Commonwealth Scientific and Industrial Research Organisation
CSM	Committee on Safety of Medicines (UK)

CTN	Clinical Trials Notification Scheme
CTTAC	Clinical Trials and Treatments Advisory Committee
CTX	Clinical Trials Exemption Scheme
CUA	Cost Utility Analysis
DCS&H	Victorian Department of Community Services and Health
DEET	Commonwealth Department of Employment, Education and Training
DHFS	Commonwealth Department of Health and Family Services
DHSH	Commonwealth Department of Human Services and Health (now DHFS)
DIFF	Development Import Finance Facility
DIST	Commonwealth Department of Industry Science and Tourism (formerly DIST {Technology})
DIST	Commonwealth Department of Industry Science and Technology
DSEB	Drug Safety and Evaluation Branch (formerly Drug Evaluation Branch - DEB)
DTA	Double Taxation Agreement
DTR	Draft Taxation Ruling
DUSC	Drug Utilisation Sub-Committee
EC	European Community
EDB	Economic Development Board (Singapore)
EFIC	Export Finance and Insurance Corporation
ELF	Electronic Lodgement Facility
EMDG	Export Market Development Grants
EMEA	European Medicines Evaluation Agency (EU)
EP	European Pharmacopoeia
EPOA	Expert Panel of Antibiotics
ESC	Economics Sub-Committee
EU	European Union
FDA	Food and Drug Administration (US)
FDCA	<i>Food Drug and Cosmetic Act 1938 (US)</i>
FFS	Fee-For-Service
FICI	Federation of Irish Chemical Industries (Ireland)
GAO	General Accounting Office (US)
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practice
GMPALS	Good Manufacturing Practice Audit and Licensing Section

GMS	General Medical Services (Ireland)
GP	General Practitioner
HHLGCS	Health Housing Local Government Community Services
HIC	Health Insurance Commission
HIF	Health Insurance Fund
HMO	Health Maintenance Organisation
HRA	<i>Health Reform Act</i> 1989 (Germany)
IAC	Industries Assistance Commission
IC	Industry Commission
ICH	International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use
IEC	Institutional Ethics Committee
IIP	Industry Innovation Program
IMS	Intercontinental Medical Statistics
IR&D	Industry Research and Development
ISO	International Organisation for Standardisation
ITES	International Trade Enhancement Scheme
IVD	In Vitro Diagnostic good
IVF	In Vitro Fertilisation
MBS	Medical Benefits Scheme
MCA	Medicines Control Agency (UK)
MEC	Medicines Evaluation Committee
MHW	Ministry of Health and Welfare (Japan)
MITI	Ministry of International Trade and Industry (Japan)
MNE	Multinational Enterprise
MRA	Mutual Recognition Agreement
NAFTA	North American Free Trade Agreement
NCCTG	National Coordinating Committee on Therapeutic Goods
NCE	New Chemical Entity
NDPSC	National Drugs and Poisons Schedule Committee
NFA	National Food Authority
NFAA	Nutritional Foods Association of Australia
NFSC	National Food Standards Council
NHMRC	National Health and Medical Research Council
NHS	National Health Service (UK)
NIES	National Industry Extension Service

NMDP	National Medicinal Drug Policy
NPDA	National Pharmaceutical Distributors Association (Sweden)
NSIB	National Social Insurance Board (Sweden)
OECD	Organisation for Economic Co-operation and Development
ORR	Office of Regulation Review
OTC	Over The Counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBB	Pharmaceutical Benefits Branch
PBM	Pharmaceutical Benefit Manager
PBPA	Pharmaceutical Benefits Pricing Authority
PBPB	Pharmaceutical Benefits Pricing Bureau
PBRT	Pharmaceutical Benefits Remuneration Tribunal
PBS	Pharmaceutical Benefits Scheme
PDF	Pooled Development Fund
PES	Pharmaceutical Evaluation Section
PHARM	Pharmaceutical Health and Rational use of Medicines Committee
PhRMA	US Pharmaceutical Research and Manufacturers Association
PIDP	Pharmaceutical Industry Development Program
PIS	Personal Import Scheme
PMAA	Proprietary Medicines Association of Australia
PPP	Purchasing Power Parity
PPRS	Pharmaceutical Price Regulation Scheme
PPS	Prospective Payments System
PRA	Pharmacy Restructuring Authority
PSA	Pharmaceutical Society of Australia
QALY	Quality adjusted life year
R&D	Research and Development
RACGP	Royal Australian College of General Practitioners
RACP	Royal Australasian College of Physicians
RHA	Regional Health Authority (NZ and UK)
RPBS	Repatriation Pharmaceutical Benefits Scheme
Rx	Prescription
SAS	Special Access Scheme
SIRF	Strategic Industry Research Foundation
SME	Small and Medium Enterprise
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TDEC	Therapeutic Devices Evaluation Committee

TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code
TGAL	Therapeutic Goods Administration Laboratories
TGC	Therapeutic Goods Committee
TGO	Therapeutic Goods Orders
TLC	Therapeutics Liaison Committee
TMEC	Traditional Medicines Evaluation Committee
TR	Taxation Ruling
TRIPs	Trade Related aspects of Intellectual Property agreement
TTMR	Trans-Tasman Mutual Recognition
USP	United States Pharmacopeia
WHO	World Health Organisation
WST	Wholesale Sales Tax
Yellow Book	Pharmacists' copy of the Schedule of Pharmaceutical Benefits

GLOSSARY OF DRUGS MENTIONED IN THIS REPORT

<i>Drug</i>	<i>Description</i>
Act-3	non-steroidal antiinflammatory
Actiprofen	non-steroidal antiinflammatory
Acyclovir	antiviral, treatment for herpes simplex
Aldomet	antihypertensive
Amfamox	peptic ulcer treatment
Amoxil	antibacterial
Amphotericin buccal	antibiotic, antifungal, treatment of mouth conditions
Becloforte	antiasthmatic
Becotide	antiasthmatic
Benzoyl peroxide	treatment for pimples, acne
Bricanyl	antiasthmatic
Canesten	antifungal
Carboplatin	cancer treatment
Carduran	antihypertensive
Ceclor	antiinfective
Ciprofloxacin	oral antimicrobial
Cisplatin	cancer treatment
Claratyne	non-sedating antihistamine
Clarithromycin	antibiotic
Clavulin	antibacterial
Clindamycin	treatment for pimples, acne
Clinoril	antiinflammatory

Codeine phosphate	analgesic
Codeine phosphate with paracetamol	analgesic
Cutivate	topical corticosteroid
Cytarabine	cancer treatment
Daivonex	psoriasis treatment
Daktarin	antifungal
Dermovate	topical corticosteroid
Dexamethasone	corticosteroid
Dicodin	analgesic
Diflucan	antiinfective
Dihydrocodeine	analgesic
Dolobid	antiinflammatory
Doryx	antibacterial
Doxazosim	antihypertensive
Dymadon	analgesic
Enalapril maleate	antihypertensive
Eryc	antibacterial
Erythromycin	antibacterial
Erythromycin ethyl succinate	antibacterial
Flixonase	perennial rhinitis treatment
Flixotide	antiasthmatic
Floxapen	antibacterial
Fluoxetine hydrochloride	antidepressant
Gyno-Daktarin	antifungal

Hismanal	non-sedating antihistamine
Hydrocortisone	antiinflammatory, anti-itch, treatment for a range of skin conditions
Hytrin	treatment for benign prostatic hyperplasia
Ibuprofen	antiinflammatory
Imdur	cardiac therapy
Imigran	migraine treatment
Indocid	antiinflammatory
Insulin	diabetes treatment
Kapanol	analgesic
Ketoprofen	antiinflammatory
Lamictal	antiepileptic
Lipex 10	lipid-lowering drug
Lispro	diabetes treatment
Lorabid	antibiotic
Losec	ulcer treatment
Lotremin	antifungal
Mefenamic acid	antiinflammatory
Minoxidil	baldness
Moduretic	diuretic
Nabumetone	treatment for osteo- and rhematoidal arthritis
Naproxen	antiinflammatory
Nicotine patch, gum	treatment to encourage smoking cessation
Noroxin ophthalmic	antibiotic eye drop
Nurofen	antiinflammatory
Nyoprin	analgesic
Nzoral	antifungal shampoo for dandruff

Oxybutinin	urinary incontinence treatment
Paclitaxel	cancer treatment
Panadeine	analgesic
Panadeine Forte	analgesic
Panadol	analgesic
Paracetamol	analgesic
PedvaxHIB	vaccine
Penicillin	antibiotic
Pepcidine	peptic ulcer treatment
Piroxicam	antiinflammatory
Plendil ER	calcium channel blocker
Ponstan	antiinflammatory
Prilose	ulcer treatment
Proctosedyl	antihemorrhoidal
Proscar	prostate treatment
Prozac	antidepressant
Pulmicort	antiasthmatic
Ranitidine hydrochloride	ulcer treatment
Relifex	treatment for osteo- and rheumatoid arthritis
Renitec	antihypertensive
Roxithromycin	antibacterial
Salbutamol sulphate	antiasthmatic
Serevent	antiasthmatic
Setamol	analgesic
Silver sulphadiazine	antibiotic for wounds, burns
Simvastatin	lipid-lowering drug

Sinemet CR	anti-Parkinson drug
Sumatriptan	migraine treatment
Tagamet	peptic ulcer treatment
Taxol	cancer treatment
Teldane	non-sedating antihistamine
Temaze 10	antipsychotic
Temazepam	antipsychotic
Thalidomide	sedative
Timoptol	ophthalmological solution
Timpilo	ophthalmological solution
Tomocard	cardiovascular
Tramal	analgesic
Triamoinalene buccal	antiinflammatory, mouth conditions
Tylenol	analgesic
Vancomycin	antibiotic, intestinal antiinfective
Ventolin	antiasthmatic
Zantac	ulcer treatment
Zinacef	injectible antibiotic
Zinnat	antibiotic
Zithromax	antibacterial
Zocor	lipid-lowering drug
Zoloft	antidepressant

TERMS OF REFERENCE

I, GEORGE GEAR, Assistant Treasurer, in pursuance of Part 2 of the *Industry Commission Act 1989* hereby:

1. refer the pharmaceutical industry to the Industry Commission for inquiry and report within nine months of the date of receipt of this reference (subsequently amended to 26 April 1996);
2. specify that in making its recommendations the Commission aim to improve the overall economic performance of the pharmaceutical industry, encompassing the prescription drug sector and the over-the-counter sector, and the overall performance of the Australian economy;
3. request the Commission to report, separately for the prescription drug and over-the-counter sectors where appropriate, on:
 - (a) emerging national and international market trends affecting the industry including its current structure, rationalisation and competitiveness, drawing international comparisons where appropriate;
 - (b) the strengths and weaknesses of the industry in Australia, based on international comparisons;
 - (c) the advantages and disadvantages of Australia as an investment location for all phases of pharmaceutical activity, from research and development through to manufacturing and export. In doing so, the Commission should report on programs in other countries designed to create a favourable environment for industry;
 - (d) the potential for the industry to capture a greater share of the global pharmaceutical market, especially of the rapidly growing markets in our region, and impediments to achieving this potential;
 - (e) the impact of current institutional and regulatory measures, including the Factor (f) Scheme, the Pharmaceutical Benefits Scheme (PBS) and the National Medicinal Drug Policy, on industry structure, performance, international competitiveness, resource allocation and growth prospects;
 - (f) the effectiveness of the current link between Australian universities, research institutions and pharmaceutical companies, including the commercialisation of new products, particularly by small and wholly Australian owned pharmaceutical companies;

-
- (g) any measures which could be undertaken to remove or compensate for impediments or otherwise contribute to the efficiency, growth or export development of the industry;
 - (h) long term policies to provide certainty and continuity for investment in pharmaceutical research and development, manufacturing and exports;
 - (i) the identification of groups which would benefit from, or be disadvantaged by, any measures flowing from 3 (g) and (h) above; and
 - (j) the implementation of proposed measures, including the impact of changes to current arrangements;
 4. having regard for both the prescription drug and the over-the-counter sectors, request the Commission to:
 - (a) identify and quantify the economic contribution of the Australian pharmaceutical industry;
 - (b) evaluate the effectiveness and efficiency of the Factor (f) Scheme, including quantifying the benefits of Factor (f) Scheme assistance; and
 - (c) identify the overall gains to the economy, including the pharmaceutical industry, if the policies recommended in 3(g) and (h) are implemented;
 5. specify that the Commission:
 - (a) take account of, but not make recommendations in relation to, the PBS and the supply of pharmaceuticals under the PBS;
 - (b) take account of any recent substantive studies, and document, where appropriate and without disclosing material provided in confidence, examples of past success and failures in the industry, both in Australia and elsewhere; and
 - (c) have regard to the established economic, social, health and environmental objectives of Government and the effect of those objectives on the industry.

GEORGE GEAR

9 June 1995

KEY MESSAGES

- A strong link between the development of the Australian pharmaceutical industry and coherence of government policy has been identified.
- There are a number of impediments to industry growth, of which the PBS is most important.

Reforms to PBS:

- Low prices, volume constraints and listing delays under the PBS play a significant part in influencing company investment decisions.
- However, there is no clear cut case for ongoing financial intervention through a Factor f type scheme.
- A preferable approach is to reform the PBS listing process as a matter of urgency.
- Also an independent pricing authority should be established.
- The welfare of the community is enhanced by the PBS but this is threatened by growing pressures on the scheme.
- There is a risk that the community's future access to some drugs may be adversely affected.
- Thus it is also necessary to review the social and economic policy underpinnings of the PBS itself.
- If fundamental reform of PBS processes is not an immediate priority, a revised Factor f type scheme could be introduced in the interim.
- For the current Factor f scheme:
 - the effectiveness has been reduced through overcompensation of some companies and undercompensation of others;
 - it is unlikely that the benefits to the community outweigh the costs; and
 - severe administrative problems are evident.

Other reforms:

- The TGA should be established as a Commonwealth statutory authority.
- The Commonwealth Government should cooperate with the States and Territories to establish the TGA as the appropriate body to undertake scheduling.
- Brand advertising of S3 products should be allowed where there is a demonstrated health benefit.
- There is scope to combine the Government's approach to a 15 year effective patent life with a period of generic springboarding and some protection of confidential information.
- The Australian Tax Office should clarify its position on transfer pricing and wholesale sales tax arrangements.
- Implementing these reforms could be completed before 1999 when the current Factor f scheme ceases.

RECOMMENDATIONS

1. The Commission recommends that under the current arrangements companies should have the option of taking their remaining Factor f payments as actual rather than notional price increases.
2. The Commission recommends that companies should have the option of delaying cost effectiveness analysis for two years to allow for the collection of costing data based on actual use.
3. The Commission recommends that a data base of Australian and international pharmaceutical prices, volumes and market shares be established.
4. The Commission recommends that, as a matter of urgency, the Pharmaceutical Benefits Scheme listing process be subject to a review.
5. The Commission recommends that all States and Territories pass complementary legislation to broaden the application of the *Therapeutic Goods Act 1989* by adopting its provisions and future amendments by reference.
6. The Commission recommends that Australia, through the Therapeutic Goods Administration:
 - continues to pursue harmonisation of standards and data requirements;
 - pursues further agreements to exchange evaluation reports and to undertake joint evaluations;
 - while reserving the option of conducting its own evaluations, on a case by case basis places greater weight on overseas approvals by regulators with comparable standards and known expertise in a particular area; and
 - in the longer term, pursues mutual recognition of drug approvals with countries with comparable regulatory standards while maintaining an independent capacity to conduct evaluations where required by unique Australian conditions or where requested by suppliers.
7. The Commission recommends that the Therapeutic Goods Administration be established as a Commonwealth statutory authority.
8. The Commission recommends that both schedule 2 'pharmacy only' and schedule 3 'pharmacist only' be retained, pending further research into the role of pharmacist counselling in ensuring improved health outcomes and the monitoring of the extent of such counselling.
9. The Commission recommends that, where it can be demonstrated that brand advertising of particular schedule 3 'pharmacist only' products will lead to improved health outcomes, such advertising should be permitted on a case by case basis, subject to appropriate industry self-regulation.
10. The Commission recommends that the scheduling of therapeutic goods becomes the responsibility of the Commonwealth Government under the Therapeutic Goods Administration.

OVERVIEW

This Report is about the Australian pharmaceutical industry.

This Report is about the pharmaceutical industry in Australia, its relationship to the global industry and its potential for further development.

The Commission was asked to examine the performance, prospects and economic contribution of the human use pharmaceutical industry in Australia and to make recommendations to improve the industry's efficiency and to remove impediments to its growth. The Inquiry was mainly concerned with the activities of companies which manufacture, import or distribute prescription or over the counter (OTC) pharmaceuticals. It extended to all stages of pharmaceutical activity, from research and development (R&D) through to manufacturing and export. It also covered the institutional research framework associated with the industry, including linkages to universities and other research institutions.

A major part of the Commission's task has been to evaluate the impact of the present Government policy environment on the industry. The most important of these policies are the Pharmaceutical Benefits Scheme (PBS) and the Factor f scheme. The terms of reference preclude the Commission from making recommendations about the PBS itself. However, the Commission is required to assess the impact of the PBS on the performance and development of the industry.

Industry development is closely linked to Government policy.

1 Policy coherence and stability

The Commission found that there is a strong link between the ongoing development of the industry in Australia and the coherence and stability of Government policy.

In a rapidly changing world, all industries face uncertainty in their business environments and success depends on the ability to adapt to change. However, for research-based pharmaceutical companies, high R&D costs, long lead times in new product development and governments' extensive involvement in markets make uncertainty a more significant issue. As a result of rapid internationalisation of pharmaceutical markets and domestic cost pressures, the Australian industry is facing extensive change in its markets and in its production and research activities.

Australia is perceived as a favourable investment location ... Australia is seen by industry decision makers as a favourable location on both economic and political considerations. However, a number of factors under the control of governments have reduced the attractiveness of the operating environment by increasing uncertainty. In broad terms, investment is claimed by the industry to be lower than it would otherwise be due to perceptions of:

- inconsistency of the Commonwealth Government's policy stance towards the industry—for example, PBS cost containment practices, failure to address satisfactorily the tension between health and industry policy and problems in administration of the Factor f scheme;
- unresponsiveness of PBS policy—particularly to developments in health policy in Australia and elsewhere in the world; and
- uncoordinated administration—particularly of closely related and interacting pricing, tax and intellectual property rules and drug evaluation and scheduling policies.

... but there are negative perceptions of some policies.

The Commission has assessed these claims in order to identify the major impediments to the future development of the industry and to comment on whether the community is receiving value for money from the financial support currently provided through the Factor f scheme.

2 Government policies affecting the industry

The NMDP brings together ...

Government health and industry policies have a significant impact on the pharmaceutical industry in Australia. Commonwealth policies relating to pharmaceuticals are brought together in the National Medicinal Drug Policy (NMDP).

... pre-market assessment ...

Consumers and manufacturers alike recognise the legitimate role of regulation in protecting public health and safety. The Therapeutic Goods Administration (TGA) undertakes pre-market assessment of pharmaceuticals to ensure their safety, quality and efficacy. Detailed schedules specify the ways that drugs may be sold: on prescription only, from a pharmacist, through a pharmacy or unrestricted. The advertising and labelling of products are also tightly regulated.

... the PBS ...

The PBS subsidises all consumers for pharmaceuticals whilst targeting extra assistance to those most in need via

concessional copayment and safety net provisions. It is one of 60 health related programs provided by Commonwealth and State Governments and accounts for approximately 78 per cent of total prescription drug sales. In 1994–95, over 118 million scripts, costing \$2.4 billion, were provided under the PBS. The Commonwealth Government contributed \$2 billion to the total cost and consumer copayments were \$445 million. The Government contribution represented 13 per cent of the total Commonwealth health budget.

National Medicinal Drug Policy

The four arms of the NMDP are:

- The supply of medicines of established and acceptable quality, safety, and efficacy. The standard of medicinal pharmaceuticals is assured through the activities of the Therapeutic Goods Administration (TGA) and the Australian Drug Evaluation Committee (ADEC).
- Timely, reliable and affordable access by the community to necessary medicines, made possible through the PBS.
- The quality use of medicines by health care providers and consumers. A key body developing this arm is the Pharmaceutical Health and Rational Use of Medicines Committee (PHARM).
- The maintenance of a viable pharmaceutical industry, which is the role of the Department of Industry, Science and Tourism (DIST), through the Factor f scheme.

Government outlays on the PBS are rising, both in real terms and relative to the total health budget. Real outlays have increased by 8 per cent annually in the decade to 1994–95, making it the fastest growing health care program. They are projected to grow in real terms by 7 per cent each year over the next five years.

*... the quality use
of medicines ...*

The Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health and Rational Use of Medicines Committee pursue research and consumer education projects aimed at ensuring that pharmaceuticals are used appropriately. Expenditure on education related to quality use of medicines was \$3 million in 1993–94.

How Factor f works

The Factor f scheme grants notional price increases for PBS products in return for increases in activity. It is called ‘Factor f’ because factors to be taken into account in setting prices are identified alphabetically—industry activity is the sixth factor. The main features of the scheme are that:

- companies are eligible to enter the scheme if they meet and maintain increases in eligible activity (R&D and value added production), or otherwise prove they are making a significant contribution to internationally competitive production in Australia;
- payments are a maximum of 25 per cent of the value of additional activity over the level that existed in the base year (typically the year before the company entered the scheme);
- payments are translated into notional price increases for PBS products. The maximum price increase is to the level of the average European price of the product. The actual prices of the products are not affected; and
- payments to companies are made quarterly in arrears.

... and Factor f,
costing \$1 billion.

The Pharmaceutical Industry Development Program, introduced in 1987, aimed to encourage the development of a viable pharmaceutical industry in Australia. The Factor f scheme was the centrepiece of this program. Phase I of the scheme commenced in 1988. Phase II commenced in 1992 and runs until 1999. Total Factor f funding to 1999 is around \$1 billion dollars. The scheme is the largest budget item of specific sector payments to manufacturing.

Factor f budgeted payments and commitments, 1988–99, \$ million

<i>Payment and commitments</i>	<i>Export value added</i>	<i>Domestic value added</i>	<i>R&D</i>	<i>Total</i>
Payments				
Phase I	128	24	18	170
Phase II	368	367	77	812
Total	496	391	95	982
Commitments				
To 30 June 1994 (Phases I and II)	582	847	244	1673
Total Phases I and II	1900	1900	540	4340

3 The pharmaceutical industry

The global industry is large ...

The global pharmaceutical industry is large, with annual sales of about US\$215 billion in 1994–95. Prescription or research-based products account for about 80 per cent of global sales with the OTC element making up the remaining 20 per cent. The global industry has experienced strong sales growth of over 10 per cent a year for an extended period. Australian sales make up about one per cent of the world market.

The industry is dominated by large multinational corporations. It features economies of scale in developing knowledge-intensive products and manufacturing active ingredients and a high level of risk in research and development (R&D). The international industry is generally considered to be competitive, despite an increase in concentration in recent years. Most of the large multinational companies have formulation or packaging operations in Australia. There are a small number of significant locally based companies such as Faulding, Sigma, CSL and AMRAD.

Australian industry trends

Production: Estimated turnover less imports of just over \$2 billion in 1993–94, up from \$877 million in 1987–88.

Sales: \$3.8 billion (including exports) in 1994. Increased by over 200 per cent between 1987 and 1994.

R&D: Estimated by industry at over \$170 million in 1993–94 and projected to increase to \$250 million by 1997–98.

Exports: \$770 million in 1994–95. Increased by \$500 million since 1989–90.

Imports: \$1.56 billion in 1994–95. Increased by \$740 million since 1989–90.

Export/import ratio: Increased from 33 per cent to 49 per cent between 1989–90 and 1994–95.

Employment: Remained stable for 20 years. Currently around 12 000.

Share of GDP: Direct value added of \$745 million representing 0.18 per cent of GDP.

Three features characterise pharmaceutical sectors in all developed economies:

- R&D and patent protection play a key role in company success;

- operations involve both significant risks and high potential returns; and
- they are subject to heavy government regulation.

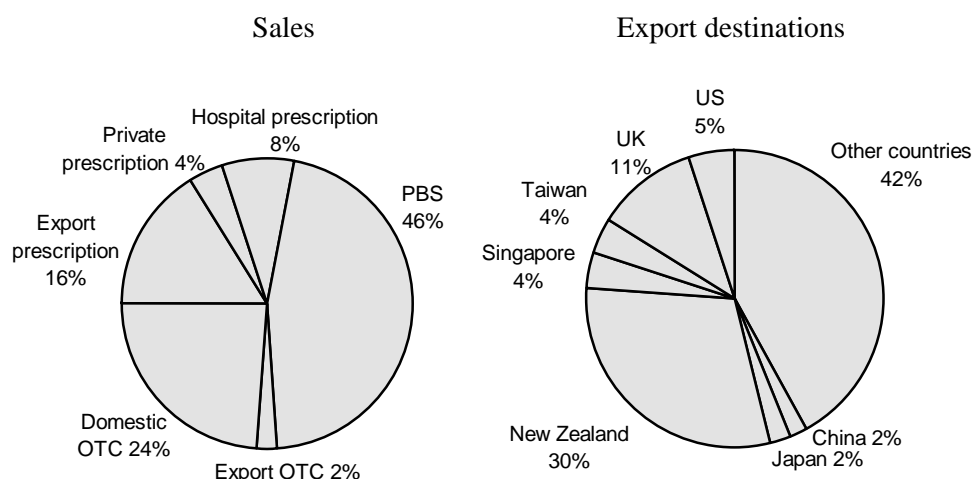
... and R&D is important.

The global pharmaceutical industry spends relatively more on R&D than most industries, about 15 per cent of sales revenue, to maintain a flow of new products onto the market. Success in this area determines longer term profitability. It can take up to US\$400 million and 15 years to develop an original pharmaceutical product and perhaps only one in 5000 chemical compounds identified will eventually lead to a marketable product. Besides uncertain R&D outcomes, there are also major risks associated with new competitor products, regulation and product liability.

Australian R&D spending is around 5% of sales.

Significant R&D is undertaken in Australia (\$172 million or 5 per cent of sales in 1993–94) but this is considerably below the world average mainly because multinational companies draw on research done by their parents. The R&D which is undertaken is generally in the areas of product development and clinical trials, although it is increasingly being directed towards basic and pre-clinical research. There are strong links between pharmaceutical companies and specialist research organisations, which account for about 40 per cent of all R&D spending.

Shares of pharmaceutical sales and export destinations, Australia, 1994



Governments in most developed countries can have a major impact on company and industry profitability. Governments typically subsidise the cost of drugs to at least some members of the community and regulate the conditions under which drugs can be supplied.

The industry has experienced strong sales growth ...

The Australian industry and the local pharmaceutical market have been growing strongly in recent years. The market is dominated by sales of prescription products through the PBS.

Although direct comparisons are difficult to make, the level of profitability of Australian pharmaceutical operations appears to be lower than those of international companies.

... particularly export sales to our region.

Export sales have surged in the 1990s. Australia now supplies pharmaceuticals to countries in the region, particularly New Zealand, as well as to wider markets.

4 Australian industry in transition

International trends

The global industry is rationalising ...

Since the mid 1980s the industry has been going through a major restructuring driven by both internal and external factors.

A key contributor to strong growth in demand for pharmaceuticals is the ageing of populations which increasingly require treatment for chronic and degenerative diseases. New treatments are becoming more expensive.

Many different approaches are being adopted worldwide to contain growing health care costs. They typically involve measures such as controls over the prices or profits of pharmaceutical companies, controls over usage of drugs, use of copayments and making health care providers responsible for containing their costs. By these means the major buyers of drugs—governments and private insurers—are putting pressure on company revenues.

There are also a number of important forces influencing company cost structures and the pattern of supply of drugs. These include rising costs of new drug development and technological developments, particularly in the formulation stages of production. For example, the expiry of the patents of many major drugs developed during the 1960s and 1970s and rising R&D costs have increased the difficulty of maintaining

... through company mergers and plant closures.

a new product pipeline. It is estimated that the cost of developing a new drug will increase to about US\$700 million by 2000.

Multinational companies are responding to these trends in demand and supply by horizontal and vertical rationalisation and by moving their operations to the most strategic locations. Such changes are directed at benefiting from economies of scale in the production of active ingredients, formulation and R&D and at acquiring research programs, potential new products and existing products in order to secure a long term future. This has led to numerous plant closures, with the prospect of still more. Having restructured their operations in Europe, companies are seeking similar gains from their Asia-Pacific operations.

This represents an opportunity for Australia.

Australia as an investment location

Changes to the international structure of the industry present opportunities for Australia. But they also pose threats. The outcomes for the local industry will depend on the strengths and weaknesses of the Australian industry and Australia's relative attractiveness as an investment location.

The Australian industry has considerable strengths ...

Strengths and weaknesses

The Commission's assessment of the industry's key strengths and weaknesses is shown in the table below.

Key strengths appear to be the ready availability of skilled research personnel and opportunities for interaction with an extensive network of publicly funded research institutions. Location in the Asian region is also an important strength.

... but the PBS is a major weakness.

The main weaknesses are the operations of the PBS in holding down prices, restricting indications for which certain drugs are listed and causing delays in the release of new products onto the market. The treatment of the industry by the Australian Taxation Office (ATO) with respect to transfer pricing and wholesale sales tax is also seen as a weakness.

Emerging opportunities and threats

The Commission has assessed the opportunities and threats facing the industry in its international and domestic environment. Its future development path will be influenced by the way it responds to these.

Many of the multinational pharmaceutical companies have a significant presence in Australia and their choices about future directions are likely to play a large part in shaping the development of the domestic industry. Ongoing global rationalisation may lead to more devolution of previously centralised activities such as R&D, providing further opportunities for external linkages with specialist companies and research institutes. On the other hand, surplus capacity in manufacturing will continue to lead to a consolidation of this function in fewer regional production centres.

Strengths and weaknesses of the pharmaceutical industry

	<i>Strengths</i>	<i>Weaknesses</i>
<i>Research and development</i>	<ul style="list-style-type: none">• Good research infrastructure• Research expertise• Research links• Clinical trial capabilities	<ul style="list-style-type: none">• Questions over adequacy of R&D infrastructure• Shortages of specialist skills
<i>Government programs</i>	<ul style="list-style-type: none">• R&D assistance	<ul style="list-style-type: none">• Uncertainty about the long term availability of assistance (esp. Factor f)
<i>Government regulation</i>	<ul style="list-style-type: none">• Efficient registration process	<ul style="list-style-type: none">• PBS pricing• PBS listing process• PBS volume constraints• Policy inconsistency• Scheduling inconsistencies• Failure to implement Government commitment to extend patent life
<i>Other factors</i>	<ul style="list-style-type: none">• Skilled local management pool• Proximity to Asian markets• Efficient manufacturing base	<ul style="list-style-type: none">• Difficulty in resolving taxation issues (transfer pricing and WST exemption)

The prospect of rapid growth in Asian markets has created considerable opportunity. Australia represents an attractive regional export base for subsidiaries of multinational companies.

Reform is needed to capture opportunities.

The major impediment appears to be the lack of attention that has been given to ensuring that the domestic policy environment responds to the growing pressures on the PBS and reflects global changes in pharmaceutical markets. Significant problems still have to be resolved in a range of

other areas such as intellectual property regimes and coordinated regulation. While the Factor f scheme has partly addressed these problems in the short term, there is a widely held view that it has been unable to mask the need for more fundamental reform.

The Australian industry can use its strengths to take advantage of the opportunities it faces if its policy environment can be improved.

5 Pharmaceutical Benefits Scheme

Under the PBS, the Commonwealth Government exerts considerable market power over the supply of drugs and, particularly, the price it pays.

Government market power keeps PBS prices low ...

Major issues for this Inquiry are the extent to which prices paid to companies in Australia are lower than elsewhere and the extent to which these lower prices affect companies' locational decisions. The Commission examined price information provided by companies and price comparison studies from a number of sources.

Most information on relative prices available to the Commission suggests that PBS prices remain significantly lower than international prices but the difference is narrowing, particularly for new drugs.

... but some new drug prices are higher.

Comparisons of prices paid to pharmaceutical companies

Study	Year	Benchmark countries	Products	Aust. price as per cent of overseas average price	
				Unweighted (%)	Weighted (%)
Parry & Thwaites	1987	11 OECD countries	top selling	55	
BIE	1990	European Union	top selling	55	
APMA	1995	OECD	top selling	71	54
APMA	1995	OECD	new	85	70
PBPA	1996	UK	top selling	84	67
PBPA	1996	UK	new	92	83

Low prices save taxpayers \$860 million ...

The Commission estimates that the Government's use of market power saves taxpayers up to \$860 million a year.

The effect of price suppression will vary across the PBS market. One way of categorising the market is as follows:

- Category 1 drugs—unique, breakthrough drugs that are the only effective form of treatment and where there is no direct comparator;
- Category 2 drugs—drugs that are first in a new therapeutic class with equivalent efficacy as other drugs but with quality of life and/or safety improvements, including better modes of delivery of active ingredients;
- Category 3 drugs—‘me-too’ drugs in the same chemical family with no additional benefits; and
- Category 4 drugs—out of patent products.

Price suppression under the PBS is likely to have a different effect for each category.

Some companies have temporary market power when their products have no close substitutes (category 1). At the other end of the market (category 4) there is fierce competition between similar products.

... but this comes at a cost.

Where government chooses to exercise market power by holding down prices below levels in comparable countries or by imposing other restrictions, drug availability and industry activity in Australia could be adversely affected. It may be possible to compensate for these effects directly—by negotiating higher prices, or indirectly—by funding programs designed to buy back some of the lost activity. However, such intervention may result in inefficient outcomes, unless the sections of the market with the greatest adverse effects can be targeted. It appears to the Commission that the case for any intervention is strongest for innovative products (categories 1 and 2).

Impact of the PBS on availability of drugs

Given increasing drug costs, it will become more difficult to maintain current subsidy arrangements for a broad range of drugs. The tension between the Government’s need to contain PBS outlays and companies’ willingness to supply pharmaceuticals on the Government’s terms can limit drug availability to the community. If this occurs the health and wellbeing of the community may be affected.

The Government tries to contain costs in various ways

which may have a direct or indirect impact on availability. When faced with an unacceptable price offer, a company can try to negotiate a better deal, leading to some delay in availability, permanently withhold the drug from the Australian market or supply the market outside the PBS. Some drugs are listed for a limited set of indications—they can be prescribed only for narrowly specified medical conditions or only after other treatments have failed. Cost effectiveness analysis, which now must be undertaken prior to listing, may narrow the range of indications. Another way is to require health professionals to seek specific authorisation for the drug's use from the Health Insurance Commission thus encouraging substitution with a lower cost alternative.

*Access to some
drugs is delayed or
rationed ...*

Companies trading internationally may be reluctant to supply to the PBS if they fear that buyers in other countries will take Australia's low prices into account. Participants argued that such benchmark pricing is becoming increasingly common, particularly for innovative drugs. While there is limited evidence of benchmark pricing with Australia, the threat of this practice could affect decisions about the supply of drugs.

There is evidence that the community's access to some drugs or important applications is adversely affected by the PBS, but to date these effects have not been significant. Australia currently has a comparable range of drugs to other developed countries.

*... causing
considerable
pressure on
the PBS ...*

However, this position is unlikely to be sustainable because the limiting of the market and delays in listing together have a significant impact on sales volumes of some drugs. When low prices are taken into account the overall impact of the PBS has been to reduce the sales revenues of some companies, increasing the risk of non-supply.

The subsidised supply of pharmaceuticals is already under considerable pressure which can be expected to increase over the next few years. The Government will want to contain costs in the face of an ageing population of consumers demanding higher cost drugs for a broader range of indications. Companies will be less willing in the future to accept prices or market restrictions that are less favourable than overseas. Increasingly, the Government will have to pay prices and impose restrictions at levels much closer to international norms.

However, increasing pressure for lower drug prices in other countries will narrow the gap between Australian and world

prices. This will reduce the adverse effects of the PBS on drug availability and industry activity.

... to which the Government will have to respond.

In attempting to maintain equitable and timely access to pharmaceuticals, the Government could respond by simply extending the use of current strategies—further copayment and safety net changes, encouraging generic substitution and providing more education on appropriate use. Such measures are only likely to be temporary and their use will not reduce current uncertainty.

Alternatively, given overseas trends and domestic pressures, the PBS may evolve into a more selective scheme, based on means testing eligibility, different subsidy arrangements or a more restricted listing of drugs. Other means of funding and supplying drugs may emerge through mechanisms such as the private prescription market, private insurance or adoption of ‘managed competition’ arrangements.

The impact of the PBS on industry activity

The PBS may constrain industry growth ...

The next important question is the extent to which low PBS prices, volume restrictions and listing delays reduce efficient domestic industry activity. To evaluate this the Commission examined evidence of activity that may have been ‘lost’ and possible direct and indirect links between the PBS and a lower level of activity.

Lost activity

Assessment of industry activity lost to Australia as a result of the PBS is difficult because of the impossibility of knowing what ‘might have been’ in the absence of a PBS. Also, the separation of the negative influences of the PBS from other influences on the performance of pharmaceutical companies is problematic.

Nonetheless, the Commission examined evidence from the Bureau of Industry Economics’ (BIE) survey, information provided by companies and some overseas evidence, notably that of the New Zealand industry. The scope of the problem is unclear in terms of the number of products and companies affected.

Direct links

... either directly ...

Despite limited objective evidence there are several direct ways in which low PBS prices could depress local activity.

One frequently cited by participants was country of origin

pricing—the practice of buyers in export destinations setting their prices on the basis of the price in a product’s home market. This would deter companies from production in low priced countries.

The Commission found little evidence of explicit country of origin pricing. A limited number of countries, which are not currently major export destinations for Australian pharmaceuticals, appear to use these policies. However, the threat of country of origin pricing may affect multinational company decisions about the location of production.

Another potential link is between the level of profits made in Australia and activity. The evidence on this is unclear, although any effect is likely to be greater for Australian companies.

... or indirectly ...

Indirect links

In the absence of strong evidence of direct links between PBS prices and local activity, examination of this question must rely on evidence of indirect links such as the contribution which low PBS prices, volume restrictions and listing delays make to the perceptions of Australia as an investment location by multinational companies. Such indirect links are difficult to demonstrate.

Investment decisions by multinational pharmaceutical companies are complex and multi-dimensional. They are not only based on a range of specific economic factors (such as prices, tax rates and return on investment) but also on companies’ perceptions of their operating environment.

Companies have indicated that low PBS prices are the most important indicator of a generally ‘hostile’ attitude in Australia. However, restrictions on indications and time to listing are also significant negative influences on company perceptions. Some broader factors are also viewed critically:

- a patent regime that is less generous than in the US and Europe;
- administration of transfer pricing policies by the ATO; and
- the lack of a ‘whole of Government’ approach toward industry leading to inconsistent treatment by different Government Departments.

The Commission considers that low prices, volume constraints

and listing delays under the PBS, combined with other policy and process uncertainties, are likely to play a part in corporate decisions about whether to locate activities in Australia. However, the weightings given to these factors by individual companies may vary.

... but the overall effect is unclear.

Based on available evidence, the Commission concludes that these factors appear to be depressing pharmaceutical activity below the level that might be achieved in a deregulated environment and impeding industry development.

The extent and significance of activity lost from price suppression and other restrictions imposed by the PBS is unclear. However, as Australia may have only marginal attractions over other possible investment locations, even a small increase in the risk associated with adverse perceptions could tip the scales against Australia as an investment location.

The Commission evaluated the Factor f scheme.

6 Evaluation of the Factor f scheme

The impact of PBS price suppression on activity was addressed by the Factor f scheme. As required by its terms of reference, the Commission evaluated the effectiveness and efficiency of the current Factor f scheme. The effectiveness of the scheme describes how well it meets its goal. Its efficiency refers to whether the reallocation of resources brought about by the scheme results in net benefits to the community.

To assist with the evaluation the BIE undertook a study based on a survey of pharmaceutical companies responsible for 70 per cent of PBS sales. The results of this study, information provided by participants and the Commission's own analysis, were taken into account. Additionally, the comparative performance of participants in the scheme and other pharmaceutical companies was analysed using information provided by the Australian Pharmaceutical Manufacturers Association (APMA).

Its purpose is to buy back efficient activity ...

Effectiveness

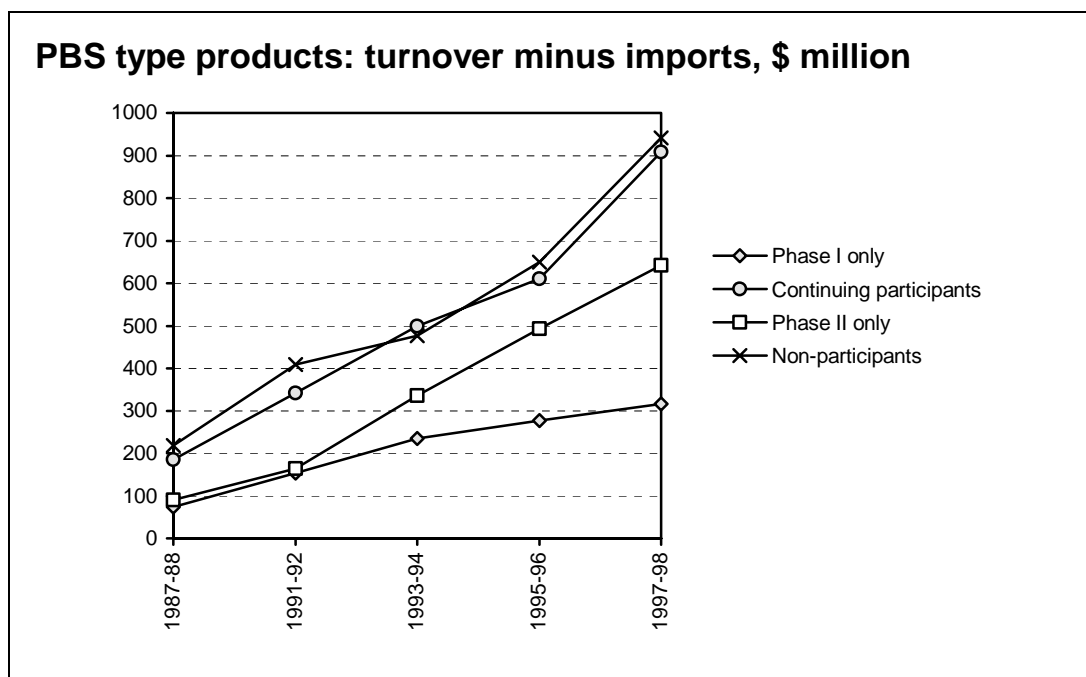
Although some participants argued that the purpose of the Factor f scheme is to promote industry development for its own sake, the Commission considers that the scheme's purpose is to restore efficient economic activity lost to Australia as a result of PBS price suppression. Effectiveness was evaluated against this goal by judging the success of the scheme in recreating the types, level and pattern of activity

which would have occurred in the absence of price suppression.

Some companies which were likely to have increased their activity were excluded from Phase II of the scheme because of imposed funding limits. Other companies were excluded because they were unable to meet the eligibility requirement that both R&D and production activity had to be undertaken. This resulted in undercompensation for the effects of the PBS on activity.

More importantly, some companies in the scheme, particularly those which continued from Phase I to Phase II, were overcompensated. One result was that Phase II payments are roughly double the size of planned investments under the scheme. Overcompensation came about mainly because the payment rate was too high.

The analysis of the comparative performance of Factor f participants and other pharmaceutical companies provided additional evidence of the impact of the scheme. It has encouraged greater exports by participants, as would be expected given the size of the financial inducement. For the most directly comparable measure, value added in PBS type products, it appears that, while the activity of Phase II only participants grew faster than that of non-participants, the overall difference in growth rates is not significant.



... but poor design hampers its effectiveness.

The Commission concludes that a number of design features of the Factor f scheme have reduced its effectiveness through overcompensation of some participants, particularly those continuing from Phase I, and undercompensation of some excluded non-participants.

An efficient scheme creates more benefits than costs ...

Efficiency

The efficiency of the Factor f scheme relates to the net contribution it makes to the welfare of the Australian community. Its assessment involved comparing its costs with the individual and broader community benefits generated by the changes in resource use arising from the scheme. The BIE calculated the benefits required for the scheme to break even in a welfare sense. This was done separately for Australian and foreign owned companies.

The Commission recalculated the BIE estimates of benefits using different leakage, inducement and taxation assumptions. The results of these recalculations confirmed the robustness of the BIE estimates.

Estimating the benefits brought about by increased activity under the Factor f scheme is significantly more difficult than measuring the costs. Some of the benefits cannot be measured at all, and others only imperfectly. The main types of potential benefits include:

- the benefits arising due to net investment;
- the impact on profitability; and
- qualitative benefits, including broader community benefits.

Benefits required per dollar of induced activity for break even: various assumptions, \$

	<i>EVA</i>	<i>DVA</i>	<i>R&D</i>
Foreign participants			
IC estimate	0.25	0.22	0.22
BIE original	0.27	0.20	0.22
Australian participants			
IC estimate	0.08	0.08	0.07
BIE original	0.05	0.04	0.04
All participants			
IC estimate	0.22	0.20	0.13
BIE original	0.22	0.17	0.11

Note: EVA—export value added; DVA—domestic value added.

For foreign participants the results show that if the scheme is to be beneficial to the Australian community each dollar of activity induced by Factor *f* must create at least 22 cents worth of these types of benefits. For Australian participants this break even figure is considerably less (8 cents) because more of the benefits will be retained in Australia.

There is evidence that some of these benefits have been realised in practice or are in prospect. Many multinational companies now have a better understanding of the capabilities of Australian manufacturers and researchers and this may result in future activity not subsidised by the scheme. The benefits of increased investment induced by the scheme can be expected to continue for some time beyond the end of Phase II.

Some important intra-industry linkages have been formed—for example, the strategic alliance between Pfizer and the Institute of Drug Technology to manufacture active raw materials. Moreover, the development of broader skills in the research community and the equipment supply sector will allow new opportunities to be taken.

The Commission concludes that it is unlikely that the benefits generated by the current scheme are large enough to cover its costs. The exclusion of some companies and the scheme's high payment rate distorted activity away from that which would have occurred without PBS price suppression. The scheme has not operated in a way which enhances the community's welfare.

Had the payment rate been lower, say 15 per cent rather than 25 per cent, the benefits required to break even for all participants would have reduced from about 20 cents to 10 cents per dollar of induced production activity. Because many of the scheme's benefits are difficult to measure, a lower payment rate is more likely to give the community assurance that the benefits of the scheme would exceed the cost. At the same cost to Government a larger number of companies could have gained access to the scheme.

Administration

The administration of Phase II of the scheme encountered problems in the selection process, particularly after total funding was capped.

It is evident that the grounds for entry to the scheme changed well after the Phase II selection process commenced. This disadvantaged a number of applicant companies and associated research organisations which had made commitments in anticipation of funding. All applications were not assessed in the same way, raising questions of fairness.

There is a lack of public information on the scheme's operation. Notwithstanding the large size of the total payments and the small number of participants, there is little publicly available information about payments to individual companies and the activities they are undertaking in return.

To increase the scheme's flexibility the Pharmaceutical Benefits Pricing Authority (PBPA) exercised considerable discretion in its decision making. However, it has provided no information on why it varied the payment rates and catch-up provisions for some companies. Similarly, it declined to comment on the basis for its decisions to exclude companies from Phase II because the matter is before the Federal Court.

... but it is unlikely that this occurred.

Allowing actual price increases would improve the scheme.

The Commission concludes that the Factor f scheme has suffered from severe administrative problems and has not operated transparently. These problems have contributed to uncertainty about the operating environment, particularly for companies excluded from Phase II.

Completion of Phase II

There are two issues to be resolved regarding the completion of Phase II of the scheme:

- should companies receiving payments under the scheme be able to extend payments and commitments beyond 1999; and
- should the scheme be modified to allow the transfer of entitlements into actual price increases.

The scheme was poorly administered.

The Commission advises against extending existing contracts. Since companies themselves drew up their Factor f proposals, they should bear the risks of not being able to complete their commitments on time. It may also be seen as unfair by those companies which missed out on Phase II funding.

The Commission sees merit in allowing current Factor f entitlements to be taken as actual rather than notional price increases. This will help overcome companies' country of origin and benchmark pricing concerns and can be made to be revenue neutral, although it will require some administrative changes.

There is a complex process for PBS listing ...

Recommendation 1 (11.1 in text)

The Commission recommends that under the current arrangements companies should have the option of taking their remaining Factor f payments as actual rather than notional price increases.

7 PBS process concerns

Participants have also brought many PBS listing process concerns to the Commission's attention. These have been assessed to establish whether the processes impose unnecessary costs or strike an inappropriate balance between health and industry policy objectives.

Coordination and delay

... leading to unnecessary delays ...

When a company applies to have a product listed on the PBS the PBAC first studies its therapeutic merits, community need and cost effectiveness. The PBPA then, applying its pricing factors, recommends a price to the Department of Health and Family Services (DHFS) to be negotiated with the company. The DHFS attempts to coordinate the process but no single body has overriding responsibility.

... and dissatisfaction with decision making.

Delays in PBS listing are of particular concern to the industry because they reduce the limited period available to generate a return while a product is under patent. Some delays arise inevitably from the strategic negotiating behaviour of the parties. However, the number of steps involved in applying for listing and the lack of clear responsibility for overall management may lead to unnecessary delay.

Transparency and accountability in decision making

The PBAC has significant discretion in decision making. Its decisions take the form of advice to the Minister and are not

subject to administrative appeal. The bases for some decisions are unclear to stakeholders and there are inadequate arrangements to ensure accountability for outcomes.

Similarly, the pricing decisions of the PBPA are not always understood by applicants. There is a lack of clarity in the application of the various factors required to be taken into account in pricing. Moreover, the criteria applied in price

reviews lack specificity and companies can be confronted with major price reviews at short notice.

The industry policy objective of the NMDP is pursued only by the PBPA and then only through the Factor f scheme. Such considerations are excluded from price negotiations with companies outside the scheme and from price reviews.

The Commission considers this to be a major failure of policy coordination. However, it is unlikely that health and industry objectives can be managed satisfactorily without reform of the current fragmented organisational structures and complex processes.

Cost effectiveness analysis

Cost effectiveness analysis is a particular problem.

The most criticised aspect of PBS listing was the application of cost effectiveness analysis to listing and pricing decisions. Whilst the industry accepts that drugs should be considered in terms of their economic benefits at the requested price, the present approach is regarded as too prescriptive and influential in price negotiations.

There are claims that cost effectiveness requirements are primarily aimed at containing Government spending on pharmaceuticals. In addition, more fundamental questions concerning the theoretical underpinning of cost effectiveness and the way it is applied have been raised. Evidence provided to the Commission tends to support these criticisms.

The current guidelines, which are 80 pages long, require companies to provide information developed in clinical trials rather than collected in the market place. Importantly, the methodology adopted compromises the reliability of the cost effectiveness estimates as predictors of the 'real value' of drugs to consumers. Indirect and intangible benefits are generally excluded and costs collected in clinical trials are unlikely to be indicative of costs of real use.

It appears to be inappropriately applied.

Despite these methodological difficulties and data deficiencies, there is evidence that undue weight is given to the calculated cost effective price in pricing negotiations. This calculation sets a ceiling which, if too low, may have an adverse effect on drug availability and company revenues. Innovative products (category 2) appear to be particularly exposed to this risk.

Using market information will improve its usefulness.

The Commission has concluded that cost effectiveness analysis in PBS listing will improve the use of community resources if it is applied appropriately, but current arrangements appear to have imposed unnecessary costs and caused delays in the market availability of some drugs. Australia could follow the lead of the few other countries applying the technique by only specifying broad principles in guidelines.

One way of increasing the accuracy of the estimates of cost effectiveness and reducing compliance costs would be to encourage companies to provide clinical trial information based on expected actual use of drugs. Companies could be given an option of undertaking the analysis after two years of marketing. Products could be provisionally listed on the basis of their therapeutic value and community need after an appropriate price has been negotiated. If, after two years, they were found not to be cost effective they would be either retained at a reduced price or removed from the PBS.

Recommendation 2 (10.1 in text)

The Commission recommends that companies should have the option of delaying cost effectiveness analysis for two years to allow for the collection of costing data based on actual use.

To address these concerns with the listing process, the Commission has also proposed organisational changes to rationalise the functions of the PBAC and PBPA and a process review to identify ways of improving their operations.

Organisational changes

The role of the PBAC is to make recommendations to Government on the drugs that should be listed on the PBS to meet the health needs of the Australian community. This objective would be better met if the clinical and economic components of the listing decision were separated and the latter made an integral part of price negotiations. To achieve this, responsibility for evaluating cost effectiveness analyses should be moved from the PBAC to the pricing authority. This would allow the PBAC to bring its clinical skills to its consideration of the relative efficacy of drugs and the community need for them. Rationalisation of functions would enable the pricing authority to apply the economic tools and

*An independent
pricing authority
should be
established ...*

skills necessary to undertake informed negotiation of drug prices.

However, as current pricing arrangements do not adequately address the trade-off between health and industry policy objectives a more fundamental organisational change, involving the establishment of a truly independent pricing authority, seems to be required. To ensure that inappropriate cost containment and industry development pressures are avoided this pricing authority would need to be independent of both the health and industry portfolios. Accordingly, the Commission considers that an independent PBS pricing authority should be located outside the DHFS and DIST with responsibility for:

- maintaining a data base of prices, market shares and indications for which drugs are available in Europe;
- evaluating cost effectiveness analyses;
- negotiating prices; and
- recommending which drugs should be listed at these prices.

At present the DHFS does not maintain a data base relating to the sale of drugs in overseas countries. To properly apply all its pricing factors and negotiate appropriate prices it is important that the authority has access to this information.

Recommendation 3 (8.1 in text)

The Commission recommends that a data base of Australian and international pharmaceutical prices, volumes and market shares be established.

... and PBS listing procedures be reviewed.

The Factor f scheme was an attempt to address these problems ...

A process review

In view of the impact of the listing process on the operating environment of the industry, the Commission considers there is an urgent need for the Government to establish a detailed and independent administrative review of the PBS listing process. An approach, similar to that used with success in the Baume review of the TGA, would involve an intensive examination over a short period of PBS listing arrangements in close consultation with the relevant agencies. This proposal, which was made in the Draft Report, has received strong support from all sectors of the industry, consumer groups and health professionals.

The review should cover all aspects of the PBS listing process. It should consider the appropriate use of economic evaluation and better methods of price negotiation and review. In addition, it should examine proposals to change current organisational arrangements, including the Commission's suggestions that the pricing authority be made independent of the health and industry portfolios and that responsibility for cost effectiveness analysis be transferred to this body. It should also develop pricing guidelines.

Recommendation 4 (9.1 in text)

The Commission recommends that, as a matter of urgency, the Pharmaceutical Benefits Scheme listing process be subject to a review.

8 The case for intervention

For the past decade, the Government has addressed the problems facing the pharmaceutical industry through financial intervention—the Factor f scheme. However, if the PBS is not serving the interests of the community, a better approach would be to address the problem at its source, either by reviewing impediments or better managing Government interventions. This could involve reform of the PBS itself.

General intervention

The Commission has found that delays, volume restrictions, complex administration processes and the current application of the main pricing tool, cost effectiveness analysis, are

*... but they are better
addressed at their
source.*

reducing the welfare of consumers by denying them timely access to some drugs and by rationing the use of others. While these problems are not severe at the moment, they appear to be worsening.

The PBS substantially enhances the welfare of the community by facilitating access to drugs at subsidised prices. However, it will be more difficult to continue to do so to the same extent in the future. Failure to reform the PBS could have significant consequences for the industry, consumers and taxpayers. For example:

- the current rate of growth of PBS budgetary expenditure may not be sustainable—even if it is, it may proceed without a commensurate improvement in health outcomes;
- current growth in domestic and export activity may decline, leading to reduced employment in the industry, reduced demand for the products of the industry's suppliers and fewer opportunities for the research sector to build its links with multinational companies; and
- as companies become less willing to negotiate on price, consumers may be denied access to the range of drugs they could reasonably expect.

*If this is done,
there is no
need to continue
Factor f.*

When taken together these consequences, and others, are likely to reduce the Australian community's wellbeing. Accordingly, the Commission has found that there is a case for general Government reform to improve the PBS environment.

Financial intervention

As the reasons to deal with the problems of the PBS go beyond the impact the scheme has on the industry, any case for financial intervention to compensate the industry for the adverse effects of the PBS depends on:

- an inability to deal directly with the impediment to continuing industry development caused by the PBS; and
- such intervention being able to bring net benefits to the community.

As the Commission's analysis of the current scheme shows, it is difficult to design an intervention that assures value for money.

Importantly, such an intervention could have unintended

consequences. It is likely to be perceived as a ‘stop gap’ measure, reducing the confidence of companies that Australia is prepared to undertake more fundamental reform. Indeed, it could reduce the incentives on Government to proceed with PBS reform.

The Commission has found no clear cut case for financial intervention.

9 Approaches to future intervention

The Government’s response to the broader problems could be to:

- reform PBS processes as recommended;
- reform PBS processes and policy; or
- compensate for impediments associated with the PBS through financial intervention.

The Commission has already highlighted the need for an urgent review of the PBS listing processes.

Such a review could be implemented quickly and has a number of benefits. Cost effectiveness analysis, properly applied, may justify broader access to drugs for consumers and higher prices for companies. Modified organisational arrangements could ensure a more rational allocation of responsibilities between the PBAC and the pricing authority. Clearer guidelines for the pricing authority in setting prices would ensure that cost containment is not given inappropriate priority over health and industry goals. Including relative weights for pricing factors in guidelines would allow greater emphasis to be placed on relevant overseas prices. It would also give greater certainty to the industry.

However, PBS process reform, while a worthy goal in itself, is unlikely to address the full range of problems facing consumers, taxpayers and the industry. A number of participants in this Inquiry pointed to the need for more fundamental policy reform. There is a widespread perception that the PBS is subsidising drugs without full regard to the consequences for the industry and consumers. This has direct implications for the domestic revenues of companies and potential indirect consequences for the international revenues of multinational companies. Moreover, the *ad hoc* adjustments made to the scheme in the past have added to uncertainty. PBS policies will need to be adapted to meet growing industry pressures for prices and market restrictions closer to international norms.

The scheme in its present form is unlikely to be sustainable as Governments seek better means of responding to consumer pressures by targeting their resources on achieving better health outcomes for those in greatest financial and medical need. With this in mind, the Council of Australian Governments has commenced a detailed review of the potential to rationalise and integrate Commonwealth and State health policies and programs. Inevitably, the PBS will come under increased scrutiny in a broad health policy context.

*... to better balance
taxpayer, consumer
PBS listing processes
and industry
should be reviewed
interests.
quickly ...*

The terms of reference of the Inquiry do not allow the Commission to make recommendations on the PBS. However, the Commission feels obliged to draw attention to the need to go beyond process reform and to review the social and economic policy underpinnings of the PBS itself.

This is necessary in order to strike a better balance between the interests of taxpayers, consumers and the industry.

Such a policy review could examine the most appropriate ways of managing growing demand and supply pressures, the level of access to subsidised drugs for different community groups, the scope to broaden the application of consumer copayments and the most efficient and equitable way of providing the subsidy.

*If minimum reform
cannot be achieved
quickly ...*

Meanwhile, significant progress in improving PBS processes would require as a minimum that the pricing authority, operating independently, would place appropriate weighting on the range of pricing factors. These would include prices in overseas markets and the real value of drugs to the community as reflected in the proper application of cost effectiveness analysis principles. If progress can be made in these areas there would be no need for another Factor f type scheme.

However, should the Government decide that fundamental reform of PBS processes is not a current priority or likely to take considerable time to implement, it could choose to introduce a Factor f type scheme as an interim measure.

*... but PBS policy
should also be
reviewed ...*

Revised Factor f scheme

The main design features of the Commission's revised Factor f scheme are:

- Price increases apply to all patented products plus non-patented innovative products.
- The scheme is open to all companies.
- Payments are transformed into price increases. Price increases are limited by EU prices. Companies have the choice of taking a notional or actual price increase.
- Eligible activities are value added production and R&D,

... the Government might implement a revised Factor f scheme.

Other policies affect the industry.

not health promotion activities.

- The same payment rate applies to all eligible activities (lower than the current rate of 25 per cent, say, 15 per cent).
- An administrative threshold applies to limit the number of claims received by the administrators. This threshold is a minimum amount of payment due to the company in a given time period.
- Only incremental activity is paid for.
- Incremental activity is measured against a three year moving average base.
- The scheme should be reviewed after five years of operation to assess its effectiveness and efficiency.

The Commission has designed a scheme which avoids many of the problems inherent in the current scheme. By having as few decision distorting characteristics as possible and being easy to administer it improves the prospects of the benefits to the community exceeding the costs.

The Commission estimated the likely cost to Government of such a scheme to be around \$235 million over 5 years.

Pre-market evaluation has improved ...

10 Other issues affecting the industry's prospects

Apart from the PBS and the Factor f scheme, the Commission identified regulatory, intellectual property and taxation issues as important to the sector's performance and prospects.

Drug evaluation

The implementation of the recommendations of the Baume Review of therapeutic goods regulation has led to significant improvements in the timeliness of pre-marketing approvals for prescription pharmaceuticals. However, concerns remain that Australia has yet to achieve a uniform, integrated and national scheme for the regulation of the safety and efficacy of drugs and the control of their supply to consumers. In addition, Australia's drug regulatory processes are isolated from those of other countries and, in a global market, this can add to companies' costs and delay consumer access to new products.

Following agreement between the Commonwealth and State Governments to rationalise responsibilities, the Commonwealth *Therapeutic Goods Act* 1989 was intended to lay the foundations for a nationally uniform system of pharmaceuticals

regulation. The Act established the TGA as the central institution. At present, only Victoria has passed complementary State legislation.

... but needs to be better linked to the rest of the world ...

Recommendation 5 (14.1 in text)

The Commission recommends that all States and Territories pass complementary legislation to broaden the application of the *Therapeutic Goods Act* 1989 by adopting its provisions and future amendments by reference.

The Commission concludes that some capability to evaluate new products is required, if the Government is to be able to respond to community interests. Such a capability is part of the infrastructure expected by drug companies and consumers. As long as the TGA continues to provide a competent and cost effective service its drug evaluation function should be retained.

However, it is important that local drug evaluation is linked into the world regulatory system. This can be achieved to an increasing extent by different measures—international harmonisation of standards and data requirements, exchange of evaluation reports and by giving weight in evaluations to the decisions of other countries. The TGA should continue to pursue these measures. Over time, Australia should seek mutual recognition with the evaluation decisions of comparable countries.

Recommendation 6 (14.2 in text)

The Commission recommends that Australia, through the Therapeutic Goods Administration:

- continues to pursue harmonisation of standards and data requirements;
- pursues further agreements to exchange evaluation reports and to undertake joint evaluations;
- while reserving the option of conducting its own evaluations, on a case-by-case basis places greater weight on overseas approvals by regulators with comparable standards and known expertise in a particular area; and
- in the longer term, pursues mutual recognition of drug approvals with countries with comparable regulatory standards while maintaining an independent capacity to conduct evaluations where required by unique Australian conditions or where requested by suppliers.

The TGA is constrained by its institutional setting.

Because of wide variations between Australia and New Zealand's technical requirements and drug evaluation procedures, therapeutic goods are to be given a temporary exemption from the Trans-Tasman Mutual Recognition Agreement. The Commission suggests that if a permanent exemption is sought, the full costs and benefits of such a course need to be considered by the Council of Australian Governments (COAG).

Institutional arrangements

As presently structured, the TGA is a division of the DHFS.

Elsewhere there is a trend towards increased independence of therapeutic goods regulators to facilitate better management. For example, the UK has established a self-funded executive agency, the Medicines Control Agency which has the reputation as one of the most efficient regulators of medicines in Europe.

It should be a Commonwealth statutory authority.

The Commission considers that the TGA has the potential to become a 'lead regulator', particularly in the Asia-Pacific region. If it is to achieve this potential it needs to continue to improve its performance and build its international reputation.

Benchmarking its regulatory outcomes with those of major overseas agencies will assist, but its present institutional setting constrains it from responding flexibly to national and international demand for competitive drug regulation.

Over recent years, Commonwealth statutory authorities have been established for the cooperative national regulation of food and agricultural and veterinary products. There is a strong case for adopting a similar institutional model for drug regulation.

Recommendation 7 (14.3 in text)

The Commission recommends that the Therapeutic Goods Administration be established as a Commonwealth statutory authority.

... especially New Zealand.

Over the counter issues

Like the prescription sector of the industry, the domestic OTC sector is experiencing strong growth, and the pressures of international rationalisation are influencing its product development and production operations. However, specific forces are shaping demand for its products. In particular, the sector is responding to an emerging trend towards responsible self-medication by consumers.

Self-medication provides benefits to the community. There is dissatisfaction with current scheduling arrangements ...

Responsible self-medication promises considerable benefits for both consumers and governments. If consumers have access to a wider range of appropriate treatments and information they will be able to manage their own health more directly. Many consumers want to assume this responsibility. To the extent that self-medication displaces less appropriate and more costly health services, the pressure on Government health budgets, including the PBS, will be reduced.

Inquiry participants raised many practical regulatory issues which are impeding self-medication and the development of the OTC sector. The scheduling system, which establishes the rules for the prescribing and dispensing of medicines, is of particular concern.

Scheduling

Many aspects of current scheduling arrangements have been criticised in the Inquiry. In particular, the national arrangements have no adequate legislative underpinning and the processes of the National Drugs and Poisons Scheduling Committee (NDPSC) do not meet modern administrative standards for transparency, procedural fairness and due process.

... which don't always classify drugs appropriately ...

A joint Commonwealth/State body—the NDPSC—compiles the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which is issued by the Australian Health Ministers' Advisory Council (AHMAC). The standard itself has no legal effect until it is adopted into State legislation. The administrative nature of the decisions made under national scheduling arrangements complicates their adoption into legislation by the States. The Commission considers that the arrangements should be put into legislation to allow the States to take up the SUSDP and its amendments by reference.

Allocation of medicines to schedules

Medicines are currently scheduled as poison substances in a single system alongside industrial, domestic and agricultural products. Because poisons are always dangerous, undue weight can be given in scheduling decisions to the hazards of using medicines. This bias may restrict access to beneficial medicines. The scheduling of drugs should be conducted separately from poisons.

Current schedule classifications and their practical application do not ensure that pharmaceuticals are allocated to the most appropriate schedule. For example, schedule 3 includes both relatively safe and well-understood products such as antihistamines and strong cough mixtures, and products more likely to be dangerous, such as insulin, asthma and peptic ulcer drugs. For effective scheduling, criteria need to be specified which are risk related, clear, measurable and capable of being applied objectively.

Classification problems are compounded by the lack of transparent and accountable NDPSC administrative processes. The Commission observed a lack of confidence in the outcomes of these processes among many participants.

... but there is insufficient evidence to change the underlying structure.

Schedule 2 (pharmacy only) and schedule 3 (pharmacist only) create two intermediate classes of drugs between prescription only (schedule 4) and general sale status. This uncommon feature of Australia's scheduling system adds to costs and potentially reduces retail competition.

In the Draft Report the Commission sought participants' views on the likely effects of discontinuing schedule 2 or schedule 3 listings. Most respondents supported retention of both schedules provided the scheduling system itself is reformed and consumers receive the professional advice required when drugs are sold in pharmacies.

The Commission considers the counselling role of the pharmacist to be the dominant consideration. However there is little available information on the effectiveness of pharmacist counselling. The case for the two schedule categories will be much stronger if such counselling can be shown to contribute to improved health outcomes.

Recommendation 8 (15.1 in text)

The Commission recommends that both schedule 2 'pharmacy only' and schedule 3 'pharmacist only' be retained, pending further research into the role of pharmacist counselling in ensuring improved health outcomes and the monitoring of the extent of such counselling.

Rescheduling

Several participants proposed changes to the way drugs are moved between schedules. At present, products can be switched from one schedule to a less restrictive schedule if they are assessed to require a lower level of supervision by a health professional.

The Commission considers that rescheduling decisions need to be guided by a more explicit approach which attempts to take into account broadly defined health and economic costs and benefits. In particular, drugs that meet the requirements of a schedule should be put on that schedule and not on a more restrictive schedule as a transitional measure. The requirement for two years of Australian marketing for new drugs before rescheduling is applied too rigidly without due regard to evidence of overseas use.

Advertising

Drug advertising is regulated by Government and industry.

Advertising is one of the major sources of information on diseases and their treatments. It is regulated directly by Government and through self regulation arrangements by industry groups.

The main issue raised by participants relates to restrictions on the advertising of schedule 3, or pharmacist only, medicines. At present, these products can be advertised generically to consumers, but not by brand name. This is claimed to depress sales and inhibit consumers' access to an important class of OTC products.

There is insufficient information about the health outcomes of advertising of pharmaceutical products to adequately assess the impact of such advertising. However, as a general principle, the Commission considers governments should avoid placing restrictions on peoples' access to information.

Where appropriate, brand advertising for S3 products should be allowed.

The Commission has concluded that *indirect* advertising can provide public benefits by raising awareness of schedule 3 products. Whether *brand* advertising of these products provides health benefits is not clear and each case should be judged on its merits.

Current practices for rescheduling drugs are too rigid.

<p>Recommendation 9 (15.2 in text)</p>

The Commission recommends that, where it can be demonstrated that brand advertising of particular schedule 3 ‘pharmacist only’ products will lead to improved health outcomes, such advertising should be permitted on a case by case basis, subject to appropriate industry self-regulation.

Reform of scheduling and registration processes

To address fully many of the more fundamental concerns about current scheduling arrangements requires reform of the process itself. At a minimum this involves:

There is scope to combine registration and scheduling.

- the establishment of an appropriate legislative base, which secures national uniformity of schedules;
- a set of objectives for the scheduling body, defined by legislation; and
- the development of a transparent, accountable and fair administrative process.

The Commission proposed options.

Additional benefits are available if the current processes of registration and scheduling are streamlined or unified. For example, product sponsors would be able to make a single application and consistent decision criteria would reduce the costs of delay, lack of uniformity and errors.

In the Draft Report, the Commission proposed options for the reform of present scheduling and registration institutional arrangements.

The first option maintained current separation of scheduling and registration but proposed a new national body with responsibility for scheduling. The quasi-national nature of existing scheduling arrangements (NDPSC/AHMAC) could be recognised formally by creating a national scheduling authority, with a structure and role similar to that of other national bodies established cooperatively in recent years.

The second option combined registration and scheduling. The Commission identified alternative ways of doing this:

- the Commonwealth and States could implement a cooperative national drug evaluation and scheduling process through the TGA; or
- the States could allow the Commonwealth, through the TGA, to run a combined scheduling and registration process.

The Commission considers that the Commonwealth Government should cooperate with the States and Territories in establishing the TGA as the appropriate body to undertake scheduling.

Recommendation 10 (15.3 in text)

The Commission recommends that the scheduling of therapeutic goods becomes the responsibility of the Commonwealth Government under the Therapeutic Goods Administration.

Patents are important to the industry.

Placing responsibility for scheduling decisions on a Commonwealth body does not mean there is no role for the States. State Governments have established administrative mechanisms for the regulation of retail pharmacy. State agencies would be relied upon to enforce national scheduling arrangements in the market place.

Intellectual property issues

Given the high risks and costs involved, pharmaceutical companies rely on a period of patent protection of successful products to secure an adequate return on their total investment in R&D.

There is scope to provide a period of patent term restoration ...

In 1987, the Commonwealth Government extended the general sixteen year patent period by four years for pharmaceuticals. At the same time it introduced a two year springboard provision (the period in which generic manufacturers can commence approval processes). Springboarding was removed in July 1995 when a standard 20 year patent term for all products was introduced to implement Australia's obligations under the Trade Related Intellectual Property Agreement (TRIPs) as part of the Uruguay GATT Round.

Effective patent period

The effective patent term can be significantly reduced when a pharmaceutical product must go through a pre-marketing regulatory approval process. For this reason, many countries have extended patent terms to allow time lost in gaining mandatory marketing

*... a period of
springboarding ...*

approval to be added to the original patent period. The cost to the community of such patent extensions is the restriction of competition from companies that produce off patent products.

The Government has made a commitment to provide an equivalent level of intellectual property protection to that provided by comparable overseas countries. Its favoured approach of a 15 year effective patent life, running from the date of Australian product approval, is close to the restoration term applying in the European Union (EU). The EU term covers, and in some cases may exceed, the period required to compensate for regulatory delay.

The Commission has found that the delay in implementing this commitment is causing uncertainty and concern in the industry.

Springboarding

Domestic generic manufacturers favour springboarding primarily because it allows them to enter the market as soon as the patent expires. In addition, they are concerned about the competitive consequences for them if Australia does not allow springboarding when it is permitted in other major supplying countries. Should this situation develop, a sudden decline in the sector's market share is likely.

The Commission considers the main argument in favour of springboarding is to provide parity between Australian generic producers and generic importers.

*... and some
protection for trial
data.*

As the currently favoured effective patent period approach can offer greater protection than is required to compensate for regulatory delay, there is scope to introduce a period of springboarding consistent with the objective of providing equivalent protection to comparable overseas countries.

Data exclusivity

Australia, as a party to the TRIPs agreement, is required to protect from 'unfair commercial use' data submitted to Government to obtain regulatory approval for pharmaceuticals. A policy to implement this obligation has yet to be adopted by Government.

Providing a period of 'data exclusivity' during which regulators cannot apply confidential information to their consideration of applications for registration from competing products or share it with other regulators adds to the level of intellectual property

*Tax is another
important issue.*

protection. It will, however, lead to some duplication when drug registration applications are made by other companies.

If commercial confidentiality cannot be assured, there is potential for new drugs to be withheld from the Australian market and it is important that Australia's obligations under TRIPs be clarified as a matter of urgency.

Taxation issues

Australia's corporate taxation requirements and administrative processes are significant issues for the sector. A 1995 APMA survey ranked Australian taxation third in the list of negative factors cited most frequently as impeding business development and new investment, and it has achieved greater prominence since.

*Transfer pricing
administration
could be improved ...*

Transfer pricing

A key tax concern relates to transfer prices—the prices charged in international dealings between related parties. They largely determine revenue and costs, and hence taxable profits, of the related parties in different tax jurisdictions.

A significant number of companies are critical of the ATO administration of transfer pricing. They consider that the ATO has endorsed the OECD guidelines in principle but, in practice, is administering them in a contrary way. Many detailed complaints were provided by companies which, in some cases, had been negotiating with the ATO over specific assessments for over ten years.

The ATO has stated that its approach is consistent with OECD guidelines on transfer pricing. It noted that its main differences with industry relate to the effect of the PBS on company profitability and choice of transfer pricing methodology. It has acknowledged that the time, resource and financial costs associated with resolution of transfer pricing disputes in its audit process are unacceptable and that it will be taking steps to resolve these problems. It has pointed out that companies wanting to minimise risk and uncertainty have the option of negotiating an Advance Pricing Arrangement which determines, in advance, how matters of significance in a company's transfer pricing arrangements are to be treated.

The ATO has a responsibility to target industries, such as the pharmaceutical industry, where significant tax revenue is most

*... and wholesale
sales tax
arrangements
clarified.*

at risk from transfer pricing arrangements. However, given that companies are required to self assess and are subject to penalties for incorrect assessments, they reasonably demand clear and concise guidelines on the ATO's expectations.

The Commission concludes that administration of transfer pricing policy by the ATO in the past has had a negative impact on the operating environment for some companies in the pharmaceutical industry.

However, the Commission recognises that the ATO is initiating processes to address this situation.

Wholesale sales tax exemption

Drugs and medicines are exempt from wholesale sales tax (WST). In a recently released draft sales taxation ruling, the ATO classified goods as drugs and medicines for the purposes of WST exemption only if they are 'marketed principally' as drugs and medicines. The effect of the draft ruling is to potentially impose WST on a range of OTC products that were previously exempt from tax. A final ruling, promised in January 1994, has yet to be issued.

Some participants believe that all goods on the Australian Register of Therapeutic Goods (ARTG) should be exempt from tax. They argue that this would ensure consistency between different arms of Government administration while providing certainty and reducing administrative costs for industry.

They are also concerned about the ATO's approach to the WST exemption. In determining exclusions the ATO has moved away from its usual product by product approach and suggested a blanket approach to classifying broad product groups. This could have the effect of excluding products from the WST exemption which are, in fact, principally marketed as drugs and medicines and generally located for retail sale with other drugs and medicines.

The ATO has noted the different purposes of therapeutic goods and sales tax legislation. According to the ATO, the purpose of the former is to ensure safety and efficacy of certain goods, while the purpose of the latter is to raise revenue by determining which goods are subject to sales tax and which are exempt.

While accepting this view of the purpose of WST policy, the Commission considers that it is the ATO's responsibility to

provide taxpayers with clear and concise guidelines on the interpretation of tax law. The departure from past practice and the lack of clarity of the draft sales tax ruling have increased uncertainty and imposed costs on the industry. Early release of a final ruling will alleviate some concerns.

11 Implementing change

The picture of the pharmaceutical industry's performance and prospects emerging from this Inquiry was complex but encouraging. Both the prescription and OTC sectors are adapting to the changes imposed by world-wide rationalisation in manufacturing and research. But parts of the policy environment of the industry are not responding to the pressures on them to meet consumer needs and to allow the industry to fulfil its potential.

The Commission looked behind these broad trends to identify remaining impediments to development and to comment, in particular, on whether the community is receiving value for money for the support provided to the sector.

The need to improve Australia's pharmaceutical policy environment has been recognised by the Commonwealth Government. Current industry policy is to introduce a broadly based program of assistance to offset the impact of the PBS when the existing Factor f program expires in 1999.

The Commission's proposals should be drawn together ...

The Commission suggests that the various strands of its proposals be drawn into a package of reforms which should be implemented quickly and with vigour. The body responsible for implementation must have the authority and Government support required to take a whole of Government approach. It will need to be able to initiate change to existing institutional arrangements and to conduct relevant Commonwealth and State negotiations.

... and implemented in stages over 2 years.

The Commission has proposed a two stage implementation program. The first stage gets reform started and lays foundations for the implementation of later change. The second stage implements the detailed changes emerging from the PBS process review and consolidates other changes.

The Commission recognises that this program is ambitious, but given sufficient priority, it could be achieved within two years. If it is started without delay, it could be substantially completed before the expiry, in 1999, of current industry development arrangements.

The Commission's proposals, if fully implemented, can be expected to have widely beneficial effects on industry participants and the community. Pharmaceutical companies will benefit from more flexible price negotiations, and prices will better reflect the value of new drugs to patients.

Implementation Stage 1: 6 Months

- Announce decisions regarding future approach (PBS process and policy reviews, intellectual property, scheduling and independent TGA).

PBS reform

- Undertake Baume style review of PBS processes.
- Establish PBS policy review.
- Commence collection of international pricing, volume and market share data.

General regulatory reform

- Establish independent TGA and introduce regular international benchmarking.
- Commence negotiations on combined scheduling and registration arrangements with the States.
- Implementation of intellectual property policy.

Interim arrangements

- Modify Factor f Phase II to allow payments to be based on actual prices.
- Introduce an option to delay cost effectiveness analysis for 2 years.

Implementation Stage 2: 12 to 18 Months

PBS reform

- Implement PBS process reforms, including modified cost effectiveness analysis.
- Establish independent pricing authority to implement new pricing guidelines.
- Finalise PBS policy review.

General regulatory reform

- Absorb scheduling into independent TGA.

Consumers may gain earlier access to new pharmaceutical products for a wider range of applications. Better information about medicines through appropriate advertising will allow them to take a greater role in the management of their own health. Health professionals and the research community will also be affected by proposed changes to the PBS and drug regulation.

Pharmaceutical research, manufacturing and supply is an important Australian industry with strong prospects. The challenge for governments is to introduce and sustain integrated policies which, while directed at improving the

performance of the industry, enhance the health and wellbeing of all Australians.

1 THE INQUIRY

This Chapter outlines the scope of the Inquiry, the approach taken by the Commission and the structure of the Report.

1.1 The reference

The Assistant Treasurer referred the pharmaceutical industry to the Industry Commission on 9 June 1995 for inquiry and report by 14 March 1996. The Commission was subsequently granted a six week extension of time.

The Inquiry's terms of reference ask the Commission to report on and recommend ways to improve the overall economic performance of the Australian pharmaceutical industry and its contribution to the performance of the Australian economy. The terms of reference were developed by Government in consultation with the pharmaceutical industry.

The Inquiry is mainly concerned with the activities of the companies which manufacture, import or market pharmaceuticals. However, the Inquiry extends to all phases of pharmaceutical industry activity, from research and development (R&D) through to manufacturing and export. It also covers the institutional research framework associated with the industry, including linkages to universities and other research institutions.

Both the prescription and the over the counter sectors of the pharmaceutical industry are covered. The biotechnology sector is considered to be within the scope of the Inquiry. Similarly, vitamins and mineral supplements are included.

Although pharmaceutical companies often manufacture, import and distribute veterinary drugs, the Inquiry did not examine the institutional arrangements and regulatory measures associated with these products.

The terms of reference preclude the Commission making recommendations about the Pharmaceutical Benefits Scheme (PBS) itself, or the supply of pharmaceuticals under the PBS. However, the Commission was required to assess the impact of the PBS on the performance and development of the industry.

1.2 Key Inquiry issues

Central to this Inquiry is the impact of current institutional and regulatory arrangements on industry structure, performance, international competitiveness, resource allocation and growth prospects.

Particular concerns about the Factor f scheme include:

- how effective it has been in achieving its objectives;
- how efficiently it has met its objectives;
- how well the scheme was administered; and
- if its continuation can be justified, what changes to the scheme, if any, should be made.

The industry is influenced by multinational pharmaceutical companies' decisions on the relative advantages (and disadvantages) of Australia as a base for all phases of pharmaceutical activity. How these decisions are made is an important consideration.

There are a number of issues related to the impact of the PBS on the industry, including the level of PBS prices, PBS listing processes, including the application of cost effectiveness criteria and the current approach to containment of costs to Government.

In addition to the PBS, the regulatory environment has a significant impact on the growth and export potential of the industry. Of particular concern are taxation and intellectual property laws and general Government policies as they relate to the sector, including:

- transfer pricing provisions, which regulate the taxation on profits derived from related party transactions, and clarity of the specification of wholesale sales tax arrangements;
- proposed patent restoration provisions which affect the effective life of a patent on a product; and
- general assistance measures designed to encourage local R&D and export activity.

Other issues under reference are:

- the National Medicinal Drug Policy;
- emerging national and international trends affecting the industry;
- the potential for the industry to capture a greater share of the global pharmaceutical market;

- the effectiveness of the current links between pharmaceutical companies and universities and research organisations; and
- measures which could contribute to the efficiency, growth or export development of the industry.

1.3 The Commission's approach

In line with its Act, the Commission approached its consideration of the issues in the Inquiry from the perspective of the community as a whole. Although the reference focuses on the pharmaceutical industry, the Commission aimed to ensure that its recommendations to improve the industry's economic performance and development also enhance the welfare of the community generally.

In this Inquiry, as in all its inquiries, the Commission has had regard for the established economic, social and environmental objectives of Government and the effect of those objectives on the industry. In addition, the Commission has also taken account of the established health objectives of Government, as specified in the terms of reference.

Further, the Commission has identified groups in the community which would benefit from, or be disadvantaged by, any suggested changes. It has also discussed how these changes might be implemented.

Some participants expected the Commission to set out a vision for the future of the industry and devise an industry development plan to achieve that vision or to propose targets for future levels of particular industry activities, such as R&D.

The Commission considers any such planning initiatives should be undertaken by companies in the industry rather than by a government body. A large amount of information is required for such complex tasks, which is generally inaccessible to government. However, the Commission has played a facilitating role by examining and reporting on the views put to the Inquiry.

Further, the Commission acknowledges the importance of government in setting an appropriate policy environment to allow the industry to fulfil its potential. The Report makes a number of recommendations which identify and remove regulatory and institutional impediments. Other recommendations aim to provide the industry with future government policies which are as coherent and stable as possible.

1.4 Inquiry process

In preparing this Report, the Commission has drawn on its own research and on participants' submissions, information tendered at preliminary discussions with a cross section of interested parties, round table discussions with invited participants, public hearings and reports of previous inquiries. The Commission also had access to information contained in surveys conducted on behalf of the Australian Pharmaceutical Manufacturers Association (APMA), Proprietary Medicines Association of Australia (PMAA) and the Bureau of Industry Economics (BIE).

A list of parties with whom the Commission held discussions appears in Appendix A, together with a list of organisations and individuals that participated in roundtable discussions and public hearings. A list of individuals and organisations that provided the Commission with written submissions also appears in Appendix A. The Commission received 208 submissions.

The Commission released an Issues Paper on 28 June 1995 and held three roundtable discussions. Prescription products was the topic of discussion on 16 August 1995 in Sydney and 22 August 1995 in Melbourne; and consumer health was discussed on the 17 August 1995 in Sydney. After the release of the Draft Report the Commission held public hearings in Sydney, Canberra and Melbourne.

The Commission engaged the BIE to evaluate the effectiveness and efficiency of the Factor *f* scheme and the Centre of Policy Studies (COPS) at Monash University to evaluate the overall economic contribution of the industry. The BIE consultancy report, *The Factor (f) Scheme*; and the COPS final consultancy report, *Modelling of economy-wide impacts of assistance arrangements in the pharmaceutical industry*, have both been released separately, but are referred to throughout this Report.

1.5 Previous inquiries

The Commission has been asked to take account of any recent relevant substantive studies.

These studies include an earlier BIE review of the Factor *f* Scheme (BIE 1991) and the inquiry by Professor Peter Baume into drug evaluation in Australia (Baume 1991).

The House of Representatives Standing Committee on Community Affairs (1992a) completed a series of reports about the prescription and supply of drugs. Part 1, relating to regulation and the pharmaceutical industry, is of most

relevance to this Inquiry. The Senate Standing Committee on Community Affairs (1992) also reviewed changes in pharmaceutical regulation.

Many of the issues relevant to the current Inquiry were also examined by the Industries Assistance Commission (1986b), in the 1986 Report into Pharmaceutical Products and by Ralph (1979) in the Pharmaceutical Manufacturing Industry Inquiry.

1.6 Guide to the Report

The Report is organised into three parts and is contained in two volumes. Volume 1 comprises parts A and B which together make up the Report proper.

Part A, Current Industry Position and Operating Environment, contains Chapters 2 to 7 describing:

- the industry in Australia, in a global context;
- the regulatory environment in Australia;
- the PBS;
- the Factor f scheme;
- global pressures; and
- the strengths and weaknesses of the Australian industry.

Part B of the Report, Key Issues and Options for Reform, contains Chapters 8 to 17 which analyse the impact on the industry of:

- the PBS;
- the Factor f scheme;
- regulation relating to drug approval and scheduling; and
- intellectual property provisions.

The final Chapter summarises the Commission's broad conclusions and sets out the reform proposals developed.

Volume 2 comprises 14 supporting Appendices.

2 PHARMACEUTICAL INDUSTRY IN AUSTRALIA

This Chapter describes the characteristics of the global pharmaceutical industry and the distinguishing features of the industry in Australia.

2.1 Introduction

With sales of about US\$215 billion in 1994–95, the international pharmaceutical industry is large by global standards (*Scrip, Review* 1995). For instance, it is of a similar size to the international aerospace industry (Hayward 1994, p. 14). Key characteristics of the industry are an integrated worldwide market, the important role played by large multinational companies and its dependence on knowledge driven, technology intensive products. Governments also play an important role through their influence on prices and the supply of pharmaceuticals.

Pharmaceuticals form an important part of the health services sector. The latter typically accounts for between 6 per cent and 10 per cent of Gross Domestic Product (GDP) in most Organisation for Economic Co-operation and Development (OECD) countries (OECD 1994, p. 38).¹ Pharmaceuticals account for from 7 per cent to 26 per cent of health services expenditure (Collins 1993).

The Australian pharmaceutical industry forms only a small part of the international industry, with sales comprising about 1 per cent of the world pharmaceutical market. However, the Australian industry is fully integrated with the international industry and any review of the industry here must take account of the international context. The first part of this Chapter provides a snapshot of the world market for pharmaceuticals and the structure of the industry. The second part profiles the Australian industry. Recent developments in the global industry and their implications for Australia are reviewed in Chapter 6.

¹ The significant outlier is the US where health services expenditure accounted for 14 per cent of GDP in 1992 (OECD 1994, p. 38).

2.2 The industry internationally

2.2.1 The world market

The US, Europe and Japan are the largest markets for pharmaceuticals. Together, these comprised about 84 per cent of global sales in 1994. The US, Japan and a small number of European countries—Germany, the UK and France—are the largest producers of pharmaceuticals (see Table 2.1).

Table 2.1: Pharmaceutical market and production shares, per cent

<i>Country</i>	<i>Share of market 1993</i>	<i>Share of production 1991</i>
Europe	32	na
France	7	8
Germany	6	9
Italy	5	na
UK	3	8
US	31	40
Japan	21	17
Others	16	na
Total	100	100

na not available

Sources: Glaxo 1994, p. 8; JPMA 1994, p. 41

Pharmaceutical products can be divided into ethical products, which are generally available only on prescription and over the counter (OTC) products suitable for self medication. The ethical component of the pharmaceutical market accounts for about 80 per cent of global sales, with the OTC element making up the remaining 20 per cent.²

Driven by increasing availability and acceptance of newer and more expensive products, the value of the key prescription market grew by an average of 12 per cent per year in the 1980s (Standard and Poor 1994). Although the rate of growth has recently slowed, it still averaged around 10 per cent per year during the early 1990s (see Table 2.2).

² Based on OTC sales in 1993 of US\$39 billion (DIST sub. 56, p. 5).

Table 2.2: Growth in sales in pharmaceutical products by country, 1990 to 1993

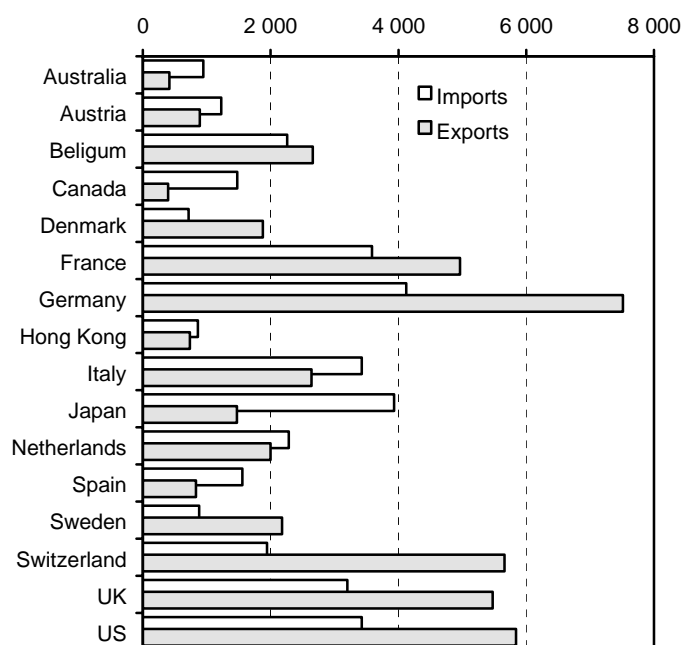
Country	1990	1991	1992	1993	Av. annual change
	US\$ billion	US\$ billion	US\$ billion	US\$ billion ^a	% pa
US	40.4	46.4	54.2	60.0	14.4
Japan	27.6	30.1	33.1	42.0	14.5
Germany	11.8	12.5	15.8	12.0	2.9
France	11.2	11.3	13.6	13.5	7.7
Italy	11.0	11.8	11.3	9.0	-6.2
UK	5.1	5.4	6.0	6.0	6.1
Other	40.3	44.4	48.9	52.5	9.3
Total	147.4	161.8	182.9	195.1	10.1

^a Converted to US dollars using average end of month exchange rates for twelve months to March 1994.

Sources: JPMA 1994, p. 9; Glaxo 1994, p. 8

Pharmaceuticals are actively traded products. This partly reflects the low average tariffs on pharmaceuticals, their high value and transportability. Exports and imports for major trading countries are shown in Figure 2.1.

Figure 2.1: Pharmaceutical exports and imports for major trading countries, 1993, US\$ million



Source: UN 1995

Figure 2.1 shows that the largest net exporters are Germany, the UK, Sweden, France, the US and Switzerland. The largest net importers are Japan, Italy, Canada, Spain and Australia.

2.2.2 International industry structure

The industry is dominated by large multinational enterprises (MNEs) with ten pharmaceutical companies being included in the 1995 Fortune³ list of the 500 largest companies.⁴ The largest companies such as Glaxo Wellcome, Merck and Hoechst each had pharmaceutical sales in 1994–95 of over US\$9 billion. The top eight companies each had sales of more than US\$5 billion (see Table 2.3).

Table 2.3: Largest ten pharmaceutical companies world-wide by sales, 1994–95

<i>Company</i>	<i>Head office</i>	<i>Sales</i> <i>US\$ billion^a</i>	<i>Market share</i> <i>%</i>
Glaxo Wellcome	UK	12.2	5.7
Merck	US	9.4	4.4
Hoechst/MMD	Germany	9.4	4.4
American Home Products	US	7.4	3.5
Bristol-Myers Squibb	US	7.0	3.3
Roche	Switzerland	6.2	2.9
Pfizer	US	5.8	2.7
SmithKline Beecham	UK	5.5	2.6
Pharmacia & Upjohn	Sweden/US	5.3	2.5
Eli Lilly	US	5.2	2.4
Other	–	140.6	65.6
Total	–	214.0	100

a The recent merger between Ciba-Geigy and Sandoz may alter the ranking of companies by world-wide sales.

Source: *Scrip*, Review 1995

³ *Fortune* 7 August 1995, pp. F-14–F-30.

⁴ Some pharmaceutical companies are also significant producers of non-pharmaceutical products such as industrial chemicals.

Although many of the largest companies are involved in both the ethical and OTC markets, most do not specialise in OTC products. None of the seven highest OTC sales companies, all of which have OTC sales of between US\$1 billion and US\$2 billion, are in the largest five companies by overall sales. Only four, SmithKline Beecham, Bayer, American Home Products and Johnson & Johnson, are in the largest 15 companies by overall sales (DIST sub. 56, pp. 5–6).

The largest companies are based in a few key countries, principally the US, Germany, Switzerland and the UK. Traditionally, their operations have been widely dispersed to capture the strategic advantages of operating in different locations.

High value adding activities such as actives⁵ manufacturing tend to occur in a small number of countries with favourable industry policies (particularly taxation regimes) such as Puerto Rico, Singapore and Ireland (Collins 1993). Formulation⁶ and packaging tend to be undertaken closer to the final market to allow closer interaction with local needs and regulatory requirements.

One of the major features of the industry is its rapidly changing structure.

There has been extensive horizontal rationalisation of companies via mergers, acquisitions and strategic alliances over the last few years. Recent examples include the mergers between Upjohn and Pharmacia and Sandoz and Ciba-Geigy, and the takeover of Fisons by Rhone-Poulenc Rorer. There are also examples of vertical integration, with several companies, including Merck, Eli Lilly, SmithKline Beecham and Schering-Plough, recently acquiring pharmaceutical benefit management companies in the US (APMA sub 31, p. 12). Strategic alliances between research based companies and specialist generic product manufacturers are also occurring.

The changing structure of the industry has created excess capacity. This has led to some plant closures as companies consolidate operations at a global level.

Recent developments in the structure of the global industry and possible causes of these changes are reviewed in Chapter 6.

⁵ Actives are the chemical or biological compounds within a drug which have the therapeutic effect.

⁶ Formulation is the combination of actives with other materials to produce a physically and chemically stable dosage form which will enable the actives to be released into the patient's body in a suitable manner.

2.2.3 Competition in the industry

Although generally considered to be competitive, there is some debate regarding the extent of competition in some segments of the pharmaceutical industry. Relatively high sales margins and profitability (compared to other manufacturing industries) are often cited as evidence of market power in the pharmaceutical industry (Comanor 1986). However, the level of concentration is low by many standards.⁷

Assessing the extent of competition in the industry is complicated by the important role played by research and development (R&D) and patents. The pharmaceutical industry is knowledge intensive (see Section 2.3.1). This means that R&D plays a key role in allowing companies to develop and refine products. At the same time, companies rely on patents to enable them to capture the returns from their investment in R&D.

Granting monopoly positions to products through the patent system promotes product competition over time by rewarding innovation through investment in R&D.

While patent protection provides companies with some market power for the life of the patent of a product, there is some dispute over the extent of this advantage. For instance, existence of substitute treatments of similar effectiveness can act to constrain market power extended by patents. ‘Me-too’ products⁸ may be forced to compete on price—despite patent protection—because of the existence of close substitutes. For generic products—which are copies of competitors products—price is often the only basis for competition. A company which attempts to raise its price for a patented product above that of close substitutes is likely to lose market share. Even where no substitutes exist initially, competition is likely to emerge over time because high prices for patented products provide incentives for rival companies to develop close substitute products.

The existence of product competition in the pharmaceutical industry is well established. Relatively high rates of product introduction and obsolescence—measured by instability in product market shares—have been used to show extensive product competition in pharmaceutical markets. Comanor found that the drug industry ranked high among major industries in terms of market share instability (Comanor 1986).

⁷ According to Hayward (1994) the five largest pharmaceutical companies account for less than 20 per cent of the global market. This compares with the automobile industry where the top five companies account for 90 per cent of global sales.

⁸ Competing products with no additional benefits over each other.

To avoid significant price competition many companies attempt to create a strong brand preference for their products. This may enable companies to sustain a price premium (earned under patent) even once a product is out of patent. In reviewing studies of prices charged by sellers of the same product, Comanor argued that:

... studies found a substantial advantage for the original patent holder who had sold the product exclusively for an extended period of time. Because of the effective brand loyalty, the original firm was not forced to meet lower prices charged by new suppliers. While there were some price declines with increased competition, they were relatively small (Comanor 1986, p. 1189).

2.3 Distinguishing industry features

Three features characterise the pharmaceutical industry in all developed economies:

- R&D and patents play a key role in company success;
- operations involve both significant risks and high potential returns; and
- extensive government regulation (DIST sub. 56, p. 1).

2.3.1 Research and development and patents

A large proportion of the profits of the major pharmaceutical companies is derived from innovative ethical products. In turn, companies invest substantial sums in R&D in order to maintain a product pipeline. Companies rely heavily on patents to capture the market advantage generated by new products or processes. This in turn helps generate the returns which are needed to fund on-going R&D. For generic and OTC products, price and brand recognition are more important than R&D and patent protection.

The ratio of R&D spending to total sales provides an indication of the importance of R&D to pharmaceutical companies.⁹ Several commentators have concluded that R&D expenditure accounts on average for about 15 per cent of annual drug sales revenue. A survey of the largest US and European pharmaceutical companies confirmed this conclusion (Collins 1993). Ratios of

⁹ R&D expenditure as a percentage of sales for individual companies should be interpreted with caution, as it only provides a 'snapshot' picture. Companies may decide to increase or decrease their levels of R&D expenditure from year to year for strategic reasons. For example, if a company has several innovations already in the pipeline, it may decide to reduce R&D expenditure the following year.

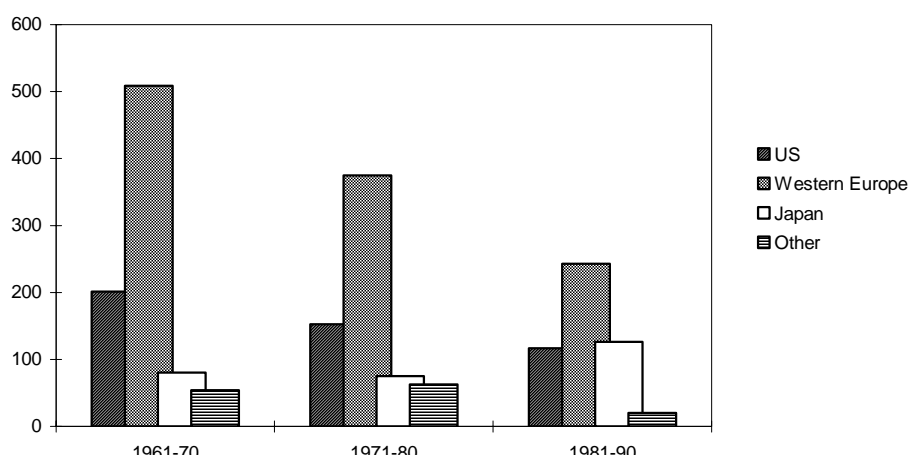
R&D expenditure to sales estimated for other industries are significantly lower than 15 per cent.¹⁰

The ten largest multinational companies are each involved in the production of about 100 pharmaceutical products at any given time. About 70 per cent of these are in-house drugs, the rest are being produced under licence (APMA sub. 31, p. 10).

Developing a new product generally requires research on tens of thousands of chemical compounds. For example, it is estimated that in the US, for every 5 000 chemical compounds identified, only 500 (10 per cent) will progress to in-vitro testing, only 5 (0.1 per cent) will reach human clinical studies and only a single drug will be approved by the US Food and Drug Administration (JPMA 1994, p. 67).

R&D activity is heavily concentrated in the US, Europe (specifically the UK, Germany, Switzerland, Sweden and France) and Japan (see Figure 2.2).

Figure 2.2: Number of new chemical entities developed by region, 1961 to 1990



Source: Ballance 1992, p. 86

The US accounts for over one third of world pharmaceutical R&D expenditure. Japan and other European countries account for a further half (Parry & Creyke 1991, p. 11). In terms of the development of new drugs, the US, Europe and Japan again dominate, with over 90 per cent of all new drugs developed since

¹⁰ A 1992 study of 100 companies across all industries showed average levels of R&D spending as a proportion of sales of 1.7 per cent, 3.8 per cent, 5.1 per cent and 3.7 per cent in the UK, US, Germany and Japan respectively (Collins 1993, p. 136).

the 1960s originating from these countries. However, there has been a gradual erosion of the dominant positions of the US and Western Europe and an increasing Japanese influence.

Naturally, companies focus their R&D efforts on areas that hold the prospect of the greatest commercial returns. However, in the US and Japan, orphan drug legislation has been introduced to encourage investment in R&D in new drugs for rare diseases and conditions which are not expected to recoup their R&D costs through market sales. This legislation typically provides incentives in the form of tax concessions, grants and periods of market exclusivity. The European Union (EU) is in the process of considering the merit of encouraging investment in orphan drugs (sub. 163).

Orphan drug legislation does not currently exist in Australia. The Therapeutic Goods Administration (TGA) does allow for reduced annual charges for drugs with low sales value and reduced evaluation fees (up to 70 per cent) for products to treat rare but clinically significant conditions (TGA 1992).

R&D entails many different stages which require different types of expertise and facilities.

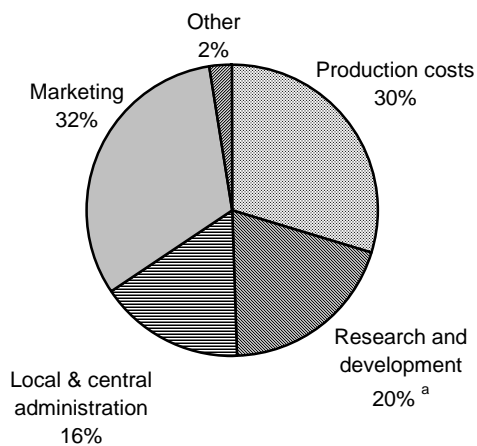
Companies' R&D strategies typically involve a combination of internal work, contracting out and linkages with specialist biotechnology and biopharmacology companies or research institutes in order to access their particular skills.

As a consequence of the high investment in R&D by pharmaceutical companies the industry has a somewhat different cost structure than for other manufacturing industries.

Whilst the hypothetical breakdown shown in Figure 2.3 will not fit every pharmaceutical product, it highlights the relatively low production costs and relatively high R&D and marketing costs.

Rising costs and risks, and the lengthening of the product development period are major issues confronting the industry. The nature and implications of these trends are reviewed in Chapter 6.

Figure 2.3: Typical cost components for a pharmaceutical product



^a R&D as a proportion of total product costs (20 per cent) differs from R&D as a proportion of sales revenue (15 per cent) because total product costs do not include profits.

Source: Collins 1993, p. 203

2.3.2 High risk but high potential returns

Compared with other industries, pharmaceutical companies are generally considered to be very profitable. For instance, *Fortune* magazine estimated that in 1992, 1993 and 1994¹¹, eight, five and five pharmaceutical companies were ranked, respectively, in the top ten companies world-wide (based on profit as a percentage of total assets).¹² Although there are some problems with using this measure of profitability, alternative measures, such as profit as a percentage of sales, give broadly similar results (see Table 2.4).

The high returns achieved by some companies should be balanced against the high cost of R&D, the long time taken to achieve commercialisation of an original product (up to 10 to 15 years) and the high risks in many aspects of the industry.

¹¹ See *Fortune* 26 July 1993, pp. 62–72; *Fortune* 25 July 1994, pp. 67–88; and *Fortune* 7 August 1995, pp. F-14–F-30.

¹² Profit as a percentage of assets is not an ideal measure for comparing profitability of the pharmaceutical sector with other manufacturing industries because a large part of its equity is held as intellectual capital and goodwill rather than plant and equipment (see Egan, Higginbotham and Weston 1982).

Table 2.4: Median profit as a percentage of assets and sales for selected industries, the largest 500 companies, 1992–1994

<i>Industry</i>	<i>1992</i>		<i>1993</i>		<i>1994</i>	
	<i>% assets</i>	<i>% sales</i>	<i>% assets</i>	<i>% sales</i>	<i>% assets</i>	<i>% sales</i>
Pharmaceuticals	9	11	8	10	12	16
Beverages	3	5	4	5	5	7
Telecommunications	na	na	na	na	5	7
Soaps, cosmetics	6	5	3	3	5	5
Food	5	3	5	2	5	3
Aerospace	-2	-3	3	2	4	4
Mining	4	6	4	9	na	na
Scientific, photo. control equip.	5	4	3	1	4	6

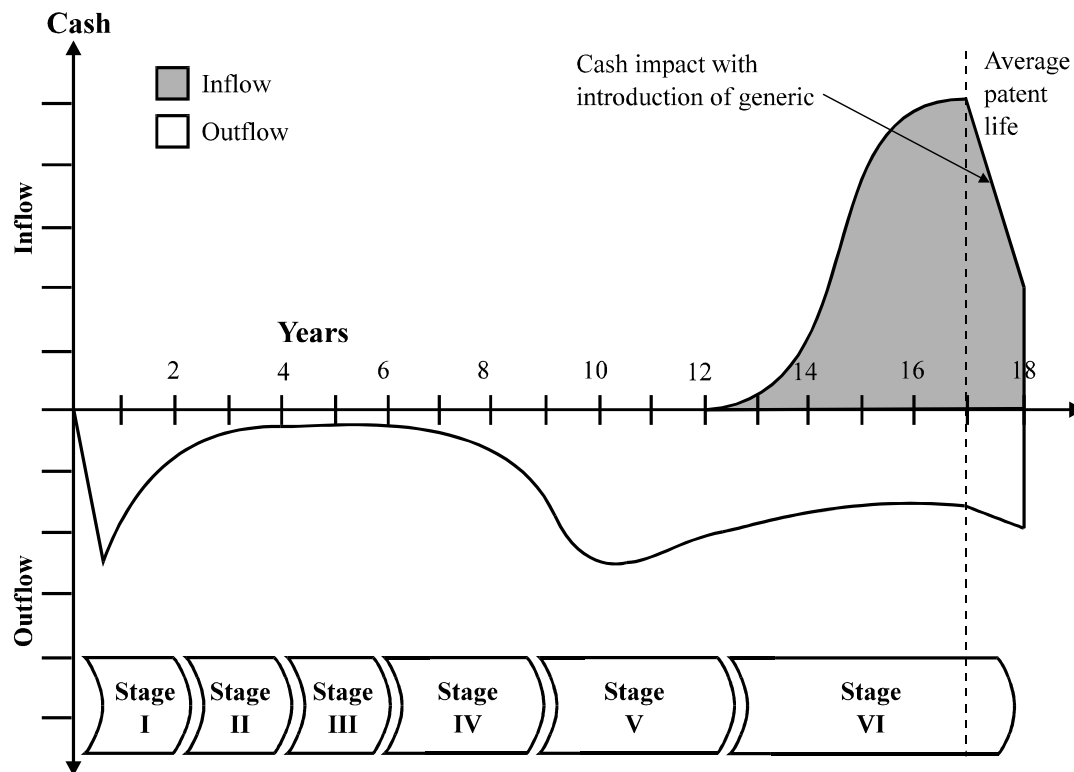
Sources: *Fortune* 26 July 1993, pp. 62–72; *Fortune* 25 July 1994, pp. 67–88; *Fortune* 7 August 1995, pp. F-14–F-30.

The estimated cost of bringing a new pharmaceutical product based on a new chemical entity onto the market ranges from US\$200 million to US\$400 million (see for example Pfizer sub. 66 and Weiss, Nick and Opsetmoen 1995). The typical cash flow pattern is shown in Figure 2.4.

Even after a new product has been developed, there is no guarantee that it will be profitable. It may face unforeseen competition from drugs developed by rival companies, or produce undesirable side effects which result in its withdrawal from the market or, worse still, major claims for compensation from affected consumers. Perhaps the best known example of a product which had disastrous outcomes was Thalidomide.

Despite the high risk of failure, the sales generated from a single breakthrough or blockbuster drug are such that investment in pharmaceutical R&D can be worthwhile. For example, the success over the last ten years of Glaxo, with world sales of nearly US\$9 billion in 1993–94, has been underpinned by sales of Zantac, an anti-ulcer drug. Zantac is currently the world's top selling pharmaceutical product, with annual sales of about US\$3.5 billion (Forman 1995). However, blockbuster drugs are exceedingly rare. For example, Alster (1995) estimated that in 1993 there were only 20 drugs on the market with annual sales of more than US\$1 billion.

Figure 2.4: A simplified model of the cash flows of an original ethical drug



Stage I	Screening (1–2 years): Review of 10 000 substances
Stage II	Chemical (1–2 years): Chemical stabilisation for production
Stage III	Biological (1–2 years): Toxicological study; review of remaining 20 substances
Stage IV	Clinical (3–4 years): Remaining ten substances in human trials
Stage V	Registration (2–3 years): Government approval and acceptance; bioequivalence
Stage VI	Market entrance: production control; packaging; patent protection

Source: Weiss 1995, p. 10

The high risk involved in R&D and the high dependence of company profitability on blockbuster products mean that there can be considerable variation over time in the profitability of individual companies. For instance, profitability may depend on past R&D success or where key products are in the development and production cycle. Alster (1995) claimed that a current lack of new products in the pipeline—to replace blockbuster products as they come off patent—is putting pressure on the profits of several leading companies and contributing to the pressure for mergers and strategic alliances (see Chapter 6).

Even over relatively short periods profit as a percentage of assets of several of the largest companies varied considerably. For example between 1992 and 1994:

- American Home Products' profitability dropped by over 50 per cent;
- Pfizer's profitability increased by 50 per cent from 8 per cent to 12 per cent; and
- SmithKline Beecham's profitability dropped from 17 per cent to 1 per cent.¹³

2.3.3 Government regulation

In most countries governments have a major influence on both price and supply conditions. Typically, governments subsidise consumption of drugs at least for some members of the community and regulate the conditions under which drugs can be supplied.

For equity and welfare reasons, most governments subsidise consumption of pharmaceuticals to ensure drugs are available to all members of the community at a reasonable cost. In many countries budgetary pressures and rapid growth in consumption of drugs have also led governments to introduce access and price regulation in an effort to restrain consumption and government outlays.¹⁴

Many governments also regulate the conditions under which drugs are supplied. Pharmaceuticals are often consumed on an irregular basis and the details of their efficacy and effectiveness are complex and technical. Consumers also tend to be risk averse about the use of products which are invasive and can have significant impacts on their bodies. To reduce these risks, consumers and their agents generally desire extensive protection and expert independent advice when making pharmaceutical consumption decisions. To meet these needs governments typically regulate:

- standards by which pharmaceutical products are manufactured;
- quality and efficacy of marketed products;
- purpose and primary use of pharmaceutical products;
- which pharmaceutical products can be sold by whom; and
- the method and manner in which pharmaceuticals are advertised.

¹³ *Fortune* 26 July 1993, pp. 62–72; *Fortune* 25 July 1994, pp. 67–88; *Fortune* 7 August 1995, pp. F-14–F-30.

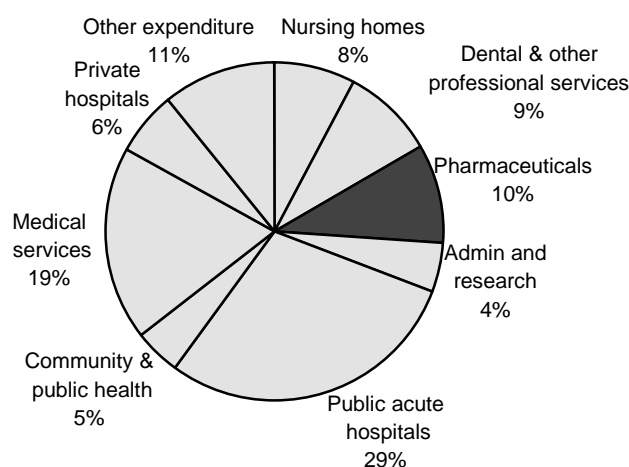
¹⁴ For a discussion on methods of regulation see Chapter 6 and Appendices D and E.

2.4 The Australian industry

To establish a profile of the pharmaceutical industry in Australia, the Commission drew on several sources of data in addition to the Australian Bureau of Statistics (ABS)—which only reports in detail on some aspects of the industry. The peak organisations representing the two major sectors of the industry, the Australian Pharmaceutical Manufacturers Association (APMA) (prescription pharmaceuticals) and the Proprietary Medicines Association of Australia (PMAA) (OTC products) provided the Commission with the results of recent surveys of the industry.¹⁵

Overall expenditure on pharmaceutical products through the PBS, hospitals and OTC made up about \$3.3 billion or 10 per cent of Australian final health care expenditure in 1992–93.¹⁶ Pharmaceutical expenditure is the third largest component of final health care expenditure behind public acute hospital services and medical services (see Figure 2.5).

Figure 2.5: Breakdown of Australia's expenditure on health care by function, 1992–93



Source: APMA sub. 31, p.13

¹⁵ Towards the end of 1995 the APMA commissioned a survey of its members (APMA 1995a) and the PMAA commissioned a survey of the OTC sector in mid 1995 (sub. 71, Attachment 1).

¹⁶ Overall expenditure on pharmaceuticals is at final point of sale or use and hence is not directly comparable with pharmaceutical company sales.

2.4.1 Size of the industry

The Australian pharmaceutical industry made up around 1.3 per cent of total employment, 1.9 per cent of total turnover and 2.1 per cent of total value added across the manufacturing sector in 1993–94. In terms of turnover, the pharmaceutical industry is about a third the size of the passenger motor vehicle and the textile clothing and footwear industries (see Table 2.5).

Table 2.5: Value added, turnover and employment for selected manufacturing industries, 1992–93, current dollars

<i>Industry</i>	<i>Value added^a</i>		<i>Employment</i>		<i>Turnover</i>	
	<i>\$m</i>	<i>% of total manuf^cg^b</i>	<i>number</i>	<i>% of total manuf^cg^b</i>	<i>\$m</i>	<i>% of total manuf^cg^b</i>
Medicinal and pharmaceutical products	1 414	2.1	11 743	1.3	3 035	1.9
Passenger motor vehicles and parts	3 151	4.8	52 490	6.0	10 277	6.4
Textiles clothing and footwear and leather	3 829	5.8	75 223	8.5	8 399	5.2

a Valued added was calculated as turnover, plus the increase (or less the decrease) in the value of stocks, less purchases, transfers in and selected expenses.

b In 1992–93, for all manufacturing industries total value added was \$66 158 million, total employment was 881 727 and total turnover was \$160 376 million.

Source: ABS 1996, Cat. No. 8221.0

In 1994, the Australian pharmaceutical industry had total sales, including exports, of around \$3.8 billion. The prescription component is worth \$2.8 billion and the OTC component almost \$1 billion. The latter, at 26 per cent of total sales, is slightly higher than the world share of 20 per cent (see Table 2.6).

Sales of the OTC sector include sales of nutritional foods—therapeutic and non-therapeutic health and nutrition products including vitamins and mineral supplements, herbal products and other dietary supplements. According to the Nutritional Foods Association of Australia, total sales of the nutritional foods sector in Australia were between \$450 and \$500 million or around half of the OTC sector in 1993–94 (sub. 108, p. 9).

Australian pharmaceutical sales have been growing rapidly (see Table 2.6). By comparison, sales of pharmaceuticals world-wide grew by between 10 per cent and 12 per cent a year over the same period. Overall, the increase in Australian sales was driven by rises in PBS sales, prescription exports and domestic sales of OTC products.

Table 2.6: Australian pharmaceutical sales, 1987, 1991 and 1993–94, current dollars

<i>Industry sales sectors^a</i>	<i>1987</i>		<i>1991</i>			<i>1993–94</i>		
	<i>\$m</i>	<i>% of total^b</i>	<i>\$m</i>	<i>% change^c</i>	<i>% of total^b</i>	<i>\$m</i>	<i>% change^c</i>	<i>% of total^b</i>
Prescription								
PBS	668	53	993	49	51	1 744	76	46
Hospital prescription	172	14	227	32	12	314	38	8
Private prescription	74	6	79	7	4	142	80	4
Export prescription ^d	na	na	167	na	9	600	259	16
Total prescription	915	72	1 468	60	76	2 800	91	75
OTC								
Domestic OTC	350	28	420	20	22	880 ^e	10	23
Export OTC	na	na	45	na	2	81	80	2
Total OTC	350	28	466	na	24	960	106	26
Total human use	1265	100	1 934	53	100	3 760	94	100

a Sales include imported products and exports valued at prices received by manufacturers.

b Percentage of total human use pharmaceutical sales.

c Percentage change from previous period (ie 1987 to 1991 and 1991 to 1993–94).

d Exports of prescription products are based on total exports for all pharmaceuticals of \$701 million less OTC exports of \$81 million and veterinary exports of \$20 million.

e OTC data in 1994 are not directly comparable to previous years.

na Not available.

Sources: APMA 1993; PMAA sub. 71

The rapid growth in pharmaceutical sales masks changes in its component shares. For instance, between the period 1987 to 1993–94 the shares of the PBS and hospital prescription sectors fell. Between 1991 and 1993–94 the share of the prescription export sector rose significantly, albeit from a low base.

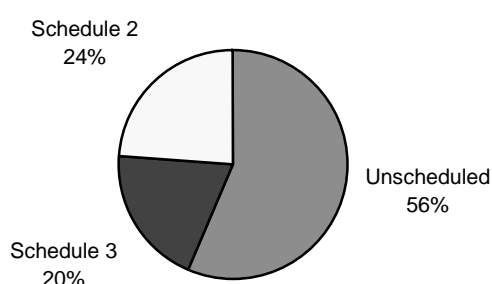
The rise in the number of new products available on the PBS is a key reason for the growth in Australian drug sales. Another factor has been a rise in the number of concession holder families who can purchase products on a heavily subsidised basis (see Chapter 4). Export sales have been encouraged by the Pharmaceutical Industry Development Program (see Chapter 5).

Based on forecasts provided by the industry sales for both the prescription and the OTC sectors are expected to continue to grow strongly over the next few years. Between 1993–94 and 1997–98, sales for the prescription and OTC sectors are projected to grow by 67 per cent and 30 per cent respectively. For

the export prescription and OTC sectors, sales are forecast to grow by 97 per cent and 30 per cent respectively (APMA 1995a, Appendix C, p. 1).

Sales of OTC products can be further broken down according to their scheduling, which reflects the different levels of risk or the need for professional advice on use associated with different products. The main schedule categories are prescription only (schedule 4), pharmacist only (schedule 3), pharmacy only (schedule 2) and general sale (unscheduled) (see Chapter 3). Market shares for different types of OTC products are shown in Figure 2.6.

Figure 2.6: Domestic sales of OTC products by schedule, 1995



Source: PMAA sub. 71, Attachment 1, p. 8

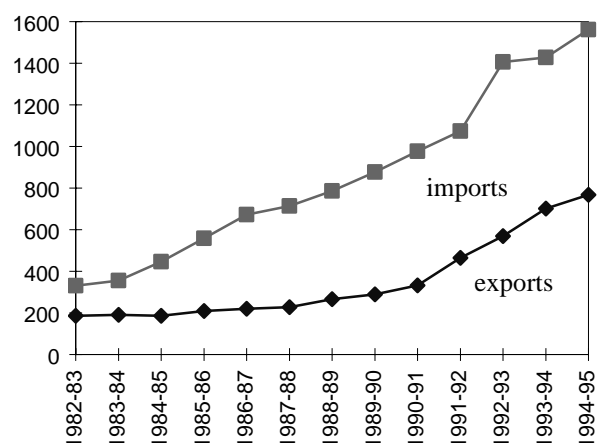
2.4.2 Trade

Australia has a significant trade deficit in pharmaceutical products. In 1994–95 exports were valued at \$770 million compared to imports worth \$1560 million. While exports increased from \$270 million in 1989–90, imports grew from \$820 million over the same period (see Figure 2.7). As a result, the export/import ratio has increased from 33 per cent to 49 per cent since 1989–90 (ABS 1995, Cat. No. 5422.0).¹⁷

Based on the Business Review Weekly–Export Finance Insurance Corporation (BRW–EFIC) Top 500 Exporters list, the main pharmaceutical exporters in 1996 were Merck, Sharp & Dohme, Glaxo Wellcome, Faulding, Bristol-Myers Squibb, Astra, Schering-Plough, CSL, Bayer, 3M Pharmaceuticals and Pfizer (BRW 29 January 1996, p. 43).

¹⁷ The ABS estimates include veterinary products and so are not directly comparable with the figures provided in Table 2.6.

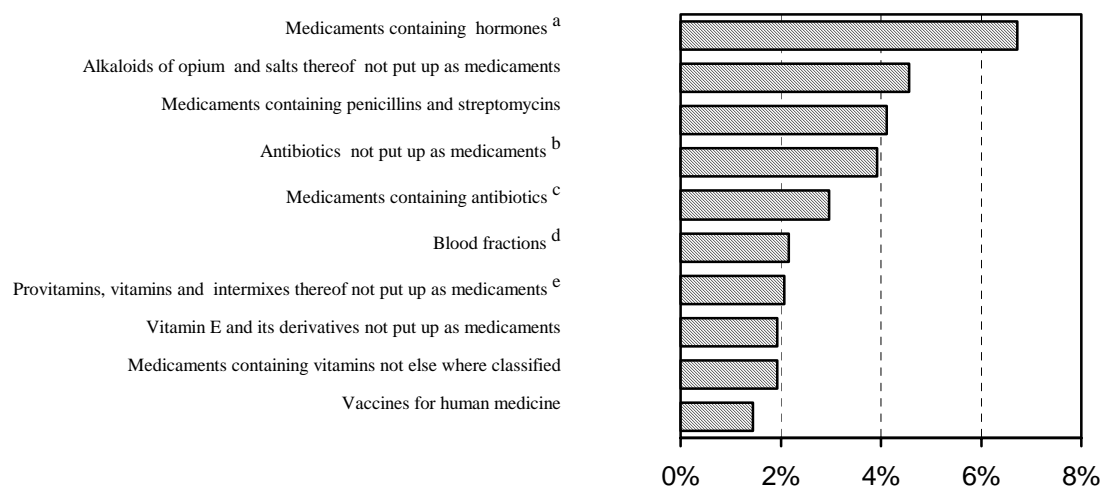
Figure 2.7: Pharmaceutical industry exports and imports, 1982–83 to 1994–95, \$ million current dollars



Source: ABS 1995, Cat. No. 5422.0

A diverse range of pharmaceutical products are exported from Australia. The ten highest selling exports accounted for 32 per cent of all pharmaceutical exports in 1994–95 (see Figure 2.8) (APMA 1995a).

Figure 2.8: The ten highest selling Australian pharmaceutical exports as a percentage of total pharmaceutical exports, 1994–95



^a Excluding antibiotics, insulin and adrenal cortex hormones.

^b Excluding penicillins, streptomycins, tetracyclines, chloramphenicol and erythromycin.

^c Excluding penicillins, streptomycins, tetracyclines, and erythromycin.

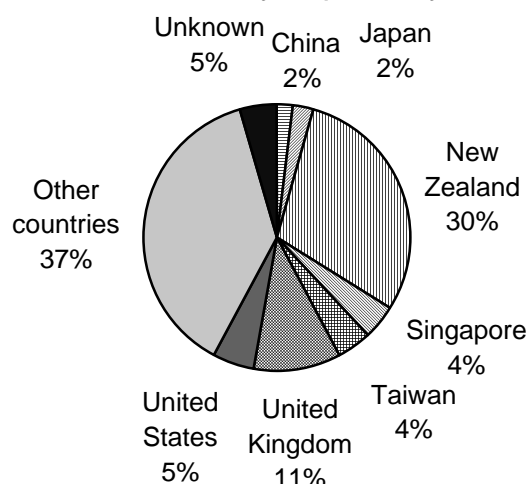
^d Excluding antisera.

^e Natural or reproduced by synthesis, excluding unmixed, including natural concentrates.

Source: APMA 1995a.

Australia's largest export destination is New Zealand, which accounted for 30 per cent of export sales in 1994–95 (see Figure 2.9). In the same year, other major destinations were the UK and the US and the Association of South East Asian Nations (ASEAN) group of countries. Overall, Asia accounted for over 30 per cent of total export sales in 1994–95 (ABS 1995a).

Figure 2.9: Pharmaceutical industry exports by destination, 1994–95



Source: ABS 1995a, Cat. No. 5422.0

Exports to most of Australia's major trading partners increased substantially between 1992–93 and 1994–95. Most notably, sales to the UK increased by 108 per cent (from \$39 million to \$81 million) and sales to China increased by 250 per cent (from \$4 million to \$14 million) over this period (ABS 1995a). As a result, the proportion of total exports going to the UK and China increased from 6.9 per cent to 10.6 per cent and 0.7 per cent to 1.8 per cent respectively.

2.4.3 Local industry structure

The Australian pharmaceutical industry comprises over 120 companies. It is dominated by subsidiaries of some of the largest MNEs but also includes a number of significant Australian owned companies such as Faulding, Sigma, CSL, AMRAD and Blackmores. Profiles of CSL and AMRAD are contained in Boxes 2.1. and 2.2.

While the core business of most Australian pharmaceutical companies is supply of human use pharmaceutical products, most also supply other products. These include veterinary pharmaceuticals, medical and scientific equipment and biotechnology related products. Because companies publish sales on a consolidated basis, their pharmaceutical and other product sales are not readily identifiable.

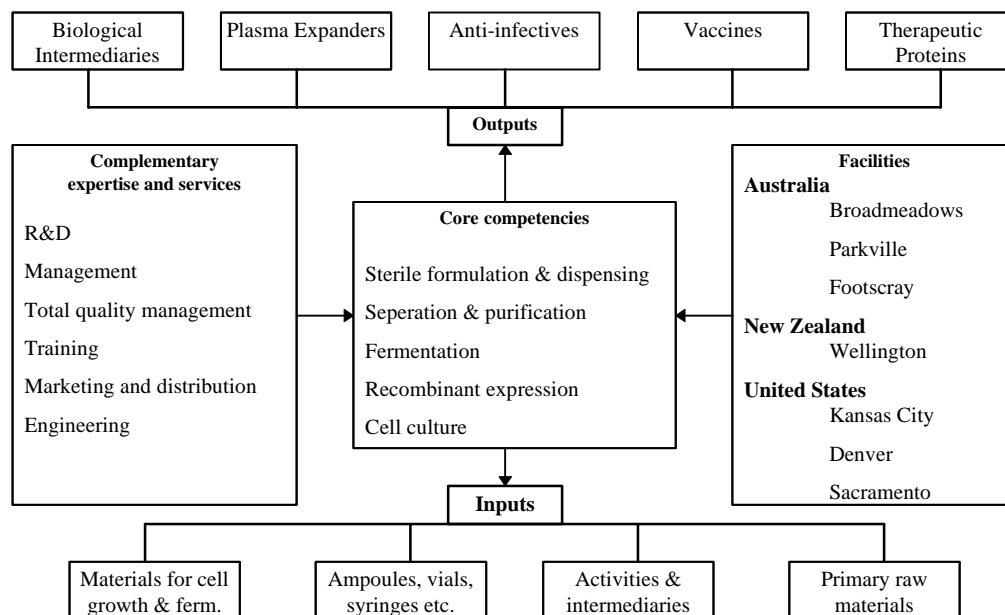
Box 2.1: Pharmaceutical company profile: CSL

CSL is one of the largest and most highly integrated pharmaceutical companies in Australia, employing around 1350 people. Established in 1916 by the Commonwealth Government, CSL became the Commonwealth Serum Laboratories under the *Commonwealth Serum Laboratories Act* 1961. In April 1991 CSL became an unlisted public company under the Corporations Law and was floated on the Australian Stock Exchange in May 1994.

The company specialises in biopharmaceuticals—or pharmaceutical products of biological rather than chemical origin. It develops, manufactures and markets human and veterinary pharmaceutical and diagnostic products, including products derived from human plasma. It makes biopharmaceuticals from Australian materials and uses its own in-house manufacturing and testing technologies.

The company has group revenue of around \$250 million a year and invests around \$25 million in R&D and \$20 million in new capital investment a year. In 1994–95 biopharmaceutical product revenue exceeded \$165 million—or around 70 per cent of total revenue. In that year biopharmaceutical exports exceeded \$20 million—or around 12.5 per cent of total revenue.

The core activities of CSL



Source: sub. 39, p. 4.

Box 2.2: Pharmaceutical company profile—AMRAD

In 1987 AMRAD was established as an unlisted company by the Victorian Government and a group of Melbourne medical research institutes. This initiative arose out of a government study identifying new business areas with prospects.

AMRAD was established as the vehicle to identify and protect potential pharmaceutical discoveries through close collaboration with medical research institutes. Collaborating institutes became shareholders in AMRAD in return for providing the company with the first opportunity for commercial development of these discoveries.

Since 1990, the number of institutes linked to AMRAD has grown from the four founding members in Victoria to 11 institutes around Australia. The shareholders of the company have also expanded through two private share placements which attracted Australian, European, Japanese and US investors. The company remains over 70 per cent Australian owned with the Victorian Government still being the principal (34 per cent) shareholder.

The most visible part of AMRAD's business is the trading division, AMRAD Pharmaceuticals, which was established in 1989 as an AMRAD majority owned joint venture with Merck, Sharp & Dohme. The trading division reported sales of \$62 million in 1994–95.

The operations of the AMRAD group can be divided into three principal areas:

- marketing of licensed-in pharmaceutical products through the majority owned joint venture company, AMRAD Pharmaceuticals;
- an integrated biotechnology product business trading under the name AMRAD Pharmacia Biotech in Australia, marketing both AMRAD's own products and a range of licensed-in products; and
- the R&D of pharmaceutical projects incorporating intellectual property management and development and commercial collaborations.

The AMRAD group employs 180 staff from a range of disciplines including R&D scientists, accountants, lawyers, pharmacists and medical practitioners.

Source: sub. 24, pp. 9–10

Sales of products under the PBS, which account for about 55 per cent of total local pharmaceutical sales, are often used as a proxy for market shares even though they underestimate the shares of companies with high OTC or export sales. Table 2.7 shows PBS sales for 1994–95 for the ten highest MNEs and the two highest placed Australian companies.

Besides AMRAD and CSL, the major Australian companies supplying under the PBS are Faulding and Sigma. There are a small number of companies specialising in supply of generic drugs under the PBS, including Alphapharm (which accounts for the majority of sales of generic drugs), Douglas

pharmaceuticals and AMRAD (as part of a joint venture with Merck, Sharp & Dohme).¹⁸

Table 2.7: The ten largest MNEs and two largest Australian companies in terms of PBS sales, 1994–95

<i>Company</i>	<i>Group head office</i>	<i>PBS sales^a</i>	<i>Share of PBS sales</i>
		<i>\$ million</i>	<i>%</i>
MNEs			
Merck, Sharp & Dohme	US	223	9.5
Astra	Sweden	200	8.5
Glaxo ^b	UK	195	8.3
Bristol-Myers Squibb	US	98	4.2
SmithKline Beecham	UK	91	3.9
Ciba-Geigy ^b	Switzerland	88	3.8
ICI	UK	83	3.6
Roche	Switzerland	82	3.5
Eli Lilly	US	74	3.2
Pfizer	US	69	3.0
Wellcome	UK	54	2.3
Australian companies			
AMRAD	Australia	67	2.9
CSL	Australia	44	1.9

a PBS figures include branded and unbranded scripts and Doctor's Bag scripts, but do not include scripts written for extemporaneously prepared items, or include corrections for bulk and manual adjustments.

b Recent mergers between Glaxo and Wellcome and Ciba-Geigy and Sandoz may alter the ranking of companies by PBS sales.

Source: PBPA 1995, p. 19

¹⁸ Generic suppliers produce copies of out of patent drugs.

The OTC sector is also dominated by multinational subsidiaries. However, there are numerous Australian companies manufacturing OTC products including Blackmores (which is the largest specialist company), Faulding and Sigma. Companies which specialise in nutritional foods, such as Cenovis, are typically wholly Australian owned.

2.4.4 Types of activities

About 40 companies have manufacturing facilities in Australia. The activities of prescription drug producers are mainly confined to formulation and packaging, with the active ingredients being imported (see Table 2.8). There is some actives manufacturing but this is confined to a small number of niche areas. For example, Glaxo Wellcome manufactures, packages, markets and distributes some morphine based products in Australia (sub. 141). The Institute of Drug Technology is an Australian based company specialising in contract manufacture of raw materials (sub. 30).

Most manufacturing facilities are located in Sydney or Melbourne. There has been a significant investment in these facilities since the commencement of the Factor f scheme in 1988 (see Chapter 5). The APMA anticipates that capital investment over the ten years to 1999 will total around \$800 million (sub. 31, p. 18).

There are over 50 companies manufacturing and distributing OTC products. Virtually all material and service inputs to the production of OTC products are sourced locally (sub. 71, p. 3).

Table 2.8: Pharmaceutical manufacture by stage in the production chain, 1991–92, \$ million, current dollars

<i>Stage of production</i>	<i>On own behalf</i>	<i>On behalf of others</i>	<i>By others on own behalf</i>
Synthesis of actives through to final packaging	36.2	0.0	3.6
Formulation of final form products through to packaging	885.7	89.1	71.2
Manufacture at final packaging stage only	218.4	9.3	31.9
Synthesis of actives sold to users outside own pharmaceuticals unit	12.7	0.0	0.0
Formulation of intermediate product sold to users outside own pharmaceutical unit prior to packaging	0.7	0.8	9.3
Total	1 153.7	99.3	116.0

Source: DIST sub. 56, p. 19

2.4.5 Research and development

The pharmaceutical industry in Australia invests a significant amount in R&D as a proportion of its turnover and as a proportion of total R&D expenditure for all industries (see Table 2.9). In 1992–93 expenditure on R&D by the industry was around \$106 million or nearly 4 per cent of industry turnover—putting the industry in the top ten industries according to this indicator.¹⁹ This constitutes around 4 per cent of business R&D expenditure by all industries in Australia. Based on the 1995 APMA survey it was estimated that R&D had grown to \$172 million or 5 per cent of sales in 1993–94.²⁰

Table 2.9: R&D expenditure by industry, 1992–93, \$ million

<i>Industry</i>	<i>R&D expenditure</i>
Computer software	635
Electronic equipment	240
Motor vehicles & parts	166
Basic Iron & Steel	145
Mining (sector)	133
Ships & boats	116
Food, beverage & tobacco	116
Industrial chemicals	108
Pharmaceutical products	106
Fabricated metal products	103
All other ^a	921
Total all industries	2 789

a All other industries includes those manufacturing industries and other industries (18 in total) with R&D expenditure of less than \$100 million (in addition to the Agriculture, forestry, fishing and hunting sector with R&D expenditure of \$58 million).

Source: ABS 1994c, Cat No. 8104.0.

Although the ratio of R&D to total sales in Australia is less than the world average of about 15 per cent of sales, this may be partly explained by the fact

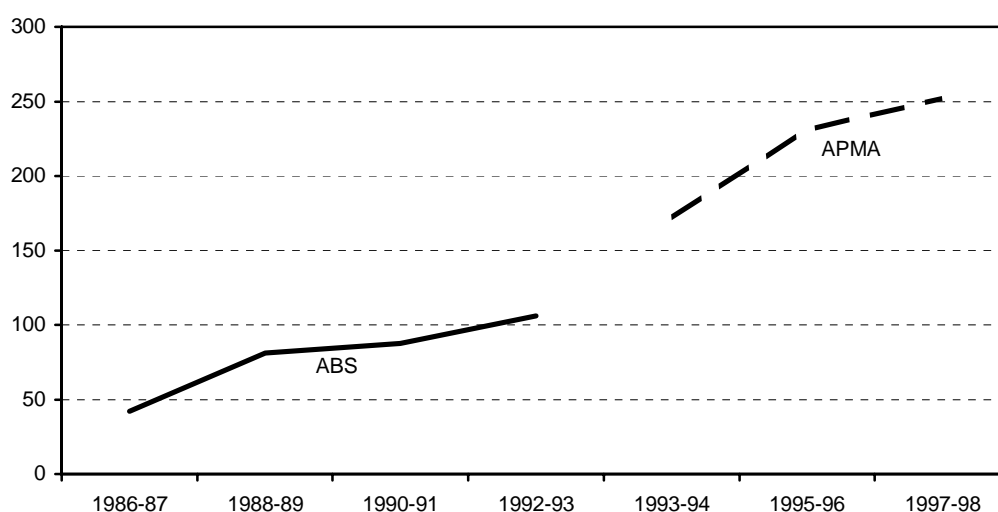
¹⁹ Pharmaceutical industry turnover for 1992–93 was \$3 035 million (ABS 1996, Cat. No. 8221.0).

²⁰ The ABS and APMA survey data are not directly comparable.

that MNEs operating in Australia draw heavily on the outcomes of research done by their parent companies in other countries.

The Pharmaceutical Industry Development Program has played a major role in promoting pharmaceutical R&D in Australia (as discussed in Chapters 5 and 10). Figure 2.10 shows actual and projected R&D expenditure by the industry from 1986–87 to 1997–98.

Figure 2.10: R&D expenditure on pharmaceutical products
(actual/projected), Australia 1986–87 to 1997–98, \$ million



Source: APMA 1995a, Figure 3.10

Most of the R&D is related to prescription products. This segment of the industry has traditionally tended to focus its R&D efforts in the areas of product development and clinical trials. However, it is increasingly directing its research towards basic and pre-clinical research.

It is estimated that the OTC sector in Australia spends around \$18 million per annum or less than 2 per cent of sales on R&D (PMAA sub. 71, p. 3). This is due to the established nature of most OTC medicines. Most OTC sector R&D concerns product refinement, market research, product presentation and so on (see Table 2.10).

Table 2.10: Pharmaceutical R&D expenditure by type of activity, 1991–92 and 1993–94, per cent of total R&D

<i>Activity</i>	<i>All companies</i>	
	<i>1991–92</i>	<i>1993–94</i>
Basic	12.5	13.2
Pre-clinical	6.8	22.2
Phase I	6.1	1.9
Phase II	12.3	7.8
Phase III	26.9	24.5
Phase IV	10.9	7.7
Total clinical trials	56.2	41.9
Manufacturing processing	17.4	18.4
Other	7.2	4.2
Total	100.0	100.0

Source: APMA 1995a, p. 13

2.4.6 Supporting industry structures

Companies have established a large number of formal and informal linkages, particularly in the R&D area. Linkages include collaborative arrangements between pharmaceutical companies and research organisations and strategic alliances between MNEs and smaller biotechnology and biopharmaceutical companies.

In Australia, most MNEs conduct a large share of their R&D through linkages with other pharmaceutical companies or research organisations.²¹ The APMA survey estimated that such collaborations account for 40 per cent of total research (APMA 1995a, Appendix B, p. 13). Examples of some of the joint R&D activities of the industry are provided in Box 2.3 (see Chapter 5 for further examples).

Similar linkages are less common for other types of pharmaceutical activity. For instance, there is limited manufacture of products on behalf of other companies. Of the total estimated manufactured output in 1993–94 only about 6 per cent was on behalf of other companies (APMA 1995a, Appendix B, p. 4).

²¹ Pfizer is an exception as it conducts its local R&D in-house, in Australia, through AUSCLIN—a branch of Pfizer Central (see Pfizer, sub. 79).

There is, however, significant cooperation between Australian based companies and MNEs in the development and commercialisation of new products. Faulding, for example, has an alliance with Glaxo Wellcome in relation to the development and international sale of its product Kapanol (sustained release morphine). Biota have licensed Glaxo Wellcome to carry out the international marketing of its therapy for influenza.

Box 2.3: Examples of R&D linkages in Australia

- Glaxo Wellcome, in collaboration with Biota Holdings and the Victorian College of Pharmacy, is developing an anti-flu drug which is now undergoing clinical trials overseas and in Australia. Glaxo Wellcome has also entered into several collaborative programs with the Centre for Drug Design and Development including a program aimed at discovery of novel compounds inhibiting the interaction between HIV and white blood cells and a 5 year program aimed at developing a generic technology for the design of peptidomimetic drugs.
- AMRAD has entered into a collaborative project with the Centre for Drug Design and Development seeking to identify and optimise novel pharmaceutical activities in the venom of cone shells.
- Eli Lilly has established a \$5 million joint venture with the Garvan Institute to conduct research into osteoporosis and diabetes.
- Astra has provided over \$10 million in funding over five years to the Queensland Pharmaceutical Research Institute for the testing of extracts from marine and terrestrial sources for pharmaceutical activity and has first option on any commercial development arising from this work.
- CSL announced, in February 1995, an agreement with UniQuest Limited (the commercialising arm of the University of Queensland) to develop and commercialise products of the Human Papilloma virus vaccine technology (human papilloma virus is implicated in genital warts and cervical cancer).
- Bristol-Myers Squibb has invested \$55 million in a study of high cholesterol by the National Heart Foundation.

Sources: DIST sub. 56, pp. 24–25; Professor Peter Andrews sub. 51, pp. 1–2

2.4.7 Profitability

Profitability of Australian operations appears to be considerably lower than the industry internationally. Median ratios of profit to sales for each of the last three years for international companies included in the *Fortune 500* ranged from 10 per cent to 16 per cent. This compares with 6 per cent to 8 per cent for Australian operations included in the *BRW* top 1000 (see Table 2.11).

Table 2.11: Median profit as a percentage of sales and assets for international and Australian pharmaceutical companies, 1992–1994

<i>Company</i>	<i>1992</i>	<i>1993</i>	<i>1994</i>	<i>Average</i>
International				
Number in sample	25	26	10	
Median profit as % of sales	11	10	16	12
Median profit as % of assets	9	8	12	10
Australia				
Number in sample	17	16	16	
Median profit as % of sales	6	8	8	7
Median profit as % of assets	8	19	17	15

Sources: International data: *Fortune* 26 July 1993, pp. 62–72; *Fortune* 25 July 1994, pp. 67–88; *Fortune* 7 August 1995, pp. F-14–F-30
 Australian data: *BRW* 22 October 1993, pp. 92–3; *BRW* 24 October 1994, pp. 101–2; *BRW* 23 October 1995, pp. 75, 94, 95

The variation in profits across companies partly reflects the different activities (or proportion of activities) undertaken such as R&D, formulation and packaging. The returns for Australian based companies and MNEs may not be directly comparable, however, because the integrated nature of MNEs' operations makes it difficult to align their world wide costs, profits and sales with those of their Australian subsidiaries.

2.4.8 Employment

According to official statistics, employment in the Australian pharmaceutical and veterinary products industry has been remarkably stable for the last 20 years. It has generally fluctuated between 10 000 and 11 700 persons (ABS 1996, Cat. No. 8221.0).

On the other hand, industry survey data suggest some growth in employment in recent years, from 8 500 in 1988 to 10 300 in 1992 and 11 300 in 1994 (APMA

1995a, Appendix C, p. 9).²² It projects further growth to 12 400 by 1998. The survey data are not, however, directly comparable to the ABS series.

The pharmaceutical industry both internationally and in Australia is not generally considered to be very labour intensive. In 1989–90 value added per employee in Australia was \$93 000, which is over 20 per cent greater than the average for all manufacturing industries in the same year. In 1992–93, value added per employee had risen to \$120 000, which was over 60 per cent greater than the average for all manufacturing industries in the same year (ABS 1996, Cat. No. 8221.0).²³

It appears that multinational subsidiaries employ fewer people than do domestic companies. Even the largest multinationals employ only a few hundred people in Australia. Higher levels of employment in Australian companies may reflect the more integrated nature of their operations.

2.5 Overall economic contribution

Several different approaches were used by participants in an attempt to measure the economic contribution of the industry. They generally focused on two aspects, its contribution to the provision of health services to the community and its value as a sector of the domestic economy.

For example, the APMA considered that its contribution should be assessed ‘both in terms of its key role in the overall health care sector and as a major economic unit within the national economy’ (sub. 31, p. 13).

2.5.1 Contribution to health of the community

Health services, including pharmaceuticals, play a vital role in reducing the economic cost of disease and ill health and improving quality of life. The development of new or improved medicinal products and better understanding of best practice in the delivery and use of existing pharmaceuticals all contribute to these benefits. As it is difficult to put a value on quality of life, the benefit of health improvement is hard to quantify.

²² The ABS and APMA measures of employment in the pharmaceutical industry include employees in the OTC sector.

²³ Value added per employee is a measure of the relative contribution of labour to value added in an industry. Industries with higher value added per employee generally utilise proportionally more capital in production.

Many products sold in Australia would be available even if there were no local industry. As a result, even if it were possible to put a value on the contribution of pharmaceuticals to health improvements, much of this cannot be attributed to the local industry. However, there may be some situations where imports are not an alternative.

The South Australian Government considered that:

Increasingly, medical science is reporting the appearance of organisms resistant to antibiotics and infection outbreaks, and the organisms involved in them can be quite localised. Outbreaks of controlled diseases resulting from failures of vaccination programs are also becoming more common. An ability to respond quickly and effectively to these outbreaks is likely to become increasingly important, and a strong local pharmaceutical industry has an important part to play in meeting these new threats (sub. 70, p. 6).

There may also be community benefits resulting from collaboration between research institutes and pharmaceutical companies leading to new solutions to health problems. For example, the Garvan Institute seeks to:

... develop new ideas to a stage where pharmaceutical companies are prepared to undertake the risk of product development and commitment to royalty arrangements. ... The Garvan will be the source of future products and techniques which solve some of society's health problems (sub. 33, p. 1).

To the extent that a local activity generates greater health benefits than would be achieved if all drugs were imported, it is contributing to community health. However, the fact that MNEs dominate Australian drugs supply suggests that local activity, mainly confined to formulation and packaging, may only make a small contribution to the overall health benefits generated by pharmaceutical products.

The importance of pharmaceuticals to the overall health of the community is reflected in the National Medicinal Drug Policy (NMDP) (see Box 2.4). During the 1980s, the World Health Organisation (WHO) recommended that national governments implement such policies. Australia has since established the NMDP with four arms. The first three arms are based on the supply of drugs to the community. The fourth arm relates to the Government's industry policy objectives (see Box 2.4 and Chapter 11).

Box 2.4 National Medicinal Drug Policy

The four arms of the National Medicinal Drug Policy (NMDP) are:

- the supply of medicines of established and acceptable quality, safety and efficacy. The standard of medicinal pharmaceuticals is assured through the activities of the Therapeutic Goods Administration (TGA) and the Australian Drug Evaluation Committee (ADEC);
- timely, reliable and affordable access by the community to necessary medicines, made possible through the PBS;
- the quality use of medicines by health care providers and consumers, overseen by the Pharmaceutical Health and Rational Use of Medicines Committee (PHARM); and
- the maintenance of a viable pharmaceutical industry, which is the role of DIST, through the Factor f scheme.

Source: DSHS 1995a

The NMDP is overseen by the Australian Pharmaceutical Advisory Council (APAC) which was established in 1991. APAC seeks to achieve an acceptable balance between the often diverse objectives of industry and other stakeholders.

2.5.2 Contribution to domestic activity

To estimate the contribution of the domestic industry to Australian economic activity, the APMA take as the starting point, the value added (wages and salaries and the gross operating surplus) it generates (sub. 31 and APMA 1995a). On this basis, value added for Australia's pharmaceutical industry is estimated to be between \$500 million and \$700 million.²⁴ Based on the view that value added generates demand in other sectors—workers spend their wages and surpluses are invested or spent on goods and services—the APMA applied multipliers of 2.3 and 2.6. This approach yields estimates of the economy wide impact of \$1.3 billion and \$1.6 billion.

The above approach has been criticised on the basis of two significant flaws.

First, given that most companies are MNEs, a part of their gross operating surplus is expatriated and hence has no impact on demand for Australian goods and services. The only benefit to Australia from a surplus in this situation is the

²⁴ This approach was also adopted by Brain (1993), when estimating the economy wide benefits of Factor f.

tax paid on it in Australia. Therefore its full value should not be included in any calculation of the direct value added of the industry.

Second, and more significantly, it ignores the fact that when one sector uses resources they are not available for use by any other sectors of the economy. In other words, resources are not unlimited. If the pharmaceutical sector was smaller in Australia then many of the resources it currently uses would be used by other sectors and hence much of the wages and salaries and gross operating surplus would still be generated. Increasing the amount of activity in the pharmaceutical industry reduces the amount of labour and capital available to other industries (see Chapter 5).

Taking the above two factors together, the benefits of pharmaceutical industry activity are confined to that part of the net increase in returns to resources it generates which is retained in Australia, after deducting the returns to these resources if they were available for other industries.

Other studies (for example Parry and Creyke 1991 and Parry and Thwaites 1988) calculate domestic value added by subtracting purchases from overseas affiliates from Australian pharmaceutical industry sales. Purchases from overseas affiliates are estimated to be about 60 per cent of sales. At current sales levels this leads to an estimate of value added of about \$1.5 billion. The weakness of these studies is that products use not only inputs from overseas affiliates but also inputs from pharmaceutical and other companies within Australia and non-pharmaceutical imports. These also need to be deducted from sales to get a value added figure.

A more appropriate way to estimate the value added of an industry is through a general equilibrium model of the economy which takes account of the interactions between the various industries. The Commission engaged the Centre of Policy Studies to model the impact on the Australian economy of the pharmaceutical industry. It estimated that the value added of the industry was about \$745 million or 0.18 per cent of GDP in 1993–94 (see Appendix L).²⁵

A further related question is the extent to which an increase in domestic activity enhances the overall welfare of the Australian community. This issue is dealt with in Chapter 11.

²⁵ The figure for value added is based on ABS Cat. No. 5209.0 (1994). The figure for GDP is a production measure of GDP sourced from ABS Cat. No. 5204.0 (1995).

2.6 Conclusion

The international pharmaceutical industry is dominated by relatively large MNEs. Pharmaceuticals are actively traded and the world market is characterised by intense competition to develop patentable products, primarily for the prescription market. As a result the industry invests heavily in R&D.

In Australia, maintenance of a viable local pharmaceutical industry is part of the Government's NMDP. About 40 companies have manufacturing facilities in Australia, mainly confined to formulation and packaging, with the active ingredients being imported.

While companies in Australia perform relatively less R&D than the world average, there are strong R&D linkages between companies and research institutions in Australia and overseas.

The market for pharmaceuticals in Australia has been growing strongly in recent years and industry expects this to continue. Exports of prescription products are also growing rapidly but Australia is still a significant net importer of pharmaceutical products.

As in most countries, governments play a significant role in the pharmaceutical industry. Chapter 3 discusses Australia's regulatory environment.

3 REGULATORY ENVIRONMENT

Pharmaceutical products have provided great benefits to society in combating disease and relieving pain and suffering. However, as medicines override, supplement or modify the natural functions of the body, their consumption may involve risk to individuals.

Moreover, as many of the costs of the use and abuse of pharmaceuticals are borne collectively, the community has an interest in ensuring that these products are supplied and consumed in ways that are medically appropriate and cost effective.

In an attempt to control the inherent risks, governments have chosen to regulate the development, production and sale of pharmaceuticals. Australia's national scheme of regulation is described in the early sections of this Chapter. In the latter part of the Chapter arrangements for the protection of intellectual property in pharmaceuticals are described.

3.1 Rationale for the regulation of the safety, efficacy and quality of pharmaceuticals

The case for regulation of pharmaceuticals rests largely on the potential for efficient promotion by governments of safety, efficacy and quality. Consumers and companies alike recognise that regulation plays a role in protecting public health and safety.

The Consumers' Health Forum believes that regulation 'gives us accountability, it gives us enforceability but it also gives consumers redress' (roundtable p. 17 1).

The Proprietary Medicines Association of Australia (PMAA) argued in its submission that the protection of public health and safety is a legitimate regulatory objective and noted the importance of high standards in maintaining the reputation of Australian pharmaceuticals. It suggested that to achieve these standards:

... an efficient, effective and proactive regulatory regime is needed (sub. 7 1, p. 5 1).

The extent of regulation of pharmaceuticals has grown steadily over this century. A brief history of significant Australian developments is provided in Box 3. 1.

Box 3.1: History of pharmaceutical regulation

Prior to the second World War, government involvement in human use pharmaceuticals was limited primarily to State Government controls over the distribution and retailing of drugs. However, since the late 1940s, there has been a large increase in Commonwealth Government involvement in the sector, particularly in the areas of product safety and quality.

Limited drug evaluation procedures were introduced in Australia in the early 1950s. The National Biological Standards Laboratory, a division of the then Department of Health began testing therapeutic agents for compliance with UK standards in 1959.

In the early 1960s, following the Thalidomide episode, there was world-wide reassessment of the need to investigate safety aspects of new drugs. In Australia, the Therapeutic Substances Branch was set up in 1963, primarily to evaluate new drugs. The Government also established the Australian Drug Evaluation Committee to advise the Minister of Health on the safety of new drugs and to monitor the safety of drugs already available on the market.

The *Therapeutic Goods Act* 1986 gave the Commonwealth greater control over standards of therapeutic substances, including prescription drugs. The provisions of the Act related primarily to prescription products and over-the-counter (OTC) products supplied on the Pharmaceutical benefits Scheme. Standards for other OTC products and the control of retail supply of scheduled substances remained the province of State Governments.

A Code of Good Manufacturing Practice was implemented in the late 1960s. The Code, developed in consultation with Commonwealth and State health authorities and the industry, relied on State legislation for its enforcement.

The Commonwealth strengthened its control in areas previously covered by State regulation with the introduction of the *Therapeutic Goods Act* 1989. The Act introduced compulsory listing of most drugs, the production of data demonstrating efficacy and safety of human use pharmaceuticals, and Commonwealth licensing of individual manufacturing premises. Also, it established the Therapeutic Goods Administration.

Dissatisfaction with the performance of Australia's drug evaluation system led to the establishment of the Baume Review in 1991. That Inquiry made a number of recommendations aimed at improving the balance between safety and availability of new pharmaceutical products (see Box 3.2).

Box 3.2: Baume Review recommendations

The Baume Review made a series of major recommendations:

- the addition of 'timely availability' to the objectives of the *Therapeutic Goods Act*;
- strict target evaluation times for the TGA, with sanctions for delays;
- easier access to experimental drugs through special access and clinical trial schemes;
- greater use of overseas evaluation reports;
- streamlining regulatory procedures;
- adoption of European Community data formats; and
- greater contact and openness between the regulator and the industry.

Source: Baume 1991, pp. 22-39

These recommendations were accepted by Government and have been implemented by the Therapeutic Goods Administration (TGA). Many participants reported that implementation of the recommendations has led to marked improvements in the drug evaluation process.

3.2 TGA risk management

As part of the management of risks associated with drugs, the TGA administers a national scheme of controls relating to the quality, safety and efficacy of therapeutic goods in Australia.¹ The TGA sets standards, evaluates and registers therapeutic goods before they enter the Australian market tests products once they have entered the market audits manufacturers to ensure Good Manufacturing Practice (GMP) is adopted and administers arrangements for reporting problems.

The major piece of Commonwealth legislation establishing regulatory controls for pharmaceuticals is the *Therapeutic Goods Act 1989*.

The objective of the Act is:

... to provide, so far as the Constitution permits, for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

¹ 'Risk management' is 'the systematic application of management policies, procedures and practices to the tasks of identifying, analysing, assessing, treating and monitoring risk' (Standards Australia 1994, para. 1.2.26).

-
- a) used in Australia, whether those goods are produced in Australia or elsewhere; or
 - b) exported from Australia (*Therapeutic Goods Act* 1989, Section 4).

In Section 4 of the Act the goals of safety, efficacy and quality, along with timely availability, are set out but they are not defined in measurable terms.

Concepts of safety, efficacy and quality are technically complex when applied to medicines. In common language, they mean:

- safety-a product poses a minimal risk to consumers, or a higher risk in proportion to greater medicinal benefit;
- efficacy-a product has the expected and desired effect; and
- quality-a product is made according to minimum standards of manufacturing practice and is itself of a consistent standard.

Pursuing these goals involves complex trade-offs between risks and costs. For example, many drugs that are intended to have therapeutic benefits also carry the risk of adverse side effects. Actions to reduce side effects, such as lowering the active ingredients, may increase the health risk associated with the drugs not working. Another trade-off arises in testing-the longer safety is pursued through testing, the greater will be the delay before a new drug, that could save or improve lives, is supplied to the market.

The TGA attempts to manage these compromises by aiming:

to ensure that the safety, quality and efficacy of therapeutic goods available in Australia are at a standard equal to that of comparable countries, and that pre-market assessment of therapeutic goods is conducted within a reasonable time (sub. 16, p. 1).

The reasons generally advanced for regulating safety, efficacy and quality of medicines are:

- consumers, even with the assistance of good professional advice, may be unable to distinguish safe from unsafe products because of the technical nature of the information involved;
- some individuals may have a propensity to consume some products at inappropriate levels; and
- given the large volume of technical information relating to the appropriate use of drugs, it may be more efficient for governments to control the supply and use of pharmaceuticals according to the level of risk and benefit.

A recent survey by Yann et al (1995) of consumer attitudes and behaviours supports the first reason. It found that there is widespread understanding that the supply of medicines should be regulated in some way by government.

The pre-marketing regulation of pharmaceuticals seeks to determine the safety, efficacy and quality of medicines before they may be supplied.

This contrasts with many other areas of product regulation, where a legal standard is established, and suppliers are left to determine for themselves whether they are operating to this standard and penalties subsequently applied when the standard is not met.

Of course, even where there is a case for government intervention, regulation comes at a cost. As well as the direct costs of enforcement and compliance, pharmaceutical regulation causes delays and limits choice. Excessive pre-marketing regulation may also create barriers to new and potentially better products.

There has been little direct examination of Australian regulators' approaches to risk management.

The Australian National Audit Office (ANAO) recently reviewed the extent to which risk management approaches have been successfully adopted by Commonwealth regulators of consumer product safety. However, in relation to the TGA, the review was confined to part of the TGA's post-market regulatory activities. It did not address the larger issues of risk/benefit trade-offs associated with therapeutic drug approvals and the difficulties of pursuing the mixed goals of timely availability, safety, efficacy and quality.

In summary, the audit found that the TGA had established the most comprehensive post-market regulatory framework reviewed by the ANAO. The comprehensive nature and links incorporated within this system were regarded as good examples for other regulators.

The ANAO also made some recommendations in relation to TGA audits of companies. It proposed that the TGA make greater use of legislative remedies in cases of non-compliance and better coordinate post-market regulatory activities (ANAO 1995, p. xiv).

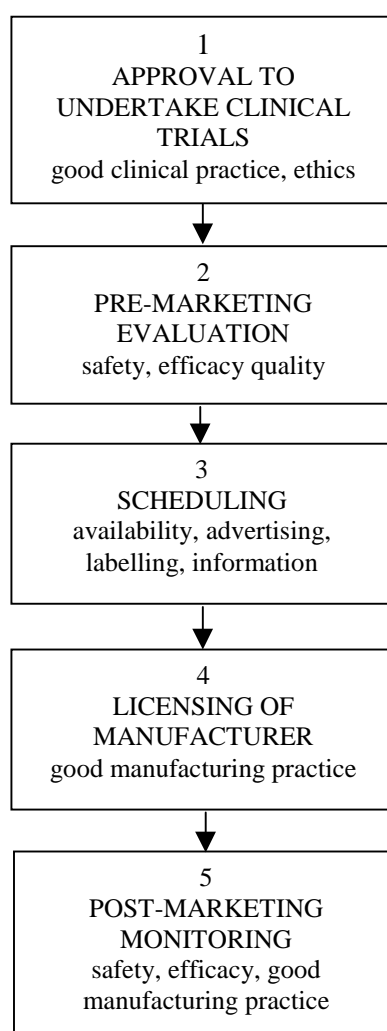
3.3 Therapeutic goods regulation in Australia

A new pharmaceutical product must pass through a number of regulatory steps before it can be made available to consumers, and it is then subject to ongoing regulation.

3.3.1 Regulatory processes in the broad

The regulatory steps through which a new pharmaceutical product must pass are broadly illustrated in Figure 3. 1.

Figure 3.1: Regulatory steps in drug approval and scheduling



Note: The Special Access Scheme and Personal Import Scheme may allow some of these steps to be bypassed for individual access to pharmaceuticals.

3.3.2 A scheme of national regulation

Because of constitutional limitations, responsibility for the regulation of pharmaceuticals in Australia is shared between the Commonwealth Government and the State Governments.² The Commonwealth Government regulates the quality, safety and efficacy of therapeutic goods supplied in Australia both directly (by using its constitutional powers over corporations, interstate trade and customs) and indirectly (through the funding of pharmaceutical benefits).

State Governments are responsible for the standard of goods manufactured and supplied by individuals and unincorporated enterprises within their jurisdictions. As most pharmaceuticals are supplied by pharmacists and hospitals, the States play a major role in the control of distribution through their scheduling systems.

In recent years, cooperation between Commonwealth and State Governments has increased the coordination of therapeutic goods regulations. The Commonwealth *Therapeutic Goods Act* is the centrepiece of a national system of control. The Act does not attempt to 'cover the field' in a constitutional sense, but rather, preserves the underlying State laws. The Act states:

It is the intention of the Parliament that the other controls forming part of the national system be imposed by the laws of the States

This Act is therefore not intended to apply to the exclusion of a law of a State ... to the extent that the law is capable of operating concurrently with this Act (ss. 4(2) *Therapeutic Goods Act 1989*).

The TGA describes the Commonwealth component of the national system as:

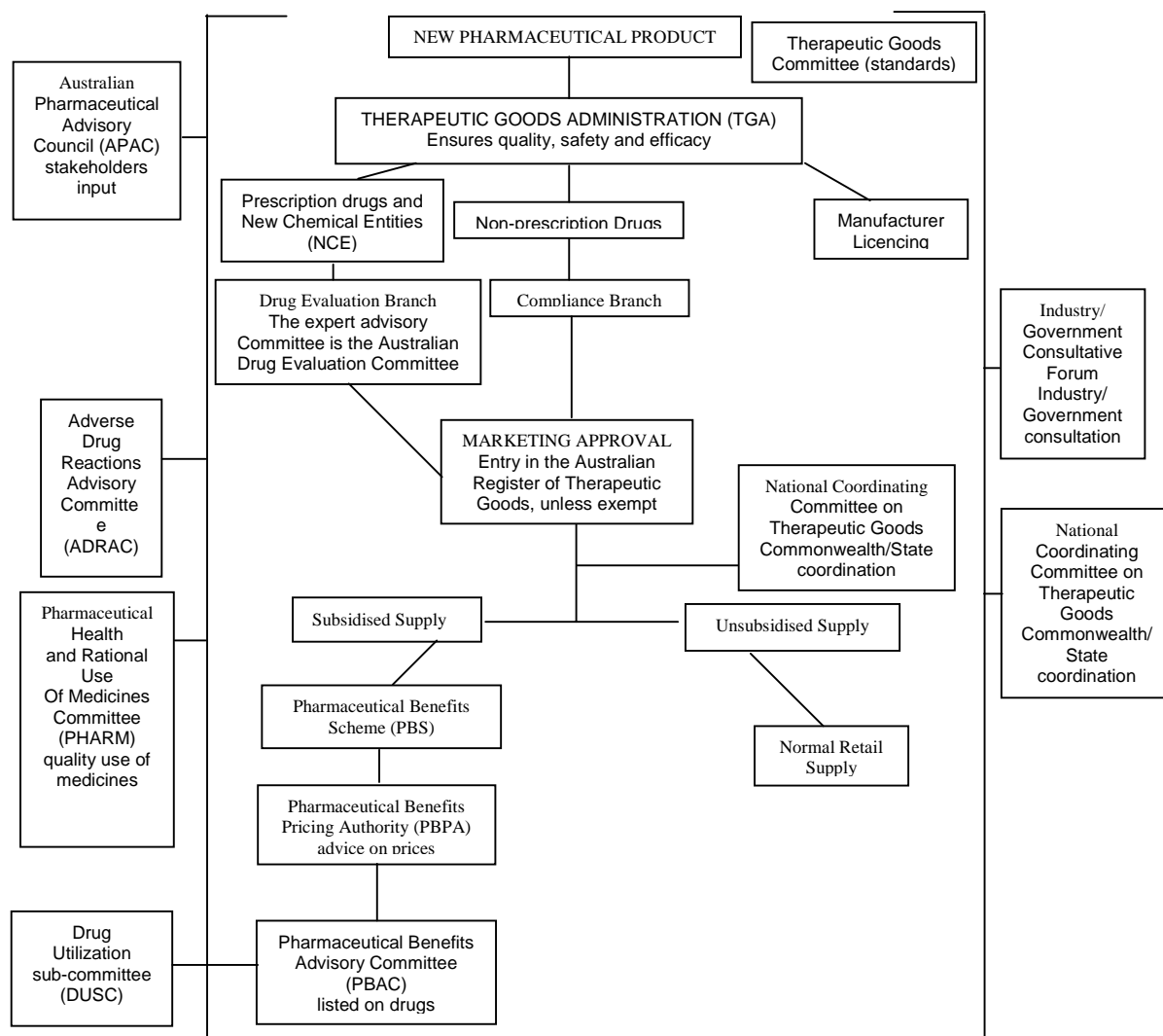
... primarily a 'market approval' scheme for both drug and medical device products, under which:

- high risk products are evaluated for quality, safety and efficacy and registered in the Australian Register of Therapeutic Goods (ARTG), and low risk products are assessed for quality and safety and listed in the ARTG;
- manufacturers are licensed to produce various classes of products; and
- standards are established for both the quality of products, and their advertising and labelling (sub. 16, p. 2).

To support the national system, a number of organisations and committees have responsibilities relating to policy oversight and the coordination and administration of regulation. Figure 3.2 illustrates the complex system of bodies involved in the regulation of pharmaceutical products.

² State refers to State and Territory.

Figure 3.2: Bodies associated with drug regulation



Source: DSH 1995a

Some of the bodies included in this figure are discussed in more detail in other parts of this Report. For example, the Australian Pharmaceutical Advisory Council (APAC), Pharmaceutical Health and Rational Use of Medicines (PHARM) and the National Coordinating Committee on Therapeutic Goods (NCCTG) are discussed in Chapter 2 and the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA) are discussed in Chapter 4.

The major policy groups and committees involved in drug evaluation and scheduling are described in more detail in Box 3.3

Box 3.3: Organisations and committees associated with drug regulation

The **Australian Health Ministers' Advisory Council (AHMAC)** is made up of Commonwealth and State Health Department officials. AHMAC 'issues' or 'approves' the Standard Uniform Schedule for Drugs and Poisons.

The **National Coordinating Committee on Therapeutic Goods (NCCTG)** comprises representatives from Commonwealth and State health authorities and makes recommendations to the Australian Health Ministers' Advisory Council. An observer from New Zealand also participates on the Committee.

The **Australian Drug Evaluation Committee (ADEC)** is the statutory body under the *Therapeutic Goods Act 1989* which advises the Minister and the Secretary of the Department of Health and Family Services (DHFS) on the products to be entered onto the ARTG.

The **Therapeutic Goods Administration (TGA)** is a Division of the DI-IFS. It provides administrative support to ADEC and acts as the national therapeutic goods control authority.

The **Medicines Evaluation Committee (MEC)** is an expert committee which, under a contractual arrangement with the Victorian Government, provides advice to the Secretary of the DHFS on the registration of non-prescription drugs (other than traditional medicines).

The **Traditional Medicines Evaluation Committee (TMEC)** is an expert committee which provides advice to the Secretary of the DHFS on the registration of non-prescription traditional medicines.

The **Adverse Drug Reactions Advisory Committee (ADRAC)** a sub-committee of ADEC, monitors the safety of therapeutic drugs.

The **National Drugs and Poisons Schedule Committee (NDPSC)** recommends retail supply restrictions for adoption by the States. It reports to AHMAC, and is supported administratively by the DHFS.

The **Drug Utilisation Committee** monitors post marketing drug use.

Institutional Ethics Committees (IECs) approve the conduct of clinical trials by their institution or organisation.

A number of inter-linking legislative and administrative instruments are used by the Commonwealth Government to achieve national regulation (see Box 3.4).

Box 3.4: Commonwealth regulatory instruments

Therapeutic goods are regulated by a range of Commonwealth instruments.

- The *Therapeutic Goods Act 1989* established the TGA, introduced compulsory listing of most drugs, the production of data demonstrating efficacy and safety of human use pharmaceuticals and Commonwealth licensing of individual manufacturing premises.
- *Therapeutic Goods Regulations* are authorised by the Act. Current regulations include references to advertisements, patient information establishing committees and fees, costs and charges. Schedules to the Regulations divide drugs into those which must be listed and those which must be registered in the ARTG.
- *Therapeutic Goods Orders* may be made by the Minister under section 10 of the Act. Matters specified in the Order constitute a standard for therapeutic goods.
- Various Australian Standards and Pharmacopoeia are given status, by reference, in therapeutic goods legislation.
- The *Standard for the Uniform Scheduling of Drugs and Poisons* (SUSDP) is drawn up by a Committee of Commonwealth and State officials and 'issued' by AHMAC. It is not a standard 'issued' under section 10 of the Act. Unlike the Regulations, and section 10 standards, the *SUSDP* is not a recognised legal instrument.
- *Interim Guidelines for Applications for Scheduling of Drugs* were issued by NDPSC in March 1995.
- The TGA has issued *Guidelines for the Registration of Non-Prescription Drug Products*.
- The TGA also issues the *Australian Approved Names for Pharmaceutical Substances*.
- The *PMAA Code of Practice* is approved by the Australian Competition and Consumer Council. The PMAA is a delegate of the DHFS for the purposes of approving certain broadcast advertisements under this Code.

3.3.3 Pre-market evaluation

To be supplied in Australia, therapeutic goods must be registered or listed in the ARTG, unless they are exempt or given special approval.

The ARTG contains two parts:

- registered goods; and
- listed goods.

Differences in the evaluation processes for registration and listing reflect the varying levels of risk associated with different products. The relationship between the classes of drugs which must be registered and listed and the scheduling system is summarised in Table 3. 1.

Table 3.1: ARTG status and schedule status

<i>Drug type</i>	<i>ARTG status</i>	<i>Poisons schedule status</i>
Prescription Drugs	Registered (AUST R)	S4 and above
Non-prescription drugs (OTC)	Registered (AUST R)	S3, S2 and Unscheduled ^a
Non-prescription drugs (OTC)	Listed (AUST L)	Unscheduled ^a

^a The regulations identify unscheduled substances which are listable. Other unscheduled substances are, in theory, open to registration provided they meet the criteria.

Source: PMAA sub. 71, p. 12

The numbers of products registered and listed on the ARTG are summarised in Table 3.2.

Table 3.2: Number of drugs included in the ARTG, as at 30 June 1995

<i>Type of drug product</i>	<i>Number</i>
Registered prescription products	3 606
Registered non-prescription products	6 885
Listed drug products	14 694
Drug products listed for export only	2 814
Total	27 999

Source: TGA sub. 16, p. 3

Registered pharmaceuticals

Therapeutic goods which could represent a high risk to users are 'registered' after a thorough assessment. These products are identified by a registration number preceded by 'AUST R' on the product label, and include schedule 4 drugs (supplied only on prescription) as well as some non-prescription drugs. Scheduling is discussed in greater detail in Section 3.2.5.

To obtain a Certificate of Registration, products are evaluated by the Drug Safety and Evaluation Branch (DSEB) of the TGA or by an approved assessor.

ADEC evaluates products such as new chemical entities, and applications that the DSEB proposes to reject.

In the case of prescription drugs, evaluation usually requires manufacturers or importers to provide comprehensive scientific data to establish the safety, efficacy and quality of a product. The evaluation process takes account of pharmaceutical chemistry and toxicological studies undertaken prior to the conduct of clinical trials and the data from extensive clinical trials.

Listed pharmaceuticals

Low risk products, typically OTC pharmaceuticals, homeopathic and herbal preparations, vitamins and mineral remedies, are subject to a lesser degree of assessment by the Compliance Branch of the TGA before being included on the Register as 'listed' goods. Drugs in this category are identified by a number preceded by 'AUST L' on the label. If an OTC product contains a substance that would be assessed by the DSEB if in a different pack size, it is also assessed by the DSEB, rather than the Compliance Branch.

In the case of non-prescription drugs, the emphasis of evaluation is directed towards quality and safety because their therapeutic use has usually been proven through established use. Certificates of listing do not verify a product's efficacy nor do they constitute TGA endorsement of any claims made by sponsors. The Certificate of Listing certifies the act of listing, contains the product's individual listing number and itemises a range of standard conditions applicable to that product.

The TGA has advised that a recently introduced computer based self assessment application system for the lowest risk products will allow registration decisions to be made within 14 working days. The legislation to permit the full introduction of this system (the *Therapeutic Goods Amendment Bill 1995* [No 2]) was intended to be in place by 30 June 1995, however, as at April 1996, the legislation had not been passed.

The TGA has had difficulty meeting its target processing times for listings (currently 30 days). Delays of eight to ten weeks have been reported.

3.3.4 Post-marketing regulation

Once a pharmaceutical product is registered in Australia, it is not subject to any formal review process (although the ADRAC monitors the safety of therapeutic drugs). This is in contrast to countries such as the M where registration is reviewed after 5 years. These differing approaches may have implications for

the level of risk acceptable to the regulator, and the degree of certainty about safety and efficacy required before registration is granted.

However, the TGA does undertake other significant post-marketing regulatory activities relating to the production and supply of medicines following their entry to the market. Post-marketing regulation is primarily undertaken by the TGA and has a number of elements:

- licensing of manufacturers;
- the inspection of manufacturing premises;
- both routine and targeted testing of products;
- recalls of unsafe products; and
- the monitoring of reports of adverse reactions.

These activities have the broad objective of providing an assurance to the community that the quality, efficacy and safety of drugs available for sale are maintained at high levels.

Licensing of manufacturers

Manufacturers of medicinal drugs in Australia must be licensed. Before a licence is granted, manufacturers are inspected to ensure their production procedures comply with internationally recognised GMP.

A GMP Code was developed after consultation with industry. It comprises a mix of quality systems specifications, with an emphasis on the adequacy of premises for sterile operations, and a set of detailed specifications and guidelines for problems peculiar to the industry (for example antibiotic cross-contamination).

Adherence to the Code allowed Australia to join the international Pharmaceutical inspection Convention and enabled greater surveillance of overseas manufacture and access to overseas markets for Australian products through exchange of inspection reports.

Inspection

The TGA inspects licensed Australian manufacturers to ensure that necessary standards are maintained. The system of inspecting factories producing therapeutic goods seeks to ensure that manufacturing practices are acceptable and that industry is aware of the requirements of GMP.

Overseas manufacturers of drugs imported into Australia are required to operate to standards equivalent to those expected of Australian manufacturers.

Manufacturers of imported drugs are either subject to similar licensing requirements in their own country or are audited by TGA inspectors where necessary.

Product testing

A large part of the post-marketing program consists of product testing. Testing is carried out by the TGA Laboratories. Samples are selected from manufacturers for a number of reasons, including:

- routine testing of a new product after gaining market approval;
- regular testing of prescription drugs on the PBS;
- where concerns are raised by GMP inspection; and
- testing of products after consumer complaints.

Product recalls

As a result of consumer complaints or product testing, recalls may be required for certain goods. Recalls are voluntarily undertaken by the sponsor of the goods but the Commonwealth Trade Practices Act 1974 allows the Minister for Small Business and Consumer Affairs to intervene if a hazard exists and the sponsor falls to take appropriate action.

Monitoring of adverse reactions

ADRAC is responsible for monitoring the safety of therapeutic drugs. It is a condition of registration or listing that sponsors report all adverse drug reactions. ADRAC also encourages the reporting of suspected adverse drug reactions by health care professionals and monitors published information and information provided by other national drug monitoring bodies.

3.3.5 Scheduling and advertising

The States are responsible for regulating the distribution of medicinal drugs to consumers. In addition to controlling the way in which drugs can be prescribed and dispensed, they impose specific requirements on advertising, packaging and labelling.

Scheduling

Where a drug substance is regarded as a potential hazard to the community, or where professional advice is required for its correct use, retail distribution of products containing the substance is restricted by 'scheduling' drug substances.

products containing specified substances are grouped into a number of schedules representing levels of restriction on distribution (see Box 3.5).

Box 3.5: Schedule descriptions in the Standard for the Uniform Scheduling of Drugs and Poisons

Schedule 1

Poisons of plant origin of such danger to health as to warrant their being available only from medical practitioners, pharmacists or veterinary surgeons.

Schedule 2

Poisons for therapeutic use that should be available to the public only from pharmacies; or where there is no pharmacy service available, from persons licensed to sell schedule 2 poisons.

Schedule 3

Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners.

Schedule 4

Poisons that should, in the public interest, be restricted to medical, dental or veterinary prescription or supply, together with substances or preparations intended for therapeutic use, the safety or efficacy of which requires further evaluation.

Schedule 5

Poisons of a hazardous nature that must be readily available to the public but require caution in handling, storage and use.

Schedule 6

Poisons that must be available to the public but are of a more hazardous or poisonous nature than those classified in schedule 5.

Schedule 7

Poisons which require special precautions in manufacture, handling, storage or use, or special individual regulations regarding labelling or availability.

Schedule 8

Poisons to which the restrictions recommended for drugs of dependence by the 1980 Australian Royal Commission of Inquiry into Drugs should apply.

Schedule 9

Poisons which are drugs of abuse, the manufacture, possession, sale or use of which should be prohibited by law except for amounts which may be necessary for medical or scientific research conducted with the approval of Commonwealth and/or State Health Authorities.

Source: AHMAC 1994, p. vii

The schedules applying to the medicinal drugs area are a subset of State based poisons schedules. Scheduling relates to 'poisons' which are not confined to medicines-registration relates to therapeutic goods alone. In 1994, the APMA, the PMAA and the Pharmaceutical Society of Australia submitted to the then

Department of Community Services and Health and AHMAC a joint *Proposal for Medicines Scheduling*. They proposed separation of the decision-making process for therapeutic goods from all other poisons. This proposal was not adopted.

The schedules relevant to pharmaceuticals are:

- schedule 8 (S8)-drugs of addiction;
- schedule 4 (S4)-drugs restricted to supply by prescription;
- schedule 3 (S3)--drugs which must be supplied under the direct supervision of a pharmacist or medical, dental or veterinarian practitioner; and
- schedule 2 (S2)-drugs which are restricted to supply through pharmacies.

Products subject to scheduling are required to have the schedule details printed on the product label and to meet any requirements for warning statements or packaging.

Australia is unusual in that the scheduling of therapeutic substances takes place separately to their registration. The registration and scheduling of drugs was originally an individual State responsibility. The introduction of the *Therapeutic Goods Act 1989* and the creation of the TGA formalised the Commonwealth's role in relation to drug registration, but left responsibility for scheduling with the States.

However, the scheduling of drugs is coordinated on a national basis by the NDPSC, with a secretariat provided by the Commonwealth. The NDPSC produces the SUSDP which is then approved by AHMAC, and may be adopted by the States.

Interim Guidelines for Applications for Scheduling of Drugs were issued by the NDPSC in March 1995. However, these guidelines did little to expand on the brief definitions contained in the SUSDP and did not provide a great deal of guidance in relation to the NDPSC's decision making process.

In a move to clarify the scheduling process AHMAC is developing, with the assistance of industry and consumer representatives, a further set of guidelines:

... on administrative aspects, including communication with and making applications to NDPSC, scheduling and rescheduling of drugs and poisons, appeal procedures, confidentiality and public consultations ... (sub. 152, p. 3).

Drug substances can be moved between schedules or become unscheduled as market place experience with the drug increases. This is known as 'switching' or 'rescheduling'. Sponsors of drugs or 'other interested parties' may apply to the NDPSC for rescheduling. The NDPSC may also initiate a review of a drug

or class of drugs for rescheduling purposes, particularly if public health concerns arise.

Scheduling has important implications for labelling and the provision of consumer product information. In 1992, it became mandatory for pharmaceutical manufacturers to provide written consumer product information for prescription (S4) medicines.³ More recently, the Therapeutic Goods Regulations required it to be supplied to customers when they purchase S3 products approved after 4 July 1995.⁴

Australian regulation of drugs and poisons labelling is currently being harmonised with that of New Zealand. This change is being phased in over a five year period which commenced on 30 June 1995. During this transitional period, drugs and poisons labelled in accordance with the old system or the new system may be sold, but after 30 June 2000 only the harmonised labelling will be acceptable.

The new requirements are set out in the SUSDP. In addition, a *Guide to Labelling of Drugs and Poisons* in accordance with the new requirements has been published by AHMAC (1995).

Advertising

There are generally two categories of advertisements for therapeutic goods:

those directed to the public, and those directed to health care professionals. Different controls apply to therapeutic goods in different schedules (see Table 3.3).

Controls on the content of the advertising of therapeutic goods aim to ensure that claims made for products are truthful, appropriate and not misleading.

Advertising to the public

Advertising to the public is subject to a number of regulations.

Commonwealth laws, including the *Therapeutic Goods Act* 1989, the *Trade Practices Act* 1974, and the *Broadcasting Act* 1942 apply primarily to sponsors of therapeutic goods. It is a requirement under the regulations of the *Therapeutic Goods Act* that therapeutic goods (unless exempted) be included in the ARTG before they are supplied in Australia. Sponsors may only advertise in relation to those indications for use accepted for inclusion in the Register.

This includes advertising on product labels.

³ *Therapeutic Goods Act* 1989, Regulation 9A and Schedule 10

⁴ *Therapeutic Goods Act* 1989, Regulation 9A (1A) and Schedule 13.

Table 3.3: Advertising controls

<i>Audience</i>	<i>Medium</i>	<i>Therapeutic Goods Act 1989 and regulations</i>	<i>Therapeutic Goods Advertising Code (Media Council of Australia)</i>	<i>Broadcasting Services Act 1992</i>	<i>PMAA Code of Practice</i>
Public	Radio, TV	Mandatory Applies to all advertisers. Adopts specific prohibited representations listed in the Therapeutic Goods Advertising Code of the Media Council of Australia	Self-regulatory Applies to MCA members only. Clearance by relevant media body	Mandatory Pre-clearance required: delegated to PMAA	Self-regulatory Applies to PMAA members only. Applies to all forms of advertising and promotional activity to all audiences
Public	Print, cinema, outdoor advertising	As above	As above	na	As above
Public	Electronic non-broadcast (narrowcast).	As above	na	na	As above
Public	Point of sale, other	As above	na	na	As above
Health care professionals	All above	na	na	na	As above

na not applicable

Source: PMAA 1993,p.16

Relevant State legislation, such as Fair Trading Acts, and State-based Therapeutic Goods Acts, also govern advertising. These laws are primarily directed towards advertising at the retail level.

Voluntary codes such as the Therapeutic Goods Advertising Code of the Media Council of Australia and the PMAA Code of Practice may also apply.

The advertising controls on OTC products advertised to the public are based on the Therapeutic Goods Advertising Code of the Media Council of Australia, which generally restricts claims to minor ailments amenable to self-diagnosis and treatment. The Code has been agreed to by the Government, the pharmaceutical industry and representatives of consumers, advertisers and the

media. The Code forms the basis for determining the acceptability of advertisements for radio and television, the print media, outdoor advertising and cinema advertising.

There have been a number of recent proposals to change the regulation of advertising to the public. These are discussed in detail in Chapter 15.

The pharmaceutical industry has proposed revision of the advertising controls to permit the advertising of S3 drugs to the public. The most recent consideration of these proposals were documented in the House of Representatives Standing Committee on Community Affairs Report (1992a) and a Report by the Trade Practices Commission (1992). Both these bodies recommended that the prohibition on the advertising of schedule 3 products to the public be maintained.

As a result of company requests, the TGA (via the NCCTG) has considered suggestions that some prescription only (schedule 4) products be 'indirectly' advertised to the public where it is deemed to be in the public interest.

According to the TGA:

While there was no over-all consensus, it was generally considered that indirect advertising of prescription products to the public might have a public interest role in the areas of anti-smoking programs and immunisation campaigns (sub. 16, p. 15).

APAC has supported moves for the indirect advertising of schedule 3 product groups in accordance with the P~ code but is not in support of brand advertising. Further, APAC supports the indirect advertising of schedule 4 product groups where the products have a public health focus, such as immunisation and anti-smoking (sub. 137, p. 3).

Advertising to health professionals

Advertising to health care professionals (including doctors, dentists and pharmacists) is controlled by a system of self-regulation by the relevant industry associations. The *Therapeutic Goods Act* 1989 and the *Trade Practices Act* 1974 provide the Government with reserve powers.

For prescription only products (S4), the relevant code is the Code of Conduct of the APMA. For non-prescription products, the relevant code is the Code of Practice of the PMAA.

For advertisements of herbal/vitamin medicines to the alternative health profession, the Nutritional Foods Association of Australia has developed a Code of Practice which includes reference to a Complaints Panel.

3.3.6 Exported products

Exported products are required generally to meet the same standards of quality as expected for products supplied in Australia. These requirements aim to protect the reputation of Australia as a source of reliable, high quality products.

Section 20 of the *Therapeutic Goods Act* makes it an offence for anyone other than the sponsor or their agent to export a therapeutic product. This means that drugs can only be exported with the knowledge and approval of the sponsor. More than one party may be a sponsor in relation to a particular product, but each sponsor must be a resident of Australia to ensure that the product can be traced in the event of recall action.

Export only listing

If a product is included in the ARTG for supply in Australia, then that product can be exported by a registered sponsor without any further involvement of the TGA. However, where a sponsor produces a product specifically and solely for export, then it must be listed in the ARTG using the 'export only' listing mechanism.

Australia is a signatory to the World Health Organisation (WHO) export certification scheme. This scheme was introduced in response to concerns that drugs for export are not always subject to the same controls as those for the home market and that some developing countries lack adequate facilities for drug analysis. The scheme is also promoted as a mechanism for combating the illicit drug trade and falsely labelled counterfeited drugs.

The TGA issues two certificates for exported products:

- the Export Only Listing Certificate for a product placed on the ARTG for supply solely outside Australia; and
- the Certificate of Pharmaceutical Product issued under the WHO Certification Scheme on the quality of pharmaceutical products traded internationally.

According to the DSHS, the Export Only Listing Certificate is intended only as documentary evidence that the sponsor's goods meet Australian requirements for inclusion in the ARTG for export purposes and is not intended to be used to support export initiatives (sub. 153, p. 25).

The legal basis for 'export only' products is found in sections 26 and 14(3) of the *Therapeutic Goods Act*. Under these provisions, applicants may list their products on the ARTG, provided the Secretary to the DHFS is satisfied that the products:

- are therapeutic goods (as opposed, for example, to foods);
- are safe for the purposes for which they are to be used;
- conform to quality standards, other than labelling standards (unless exempted by the Secretary);
- are manufactured by a licensed manufacturer; and
- are of acceptable presentation (the product contains the substance(s) specified on the label and the information presented is not false or misleading).

Products which are accepted by the Secretary as meeting these requirements are listed for 'export only' and are not required to meet Australian labelling and advertising requirements.

Section 14 of the *Therapeutic Goods Act* gives the Secretary a discretion to approve products for export which have been produced to a standard which is different from that required in Australia. Such exemptions have been granted by the TGA where sponsors have produced evidence from the importing country that they will accept a different quality standard.

The Certificate of Pharmaceutical Product is intended for use by companies to establish the status of products for export. This certificate is the same as that recommended under the WHO system. The TGA intends to move to a new simplified WHO format, expected to be endorsed by the WHO Executive Board in May 1996 (sub. 153, p. 25).

3.3.7 Clinical trials

Unapproved products may be supplied in clinical trials under special provisions which exempt these products from the need for prior registration. Approval is required for use in clinical trials of.

-
- any drug product (or therapeutic device) not entered in the ARTG, including any new formulation of an existing drug product or any new route of administration; and
 - any use of a drug product (or therapeutic device) beyond the conditions of its marketing approval, including new indications, extending the use of a drug or drug product to new patient groups (for example children, pregnant women or the elderly) and extending the doses or duration of treatments outside the approved range.

Following the implementation of the Baume Review recommendations and the subsequent 1993 review (Day 1993) of the clinical trial notification scheme, there are two mechanisms under which clinical trials may operate:

- the Clinical Trial Exemption (CTX) Scheme requires assessment of data by the Drug Evaluation and Safety Branch of the TGA prior to approval; and
- the Clinical Trial Notification (CTN) Scheme under which responsibility for assessment lies with individual Institutional Ethics Committees (IEC).

The choice of which scheme to follow lies firstly with the sponsor and then with the individual IEC of the body or institution conducting the trial. Most companies prefer to use the CTN scheme because they do not need to compile the CTX application nor undergo a TGA evaluation, and they can avoid substantial TGA fees (currently \$10 100 on submission of a CTX application, compared to a \$110 CTN notification fee). Clinical trial submissions must be approved by an IEC under both the CTX and CTN schemes.

Guidelines for Good Clinical Research Practice in Australia were produced in December 1991.

3.3.8 Special access to unapproved drugs by individuals

Special Access Scheme

The Special Access Scheme allows medical practitioners, under certain circumstances, to prescribe drugs not yet approved for the Australian market for treatment of patients with serious medical conditions. The informed consent of the patient is required.

The treating practitioner deals directly with the DSEB on a case by case basis. Alternatively, requests can be made to delegates within some medical institutions.

Personal Import Scheme

Individuals can legally import most therapeutic goods for personal use under the Personal Import Scheme. This scheme includes drugs such as alternative medicines that have a cultural basis rather than a background of development through the pharmaceutical industry, as well as pharmaceutical products available overseas but not in Australia.

The scheme allows for treatments to be imported for personal use in quantities that are no greater than three months supply (at the maximum dose recommended by the manufacturer). It does not allow the importation of drugs that are prohibited by customs legislation or injectable drugs that contain material of human or animal origin. These require prior approval to import.

3.4 Other regulation

3.4.1 Regulation of wholesalers

Pharmaceutical wholesalers act as the distribution link between manufacturers and community pharmacies and hospitals, although some manufacturers distribute directly to pharmacists. Wholesalers are subject to State based licensing arrangements. They are not subject to direct Commonwealth regulation, although they are affected by Government policy.

As discussed in Chapter 4, the wholesale price of PBS drugs is set by negotiation between the PBPA and pharmaceutical companies. It is the sum of the company's price to the wholesaler and an allowance for a wholesaler's margin of 10 per cent. However, wholesalers do not participate in the negotiations between manufacturers and the Government on PBS prices. The 10 per cent margin is a maximum and wholesalers are able to compete by lowering this margin, for example by discounting for volume orders.

3.4.2 Regulation of pharmacy

Community pharmacy provides the main delivery mechanism for prescription (schedule 4) and OTC (schedule 3 and schedule 2) pharmaceuticals. The States are primarily responsible for the regulation of the practice of pharmacy and the licensing of pharmacy businesses. However, the Commonwealth Government influences the profitability and structure of the community pharmacy sector through its control of pharmaceutical benefits.

In recent years the sector has undergone considerable restructuring through a program of managed change agreed to by the then Minister for Human Services and Health and the Pharmacy Guild.

Current arrangements provide for, amongst other things:

- remuneration for PBS items;
- Isolated and Remote Pharmacy Allowances to encourage the provision of services in remote areas; and
- special conditions for items which fall below the appropriate patient contribution level.

Two Commonwealth Government bodies are involved in determining the level of pharmacy remuneration and in restructuring community pharmacy to encourage more cost effective locations of pharmacies.

The Pharmaceutical Benefits Remuneration Tribunal determines remuneration to pharmacists for dispensing benefits on the basis of submissions put forward by the Commonwealth, the Pharmacy Guild and other interested parties.

Pharmacists receive a retail margin on the wholesaler's price of 10 per cent up to a retail price of \$180, \$18 for retail prices from \$180 to \$360, and 5 per cent for retail prices above \$360. As at 1 August 1995, pharmacists also received a composite fee (made up of a dispensing fee and an administration fee) of \$4.27 for ready prepared items, and \$6.10 for extemporaneous items (mixed at the pharmacy). Other special fees may apply such as a loading on the dispensing fee for isolated pharmacies and a pharmaceutical of addiction recording fee (see Chapter 4).

The Australian Community Pharmacy Authority replaced the previous Pharmacy Restructuring Authority in 1994.

It makes recommendations to the Secretary of the DI-IFS concerning:

- applications for new PBS pharmacy approvals;
- relocations of existing approvals;
- payment of Isolated and Remote Pharmacy Allowances;
- approval of pharmacists to receive supplementary allowances for specified additional professional services; and
- any other matter referred to it by the Minister, including matters raised by the Guild.

Notwithstanding the Government/Guild agreement, pharmacies without approval to dispense drugs under the PBS may open (and have done so) and,

under certain restricted circumstances, general practitioners may seek approval to dispense pharmaceutical benefits.

3.5 Funding of the TGA

It is Government policy for the TGA to generate 50 per cent of its operating costs through revenue collection. The TGA has an annual budget of about \$35 million. Costs are recovered through annual charges, inspection fees, evaluation fees and other charges.

In 1991-92, the income from fees and charges was \$9.4 million. This was about 26 per cent of that year's operating costs and 50 per cent of the ultimate cost recovery target. In 1992, a five year plan for TGA revenue was developed to achieve 50 per cent industry contribution by 1996-97 (sub. 16, pp. 3-4). This plan is summarised in Table 3.4. The TGA stated that they have been able to reach all revenue collection and performance targets set out for the five year phase-in period (transcript, p. 88 1).

In relation to drugs, the TGA charges fees for applications for registration or listing, evaluation fees and annual charges. It charges licensed manufacturers an application fee, inspection fees and annual charges. Fees are also charged for export certification and clinical trial approval.

Table 3A Five year plan for TGA revenue, \$ million

<i>Source of income</i>	<i>1992-93</i>	<i>1993-94</i>	<i>1994-95</i>	<i>1995-96</i>	<i>1996-97</i>
Fees and charges	11.79	13.22	14.65	16.46	18.28
TGA budget	18.06	17.86	17.86	18.28	18.28
Department subsidy	2.00				
Department of Finance subsidy	4.26	4.64	3.22	1.83	0.00
Total	36.11	35.72	35.72	36.57	36.57
Per cent industry contribution	33%	37%	41%	45%	50%

Source: TGA sub. 16, p. 4

3.6 Patents

A patent is a government granted monopoly which gives owners of inventions the legal right to prevent others from making or using the invention for a fixed period of time.

A patent can be obtained for any 'invention'-a device, substance, method or industrial process that is new, inventive and useful.

In Australia, patents are issued by the Australian Industrial Property Organisation on behalf of the Commonwealth Government.

Until 1987, pharmaceuticals were subject to the same rules as other patented inventions-normal 16 year patents could be extended by up to 10 years on the grounds of 'inadequate remuneration'. The extension procedures required complicated evidence and argument to be presented in lengthy court proceedings. These were costly to industry and the Government and the outcomes often remained uncertain for years.

In total, some 47 extensions of term were sought under these arrangements, and just over 20 extensions of patent were granted under this system, 15 being for the full ten years (sub. 56, p. 29).

In 1987, the 10 year extension period was removed for all inventions. However, in the same year the Government announced the Pharmaceutical Industry Development Program. One of the elements of the Program was to provide an administratively simple four year extension of the 16 year standard patent term for pharmaceuticals for human use-leading to a 20 year patent term.

The Government also allowed a two year 'springboard' for generic copies of patented drugs which had been granted an extension. This meant that a sponsor of a generic could apply for registration after the eighteenth year of an extended patent (that is, after sixteen years normal patent plus two years of the extension).

In July 1995, the patent term for all products, including pharmaceuticals, was extended to a standard period of twenty years, in accordance with Australia's commitment to the Trade Related Intellectual Property (TRIPs) Agreement under General Agreement on Trade and Tariffs (GATT). At the same time, generic springboarding was discontinued. Allowing springboarding during the 20 year period would be an exception to the minimum patent rights set out under the TRIPs agreement.

The Government has announced its intention to provide extended patent protection to pharmaceuticals. In February 1993, the then Prime Minister stated that 'a Labor Government would provide 15 year effective patent life for pharmaceuticals in line with US and European standards (Keating 1993). In September 1995, the then Minister for Industry, Science and Technology, confirmed this commitment in an address to the APMA:

The Government has made a commitment to provide 15 years of effective patent life for pharmaceuticals. But there are a range of options it can adopt to achieve this. Options which will have varying ramifications for different parts of the industry and for the Government (Cook 1995, p. 9).

In October 1995 the Department of Industry Science and Technology (now the Department of Industry Science and Tourism) (DIST) released a discussion paper listing options for patent term restoration and invited interested parties to make their views known (DIST 1995c). Two roundtable discussions were held with industry representatives in October/November 1995. No further public progress had been made as at April 1996.

3.7 Outstanding regulatory issues

The Commission has identified several key regulatory issues to be resolved.

These include:

- potential for further integration of Australia's regulatory system with those of comparable countries;
- the appropriate structure for the TGA;
- inadequacies in the current scheduling system;
- the role of advertising of therapeutic goods;
- the potential to streamline the registration and scheduling process; and
- issues relating to the protection of intellectual property.

These issues, and other regulatory concerns raised with the Commission, are addressed in Chapters 14, 15 and 16.

4 PHARMACEUTICAL BENEFITS SCHEME

The PBS is a Commonwealth Government scheme for subsidising the cost of pharmaceuticals to the Australian community. PBS expenditures represent a significant proportion of Commonwealth Government outlays on health, having grown at an average 8 per cent per annum in the decade to 1994–95. Pharmaceuticals supplied under the PBS cost \$2.4 billion in 1994–95, of which the Government funded \$2.0 billion, representing approximately 13 per cent of total Government health expenditures. The PBS has evolved to now cover pharmaceuticals for most medical conditions for which they are an accepted form of treatment.

The Government uses the provision of such subsidies as a lever to secure lower drug prices from pharmaceutical companies. Companies, however, can respond by choosing not to supply the PBS market.

This Chapter offers a brief description of the PBS scheme, paying particular attention to those characteristics of the scheme which have the greatest impact on the pharmaceutical industry.

4.1 What is the PBS?

4.1.1 Main features of the PBS

The Pharmaceutical Benefits Scheme (PBS) was introduced by the Commonwealth Government in 1950 to provide reliable and affordable access to medicines for the Australian community. The PBS provides universal coverage for the community, other than those receiving treatment in public hospitals for whom pharmaceutical care is covered under the Commonwealth/State Medicare Agreement.¹ It is one of the four arms of the National Medicinal Drug Policy (NMDP) as described in Chapter 2.

The PBS is administered by the Pharmaceutical Benefits Branch (PBB) within the Commonwealth Department of Health and Family Services (DHFS).

¹ Section 100 drugs are supplied through hospitals, with the Commonwealth paying the drug costs for outpatients, and the States paying, via the Medicare Agreement, for in-patient costs in public hospitals (PBPA, 1994, p. 8).

Most prescription medicines available in Australia are provided under the scheme.² The PBS system accounts for approximately 78 per cent of total prescription drug sales. The hospital sector represents 10 per cent of sales, and the private prescription market (prescription drugs not sold under the PBS) represents a further 9 per cent of sales (see Table 4.1).

Table 4.1: Commonwealth and patient expenditures on prescription drugs, 1992–93

<i>Type of expenditure</i>	<i>\$m</i>	<i>%</i>
Subsidised PBS		
Commonwealth payments	1 417.5	50.1
Patient contributions	359.5	12.7
Unsubsidised PBS ^a	428.0	15.1
Total PBS	2 205.0	77.9
Repatriation Pharmaceutical Benefits Scheme (RPBS)	86.7	3.1
Hospital prescriptions	274.0	9.7
Private prescriptions	263.3	9.3
Total non-PBS	624.0	22.1
Total cost of prescribed medicines	2 829.0	100

a Unsubsidised expenditure includes expenditure on drugs priced below the patient copayment.

Source: AIHW 1994, pp. 141–143

Under the PBS, the cost of pharmaceuticals to consumers is limited by capped copayments and safety nets, with the Government paying the remainder. The largest proportion of subsidies are directed towards those most in need, that is, concession health card holders, pensioners, and high users of medicines (see Section 4.8.2.).

In 1994–95, over 118 million scripts, costing approximately \$2.4 billion, were provided under the PBS, of which the Government contributed \$2 billion, and consumers paid \$445 million in copayments. This Government expenditure represented approximately 13 per cent of the total health budget.

In 1994–95, the number of PBS prescriptions per capita was 6.6, while the average PBS prescription price was \$19.71 (DHS 1995b, p. 3).³

² All drugs subsidised under the PBS appear in the Schedule of Pharmaceutical Benefits, which is published quarterly.

³ Does not include private prescriptions

4.2 History of the PBS

The PBS has been subject to several detailed inquiries over the last 20 years. It has also been modified several times, as outlined in Box 4.1. The inquiries recommended significant reforms of the PBS but their recommendations were not generally accepted (see Box 4.2).

Major changes to the PBS over the years have largely related to the extension of the drugs covered by the scheme, the share of the population receiving subsidies, and the introduction of measures to contain Government costs, such as user copayments, usage constraints and suppression of manufacturers' prices.

Box 4.1: History of the PBS

The PBS started in 1950, when a scheme subsidising 139 life saving and disease preventing pharmaceuticals came into operation. It has gradually evolved to include most pharmaceuticals, covering 537 drug substances and containing over 1600 products.

There has been no significant change to the basic nature of the PBS since its inception. Nevertheless, it has evolved into a quite different scheme to its original form. The PBS has increasingly focused on providing benefits to less well off consumers. This trend started in 1951 when the list of free pharmaceuticals available to pensioners was extended to include all pharmaceuticals listed in the British Pharmacopoeia.

In 1960, a general user copayment was introduced. This general copayment has gradually increased whilst the real price of pharmaceuticals has fallen so that many pharmaceuticals are no longer subsidised for general users.

In 1983, the category of 'concessional users' (unemployed and other low income users) was introduced at a \$2.00 copayment (compared with the general copayment of \$4.00). In 1990, pensioners were also included in the concessional user category, with the introduction of a \$2.50 copayment.

From the beginning of the scheme, Department of Health officials had unofficial discussions with suppliers in an attempt to secure reasonable prices. In September 1963, this process was strengthened and formalised by the establishment of the Pharmaceutical Benefits Pricing Bureau. It recommended prices to the Department of Health for use in its pricing negotiations for pharmaceuticals which the Pharmaceutical Benefits Advisory Committee (PBAC) recommended as suitable for listing. In 1988, the Pharmaceutical Benefits Pricing Authority (PBPA) was established, replacing the Pricing Bureau. The PBPA was established as one of the arms of the Pharmaceutical Industry Development Program.

Source: Sloan 1995, p. 75

Box 4.2: Inquiries into the PBS**Pharmaceutical Manufacturing Industry Inquiry (Ralph Inquiry 1979)**

This Inquiry examined the impact of the PBS on the pharmaceutical industry, in response to industry concerns about the impact of PBS prices on the viability of the pharmaceutical industry.

Recommendations included:

- replacing the fixed patient contribution arrangements with a variable patient contribution for different drugs;
- relaxation of the controls over PBS drug prices;
- liberalisation of pharmacy ownership arrangements; and
- discounting of the patient contribution.

In general, the recommendations were not implemented, although the Government granted an across the board price increase of 20 cents from November 1980.

Industries Assistance Commission (1986)

This Inquiry examined the potential for development of the pharmaceutical industry, the PBS and its impact on the industry. In regard to the PBS, under the IAC recommendations:

- only concessional users would receive drug subsidies automatically;
- general users would receive no subsidies, but would be able to purchase concessional status for a fee of, say \$150 per year;
- drugs would be classified into therapeutic categories. Within each category, a drug would be nominated as the base drug (the cheapest in the category). Those who opt for dearer drugs from that therapeutic category would not receive any greater subsidy;
- optional generic substitution would be introduced;
- competition amongst retailers would be promoted through removing the restriction preventing discounting the PBS retail margin, and by removing restrictions on the ownership of pharmacies; and
- a copayment for pensioners would be introduced with a ceiling on annual expenditure, an increase in the pension to accompany the introduction of the copayment and the inclusion of concessional users.

Most of the IAC recommendations in relation to the PBS were not implemented immediately by the Government. However, IAC recommendations such as a form of general patient catastrophe cover, a pensioner copayment and generic substitution have been implemented subsequently.

Source: Sloan 1995, pp. 65–68

4.3 Objectives of the PBS and how they are met

The stated objectives of the PBS are:

- to provide access for the Australian community to necessary, cost effective medicines; and
- to do so at the lowest possible cost to the Government and consumers (Willis & Beazley 1995, pp. 3-98).

4.3.1 Providing access

There are currently 1600 products and 537 pharmaceutical substances listed on the PBS schedule. The PBS provides a universal pharmaceutical subsidy but provides extra assistance to those most in need via differential concessional copayment and safety net arrangements.⁴ Both the copayments and the safety nets are Consumer Price Index (CPI) indexed annually and the safety nets operate on a calendar year basis. As at April 1996, concessional users paid a copayment of \$2.60, while general users pay \$16.80.⁵

In 1994–95, the Commonwealth spent \$303 million on the 17.5 million prescriptions provided through the concessional safety net arrangements. The general safety net outlays were \$93 million, and covered approximately 4.7 million prescriptions (DHS 1995b, p. 2).

Figures 4.1, 4.2 and 4.3 show the subsidy levels over a range of drug prices, for both general and concessional users. They illustrate that the lower the price of the pharmaceutical, the lower the extent of the subsidy and that concessional users make little contribution to their drug costs for all but very low priced drugs.

The ten highest cost drugs to Government accounted for approximately 20 per cent of PBS expenditure. The highest cost items are used for treating ulcers, depression, cardiovascular and nervous system problems.

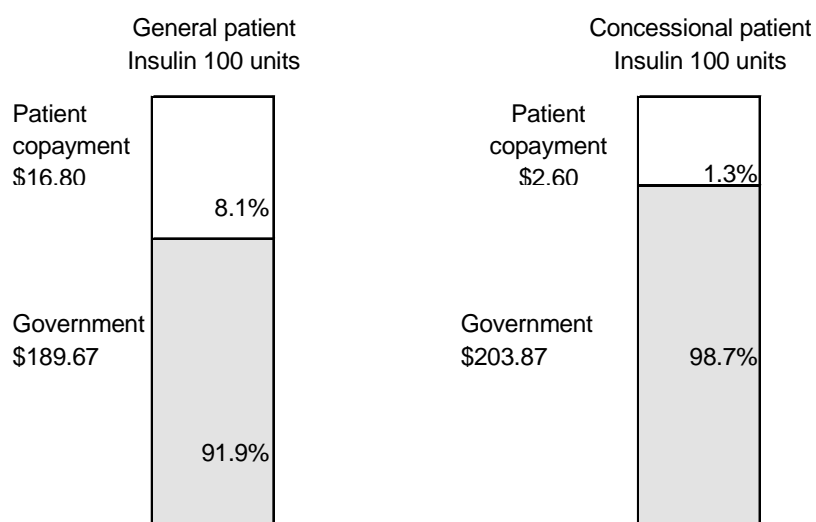
The ten most prescribed drugs accounted for 12 per cent of PBS expenditure in 1994–95. It is noteworthy that the maximum costs to Government are

⁴ Further details of the changes in copayment arrangements are provided in Section 4.6.2.

⁵ When agreement on price cannot be reached for a unique pharmaceutical, there is a provision for special patient contributions to provide a mechanism whereby patients can access the drugs at a higher cost, although this currently applies to only four listed products. In these circumstances, the drug will be subsidised by the PBS to the agreed level, with the patient paying a special contribution to cover the margin between this and the retail price.

associated with relatively expensive drugs but that the most prescribed items are usually relatively cheap.

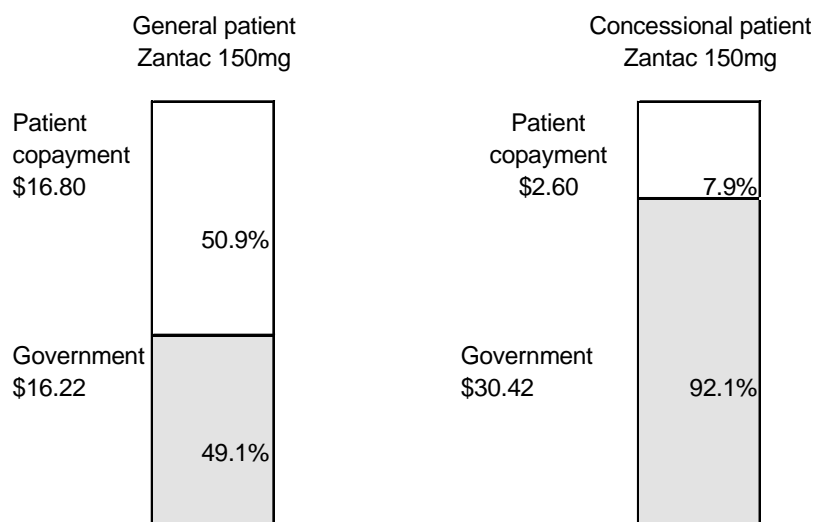
Figure 4.1: Who pays what for insulin^a—dispensed price \$206.47



^a Insulin is used to control diabetes.

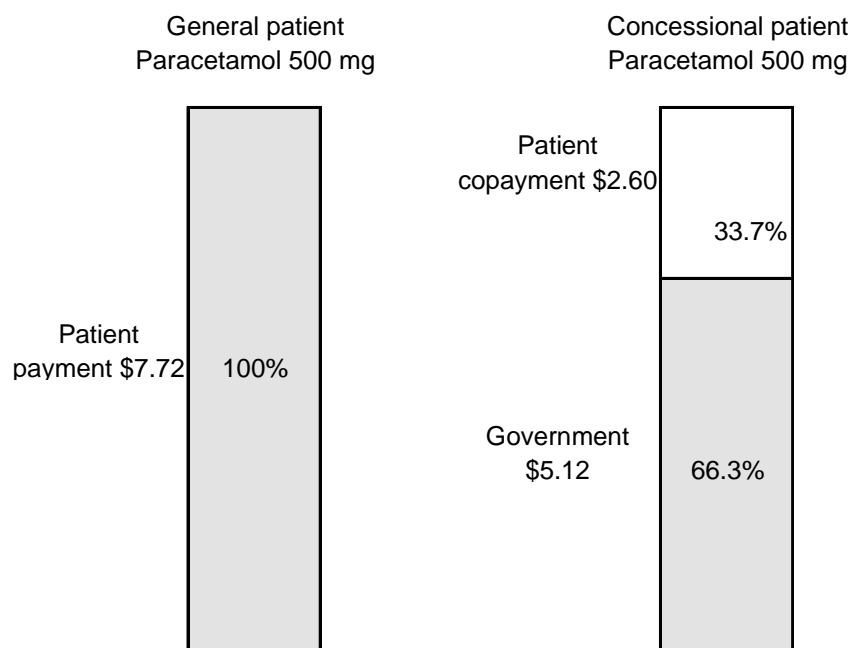
Source: DSHS 1995f, p. 18

Figure 4.2: Who pays what for Zantac^a—dispensed price \$33.02



^a Zantac is an ulcer treatment.

Source: DSHS 1995f, p. 18

Figure 4.3: Who pays what for paracetamol^a—dispensed price \$7.72

^a Paracetamol is a painkiller (analgesic)

Source: DSHS 1995f, p. 101

Table 4.2 shows some of the highest cost items on the PBS and Table 4.3 shows some of the most commonly prescribed items.

Table 4.2: PBS—highest cost items, year ending 30 June 1995

<i>Item^a</i>	<i>Purpose</i>	<i>Form</i>	<i>Cost to Govt</i>	<i>Dispensed price^b</i>	<i>% of PBS expenditure</i>
			\$m	\$	%
Ranitidine hydro-chloride (eg Zantac)	Ulcer treatment	Tablet 150 mg (base)	65.4	33.02	3.5
Simvastatin (eg Lipex 10)	Lipid-lowering	Tablet 10 mg	54.2	41.99	2.9
Simvastatin (eg Zocor)	Lipid-lowering	Tablet 20 mg	43.9	58.05	2.3
Enalapril maleate (eg Renitec)	Antihypertensive	Tablet 20 mg	41.0	34.97	2.2
Fluoxetine hydro-chloride (eg Prozac)	Antidepressant	Capsule 20 mg (base)	37.2	55.53	2.0

^a Different forms of the same drug are listed as separate items.

^b Dispensed price for maximum quantity.

Sources: DSHS 1995b, p. 31; DSHS 1995f, pp. 9, 27, 28, 34, 112

Table 4.3: PBS—most prescribed items, year ending 30 June 1995

<i>Item</i>	<i>Purpose</i>	<i>Form</i>	<i>Script volume</i>	<i>Cost to Govt</i>	<i>Total PBS cost</i>	<i>Dispensed price for maximum quantity</i>
			'000	\$m	\$m	\$
Paracetamol (eg Dymadon)	Analgesic	Tablet 500 mg	3 493.8	19.0	26.0	7.72
Codeine phosphate with paracetamol (eg Panadeine Forte)	Analgesic	Tablet 30 mg –500 mg	2 493.4	13.2	18.4	6.79
Ranitidine hydrochloride (eg Zantac)	Anti-ulcer	Tablet 150 mg (base)	2 387.8	65.4	78.2	33.02
Temazepam (eg Temaze 10)	Antipsychotic	Capsule 10 mg	2 296.2	9.1	13.8	8.27
Salbutamol sulphate (eg Ventolin)	Antiasthmatic	Oral inhalation 100 µg, 200 doses	2 019.5	13.6	17.9	9.23

Sources: DSHS 1995b, p. 32; DSHS 1995f, pp. 9, 101, 111, 118

4.3.2 Ensuring lowest cost to Government and consumers

The Government uses the market power achieved through its granting of product subsidies under the PBS to hold down the prices paid to producers for listed drugs and hence its PBS costs. The Government further contains its costs through its listing process which restricts the availability of the subsidy for some new and expensive products.

The PBS can reduce prices paid by consumers in two ways.

First, a subsidy is provided where the patient copayment is less than the negotiated price of the drug. In Figure 4.2, for general users, this is equal to \$16.22 (49.1 per cent) of the final price for Zantac of \$33.02.

Second, where the maximum copayment (\$16.80 as at April 1996) is higher than the negotiated drug price, the consumer receives the full benefit of any suppression of drug prices which the Government achieves through use of its monopsony power.

For example, in Figure 4.3, where general users pay the full price of \$7.72 for paracetamol, they enjoy the full effect of the Government's price suppression.

4.4 Institutional framework

The process of obtaining PBS listing of products is complex and involves numerous linkages and loops between various regulatory bodies. Its institutional arrangements are shown diagrammatically in Figure 4.4.⁶ The process usually does not begin until drug registration with the TGA has taken place.⁷

The PBB outlined the series of steps and the various parties involved in a pharmaceutical proceeding through the listing process (sub. 11).

Application is initially made to the PBAC which is required to make a recommendation on the suitability of the drug for subsidy by the Government. In coming to a decision on listing, the PBAC takes advice from its Economics Sub-Committee (ESC) on the cost effectiveness of the drug compared with other treatments. The ESC reports to the PBAC, which then passes on a recommendation to the PBPA. The PBPA is required to take this advice, along with several other factors, into consideration when recommending a final price to be negotiated by the DHFS with the manufacturer. Both the PBAC listing recommendation and the PBPA pricing recommendation are referred to the Minister for approval. For drugs estimated to cost more than \$10 million per annum, Cabinet approval is required. The roles of the various bodies involved in the listing approval process are outlined in Box 4.3.

Both the PBAC and the PBPA are serviced by secretariats within the PBB. The PBB has a pricing section, which provides secretariat support for the PBPA, and a listing section, which provides secretariat support for the PBAC. Both secretariats are located in the Department of Health and Family Services (DHFS).

The nominated time frame for listing on the PBS is eight months. This comprises three months (11 weeks) from the cut off date for PBAC applications to the PBAC meeting; and a further five months (20 weeks) from the PBAC meeting to product listing on the PBS.

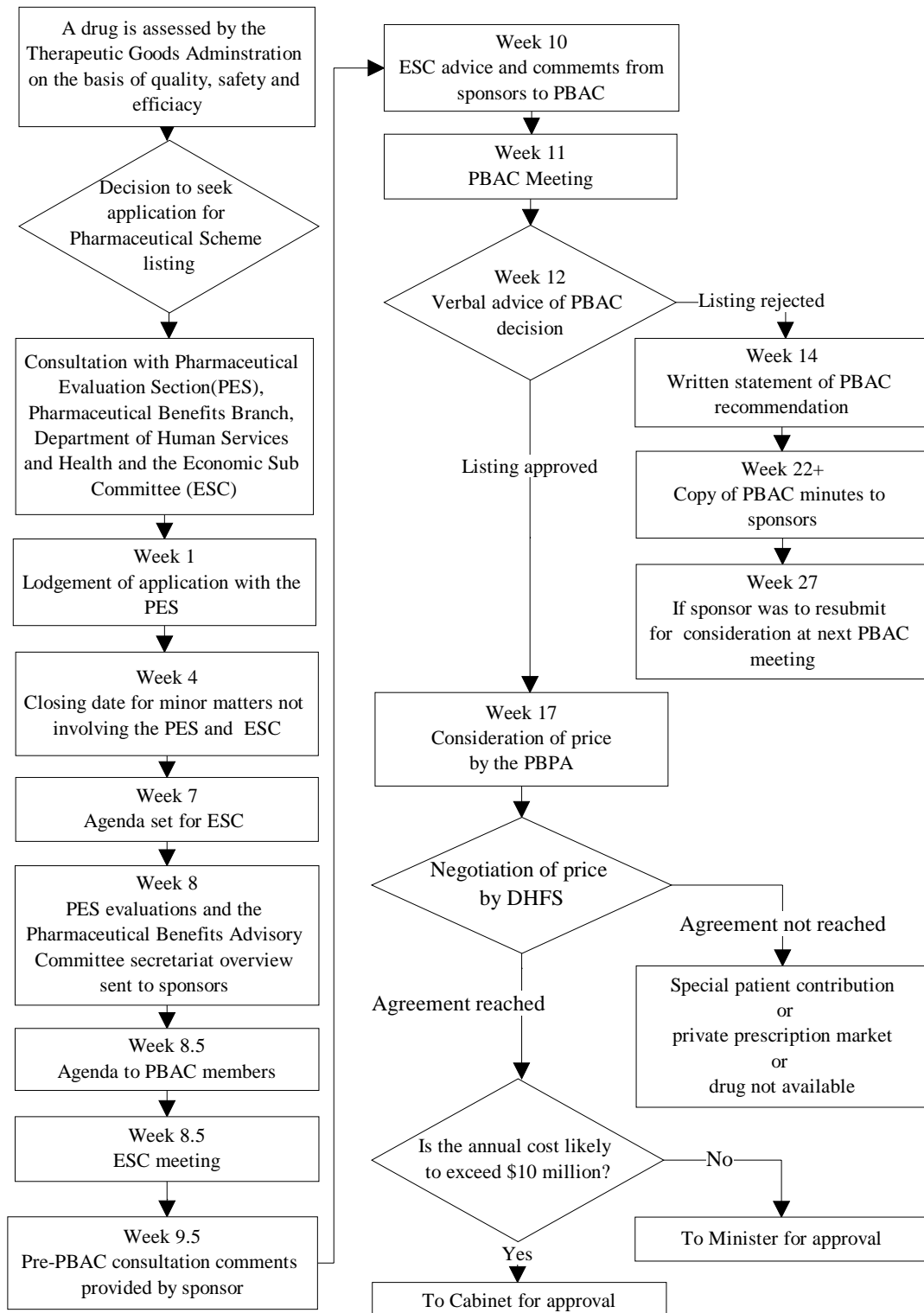
According to DHFS:

⁶ The potential for streamlining registration and PBS listing is discussed further in Chapter 9.

⁷ Submissions to the PBAC can be made after Australian Drug Evaluation Committee (ADEC) consideration and before marketing approval, if the process is initiated by the product sponsor (sub. 11, p. 9).

... meetings of the PBAC and the PBPA and the timing of the printing of the PBS schedule have been coordinated so that the time between PBAC application and implementation of the PBS subsidy should be a maximum of eight months ...

Figure 4.4: PBS listing process



Source: Derived from PBB sub. 11, pp. 10–11

Box 4.3: PBS institutions and their roles

Pharmaceutical Benefits Advisory Committee (PBAC)—is an independent statutory committee which advises the Minister for Health on matters relevant to the listing and availability of drugs on the PBS. It has two subcommittees:

- **Drug Utilisation Sub-Committee (DUSC)**—monitors the patterns and trends of drug use and makes such utilisation data available to Australian and international consumers, research groups and interested bodies; and
- **Economics Sub-Committee (ESC)**—advises on cost effectiveness policies and evaluates cost effectiveness aspects of submissions received from drug manufacturers.

Pharmaceutical Benefits Pricing Authority (PBPA)—is a non-statutory body that reviews the prices of products supplied under the PBS, and recommends to the DHFS prices at which new pharmaceuticals should be listed.

Source: PBB sub. 11, pp. 8–12

Clearly this time frame relates to applications for which no particular problems arise, such as more information required by the PBAC, price negotiations are not overly protracted, the product fails assay, or the sponsor cannot give an assurance that stock will be available on time (sub. 183, p. 1).

The DHFS provided the Commission with recent data on the number of applications which achieved PBS listing within the nominated time frame (see Table 4.4). Nearly 60 per cent of applications considered achieved listing on the PBS in eight months for PBAC meetings held between February 1994 to September 1995.

Table 4.4: PBS listing process data, February 1994–September 1995

<i>Year/month of PBAC meeting</i>	<i>No. of applications</i>	<i>No. recommended</i>	<i>No. rejected</i>	<i>No. deferred</i>	<i>No. considered by PBPA</i>	<i>% listed in 8 months^a</i>
February 1994	32	18	12	2	16	63
May 1994	37	21	13	3	16	63
August 1994	32	20	8	4	17	47
November 1994	38	19	15	4	17	71
March 1995	38	20	12	6	13	77
June 1995	36	24	11	1	21	43
September 1995	24	18	6	0	16	56

^a The percentage of applications considered by the PBPA which were listed in eight months.

Source: DHSH sub. 183, pp. 3–4

4.4.1 Pharmaceutical Benefits Advisory Committee

New applications

The PBAC considers applications for PBS listing in terms of the effectiveness, the cost effectiveness and clinical place of the drug compared with other products already listed on the PBS for similar indications to those for which the drug has been registered by the Therapeutic Goods Administration (TGA). If there is no listed alternative, the PBAC compares the product to standard medical care, or the benefits the new product will provide to patients compared with the cost of achieving those benefits. The PBAC also advises on the quantities, number of repeats and any restrictions on clinical uses for benefits.

The PBB indicated that new pharmaceuticals may be recommended for listing if:

- they prevent or treat conditions not already covered by pharmaceuticals on the list and are of acceptable cost effectiveness;
- they are more effective (in terms of health outcomes), or less toxic (or both) than a pharmaceutical already listed for the same indications and are of acceptable cost effectiveness; or
- they are at least as effective (in terms of health outcomes) and as safe as a pharmaceutical already listed for the same indications and of similar cost (sub. 11, p. 8).

Economic analysis

An application for a new listing is required to demonstrate the cost effectiveness of the product in line with guidelines developed by the DHFS. Revised guidelines were published in November 1995.⁸

The Guidelines indicate that three different types of economic analyses may be applied as part of the consideration of a listing application depending on the extent to which similar products are already listed. They are:

- cost effectiveness analysis—used where the new pharmaceutical for a disease is clinically superior to the ones already listed. The additional cost per additional clinical outcome is calculated and used to decide whether the extra benefit is worth the extra cost;

⁸ The guidelines are set out in DSHS (1995e) and summarised in Appendix I.

- cost minimisation analysis—used where the new pharmaceutical is no better or worse clinically than alternatives already listed. The analysis is suitable where different pharmaceuticals, or a pharmaceutical and an alternative intervention, have been shown to have identical outcomes; and
- cost benefit analysis (CBA)—involves a monetary valuation of all costs and benefits, including indirect benefits flowing from changes to an individual's productive capacity.

It should be noted that although CBA is listed in the guidelines, they state that except in rare circumstances, CBA is not encouraged (sub. 22, p. 4).⁹

The three types of analyses are discussed more fully in Appendix I.

PBS schedule reviews

As well as considering new applications, the PBAC reviews the entire PBS schedule regularly to ascertain whether pharmaceuticals should still be subsidised through the PBS.¹⁰ Circumstances which may result in the removal of a pharmaceutical from the list include:

- a more effective or equally effective but less toxic pharmaceutical becomes available;
- toxicity or abuse potential proves to outweigh the therapeutic value;
- treatment with the pharmaceutical is no longer deemed cost effective relative to other therapies;
- the product is used solely for treating minor conditions which do not require monitoring by a doctor;
- the product can be purchased without a prescription; and
- its removal will not result in inappropriate prescribing of alternative products remaining in the scheme.

⁹ For example, a willingness-to-pay estimate for an appropriately defined outcome of therapy.

¹⁰ The PBAC has reviewed the entire schedule annually over the last few years, reviewing a quarter of the schedule every meeting. The PBAC is moving towards reviewing the schedule every two years.

At one stage, paracetamol was removed, but an immediate shift to the prescription of more expensive drugs, led to the drug being re-listed.¹¹

Transparency

The timing of PBAC meetings and the procedures relating to applications are tightly defined and well publicised. It is based on an 11 week cycle. The PBAC has argued that over the past three years, annual meetings with the APMA have facilitated discussion on the transparency, policies and practices of the PBS listing process, both from the industry and Departmental perspective (PBB sub. 11, p. 10).

The PBAC listed some of the initiatives adopted from these meetings:

- provision for four PBAC meetings per year instead of the previous three;
- re-structuring of the PBAC agenda to reflect APMA agreed priorities;
- provision to sponsors of relevant documents and evaluations considered by the PBAC;
- provision for written pre-PBAC comment from sponsors in relation to papers to be provided to the PBAC for new submissions for the listing of drugs (following the 1995 meeting pre-PBAC consultation will be extended to include re-submissions for the listing of drugs);
- access to immediate feedback from PBAC meetings and provision of advice of Committee decisions within 15 working days of each meeting; and
- provision of the relevant extracts of PBAC and ESC minutes within a few days of their ratification (sub. 22, p. 2).

4.4.2 Pharmaceutical Benefits Pricing Authority

The PBPA is a non-statutory body that reviews the prices of products supplied under the PBS, and recommends prices to the DHFS at which new pharmaceuticals should be listed.

There are nine factors that the PBPA is required to take into account when recommending prices (see Box 4.4). All but Factor f, which relates to the level of local activity, are considered by a secretariat within DHFS. Factor f is

¹¹ For concessional users, it was cheaper to get prescription codeine, a more expensive and powerful pharmaceutical, at \$2.60, than to purchase paracetamol at the pharmacy or supermarket.

considered by a separate specialist secretariat within the Department of Industry, Science and Tourism (see Chapter 5).

Box 4.4: The factors considered by the PBPA in recommending and reviewing prices

In reviewing the price of each listed item and in considering the price of items recommended for listing, the PBPA is required to take account of:

- (a) PBAC's comments on clinical and cost effectiveness aspects;
- (b) the prices of alternative brands of a drug;
- (c) comparative prices of drugs in the same therapeutic group;
- (d) cost information when provided by the supplier or estimated by the PBPA;
- (e) prescription volumes, economies of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements;
- (f) the level of activity being undertaken by the company in Australia, including new investment, production, research and development;
- (g) prices of drugs in reasonably comparable overseas countries;
- (h) other relevant factors which the applicant company may wish the PBPA to consider; and
- (i) other directions as advised by the Minister.

Source: PBPA 1994, p. 4

The methods used to determine prices are as follows:

- for pharmaceuticals which are therapeutically interchangeable, the PBPA only recommends the price on which PBS payments will be made, based on the lowest priced brand. Suppliers of other brands can set their own prices with the difference being paid by the consumer. This Minimum Pricing Policy applies to approximately 184 items on the PBS;
- for pharmaceuticals for which there are alternative items available in the same chemical group, the price is determined by the cheapest priced product available in the group (benchmark pricing). This applies to 40 per cent of PBS pharmaceuticals; and
- for pharmaceuticals for which there are no directly comparable products, pricing is based on the cost of manufacture plus a margin, but also takes account of PBAC assessment of the cost effectiveness of the pharmaceutical at the price requested by the supplier.

The PBPA processes are discussed further in Chapter 9.

4.4.3 Pricing the delivery system

The margins on PBS products are closely regulated. The wholesale margin is regulated by the Government at a maximum of 10 per cent. However, wholesalers are able to compete by lowering this margin, as described in Section 3.4.1.

The Pharmaceutical Benefits Remuneration Tribunal determines remuneration to pharmacists for dispensing benefits, as described in Section 3.4.2.

The mark-ups for products across a range of prices are shown in Table 4.5. It highlights the significant impact of percentage mark-ups on the final selling price of products.

Table 4.5: Mark-ups on PBS products

		<i>Paracetamol—final selling price \$7.72</i>	<i>Zantac—final selling price \$33.02</i>	<i>Insulin—final selling price \$206.47</i>
Retail portion	%	59.3	20.8	10.8
Wholesale portion	%	3.8	7.2	8.1
Manufacturer portion	%	36.9	72.0	81.1
Price ex-manufacturer	\$	2.85	23.76	167.45
Wholesaler mark-up	\$	0.29	2.38	16.75
Price to pharmacy	\$	3.14	26.14	184.20
Pharmacy mark-up	\$	0.31	2.61	18.00
Dispensing fee	\$	4.06	4.06	4.06
Administration fee	\$	0.21	0.21	0.21
Final selling price	\$	7.72	33.02	206.47

Source: DSHS 1995f, pp. 9, 18, 101

4.5 PBS outlays in the context of broader health policy

Growth in expenditure on PBS and medical services has contributed to an overall increase in spending on health and community services in the past decade. This growth in health outlays has become a major concern for the Government. A recent Council of Australian Governments (COAG) paper commented:

Over the last decade, spending on health and community services has risen from around 8 per cent to 9.5 per cent of GDP. Much of the cost of these services is borne by governments, whose spending on health and community services has increased from around 12 per cent to 16 per cent over the same period. Individuals also bear costs directly, for example, in the form of private health insurance premiums and out-of-pocket medical treatment costs (COAG 1995a, p. 2)

As a result, the growth in health outlays has averaged 4 per cent per annum in real terms since 1985–86, the first year reflecting the full cost of Medicare.

The PBS is one of the 60 health related programs funded through Commonwealth and State Governments. The PBS and the Medical Benefits Scheme (MBS) are the only two entitlement programs for which Government outlays are uncapped and are determined by the claims submitted by patients or medical providers.

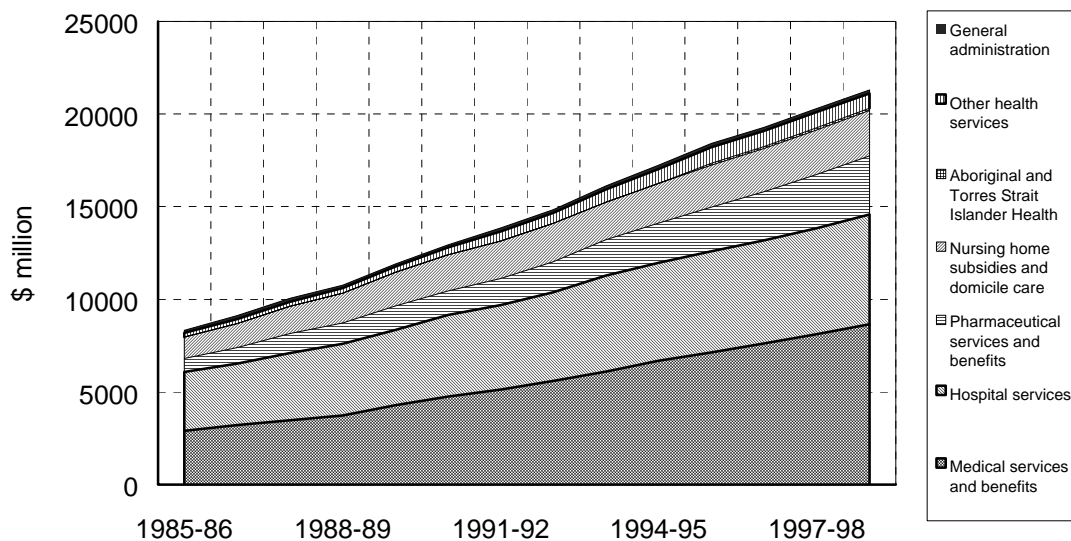
Partly as a result of their uncapped nature, real expenditures on PBS and MBS have grown rapidly in recent years. In the decade to 1994–95, real PBS expenditure has grown the fastest of all components of health expenditure, at 8 per cent, followed by MBS at 5.2 per cent. Recent trends and forecasts for both total health expenditure and its components are shown in Figure 4.5 (Willis & Beazley 1995, p. 3-94).

Thus, expenditure on the MBS and PBS are increasing as a proportion of the health budget.

The PBB argued that the factors contributing to the PBS outlay growth included:

- increasing expense in developing new drugs, leading to more expensive products;
- the promotion of drugs by companies;
- transfer of prescribing to the use of newer and often more expensive drugs;
- ageing of the Australian population;
- success of new medicines to treat difficult diseases;
- changes in patient expectations;
- increase in the number of medical practitioners; and
- costs associated with the supply of medicines (sub. 11, p. 6).

Figure 4.5: Actual and forecast Commonwealth Government health services outlays, 1985–86 to 1997–98



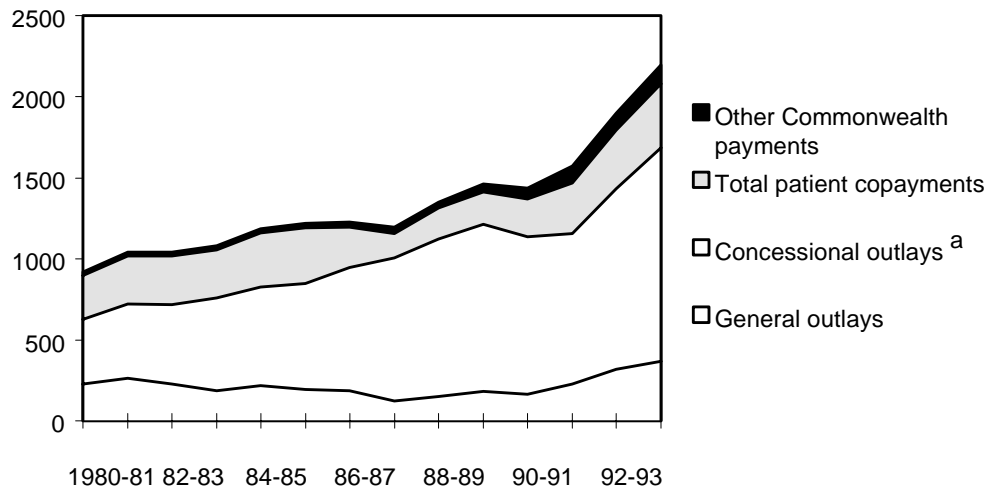
Source: Willis and Beazley 1995, pp. 3-90

Of these, the key drivers are likely to be the listing of new, more expensive drugs on the PBS and the underlying growth in demand reflecting both growth in utilisation and changes in the size of the population. The Victorian Department of Health and Community Services argued that this growth in utilisation can be partly attributed to unsatisfied demand from the other 58 capped programs spilling over to both the MBS and PBS (Victorian DHCS 1995, p. 19).

Strong real growth in PBS expenditure of around 7 per cent per annum is expected to continue in the next five years, driven by the same factors as described above (Willis & Beazley 1995, p. 3-94).

As demonstrated by Figure 4.6, PBS outlays growth is being driven mainly by the concessional group. In 1983–84, the concessional category made up 57 per cent of the total cost of benefit prescriptions. By 1994–95, this proportion had risen to 74 per cent, although concession holders comprised only 30 per cent of the population. Appendix B shows the key statistics for the PBS covering the period 1989–90 to 1994–95.

Figure 4.6: Contributions to expenditure on PBS items, 1980–81 to 1994–95, \$ million



^a Pensioners and the unemployed

Source: DSHS 1995b, p. 33

The number of concession holder families has expanded significantly over recent years, increasing from 544 283 in 1990–91 to 730 505 in 1992–93, due largely to increased unemployment (AIHW 1994, p. 142).

Other countries have experienced similar trends in health expenditure over the last decade, resulting in increasing pressure to contain health costs generally, and pharmaceutical costs in particular.

4.6 Cost control measures

The growth in health expenditure has become a source of concern for the Commonwealth Government, resulting in a coordinated approach to health reform through the COAG process (see Appendix B). In particular, the strong past growth in PBS outlays outlined in Section 4.5 has prompted the Government to attempt to suppress the prices paid to manufacturers and the use of pharmaceuticals. Some direct measures have included:

- holding down the prices paid to manufacturers;
- creating price signals for consumers and prescribers;
- monitoring utilisation, restricting supply and education for appropriate pharmaceutical use; and
- indirect cost controls.

4.6.1 Holding down prices

The primary mechanism used by the Government to control PBS outlays is the holding down of prices received by manufacturers by the exercise of monopsony power. The Government has significant market power because only products listed on the PBS are subsidised and doctors tend to confine their prescribing to the PBS list.

If the manufacturer cannot agree with the Government on a price, there is the option of selling on the private prescription market. However, the existence of subsidy through the PBS for most products makes the private market option unattractive in many cases. In most cases, manufacturers are faced with supplying through the PBS or not supplying at all.

Australia has a reputation for maintaining low prices for its PBS pharmaceuticals relative to other industrialised countries. The issues arising from low PBS prices are discussed more fully in Chapter 8.

4.6.2 Price signals

Copayments

Copayments for both the general and concessional patient categories place some restraints on demand for Government funds.

In relation to copayments, there are three categories of patients:

- general users—the copayment has increased steadily from \$0.50 in 1960 to \$16.80 in 1995, and is now Consumer Price Index (CPI) indexed;
- concessional users (including health care card holders, low income groups and the unemployed)—this category was introduced in 1983, with a copayment of \$2.00. Previously, this group paid the general copayment, which was \$4.00 in 1983. The copayment is currently \$2.60, and is also indexed; and
- pensioners—made no copayment until 1990, when they joined the concessional category. They now pay the \$2.60 concessional copayment.

The impact of copayments on general users has steadily increased over the last 15 years due to increasing levels and broader application (see Appendix B). For health care concession card holders, copayments have been reduced over time with the introduction of the concessional users category.

The general copayment has been a major tool used to moderate general category outlay growth, since its introduction in 1960. A large number of prescriptions for cheaper pharmaceuticals no longer attract a PBS subsidy for general users.

It should be noted that, for both concessional and general users, the safety net has reduced the impact of copayments in restraining demand for drugs. However, in the 1995–96 Budget, the Government significantly increased these safety net thresholds, from \$407 to \$600 per annum for general users and from \$135.20 to \$140.40 for concessional users.¹² The budgetary impact of this and other cost control measures introduced in 1995–96 is summarised in Table 4.6.

Table 4.6: 1995–96 budget measures, effect on PBS outlays, \$ million

	1995–96	1996–97	1997–98	1998–99
Deletion of certain discretionary pharmaceuticals from the PBS	-7.1	-10.9	-12.5	-14.5
Restricted listings for certain discretionary pharmaceuticals	-0.5	-0.6	-0.7	-0.8
Increase the PBS safety net threshold for general patients from \$407 pa to \$600 pa	-10.0	-30.0	-30.0	-30.0

Source: Willis and Beazley 1995, p. 3-99

Minimum pricing policy

A minimum pricing policy was introduced in December 1990. Under it the Commonwealth Government only subsidises a pharmaceutical to the level of the lowest priced brand.

Suppliers of multi-branded items are free to set prices at the level they estimate the market will bear. A brand premium represents an additional out of pocket cost to consumers and does not count for safety net purposes (PBB sub. 11, p. 13). It therefore limits PBS costs and to the extent, that it increases retail prices, could contain consumer demand.

An amendment to the *National Health Act* 1953, which took effect in December 1994, permitted pharmacists to supply a generic substitute for items with a brand premium without reference back to the prescriber. This amendment was consistent with an IAC (1986) recommendation (see Box 4.4). Generic (or

¹² Once concessional users' copayments in a calendar year reach a total of \$140.40 a safety net operates under which no copayments apply for further drug expenditures in that year. For general users, a safety net of \$600 applies, after which the copayment falls to \$2.60.

brand) substitution reinforces the Minimum Pricing Policy by increasing the ability of consumers to have access to the lowest priced drug. Previously pharmacists had to dispense the brand prescribed by the doctor unless they contacted the prescriber directly for each prescription.

It should be noted that the Government stated that generic substitution was introduced primarily to increase consumer choice rather than to constrain Government expenditure. The PBB argued:

If any benefits were to come they should be for the benefit of the patient/taxpayer (sub. 11, p. 14).

Currently, there are more than 120 brands of pharmaceuticals under the PBS identified as having the same clinical effect as leading brands, and therefore able to be substituted. On average, generic substitution saves the consumer \$1.53 per prescription, and on some oral contraceptives, the saving on each prescription can be up to \$4.88 (Lawrence 1995). There seems to be growing acceptance of generic substitution, with the number of generically prescribed drugs increasing from 8.3 per cent of drugs in September 1994, to 10.3 per cent in June 1995 (DHS 1995b, p. 38).

4.6.3 Utilisation controls

Utilisation controls or interventions aim to encourage appropriate prescribing habits in doctors and appropriate use of pharmaceuticals by patients. They include:

- restrictions on indication and clinical uses;
- requiring special approval for prescription under the PBS;
- monitoring utilisation, so as to prevent abuses; and
- educating patients on the appropriate use of medicines.

Clinical uses and prescription restrictions

When products are listed on the PBS, benefits are frequently available only for specified indications or clinical uses. Indications may restrict the prescription of certain products to a particular class of person, and for a specified purpose, disease or condition. The manner of use for the prescribed indication is also specified. This includes dosages, quantities per prescription and the number of repeat prescriptions. In this way, costs are further constrained by limiting the indications for which drugs are listed which in turn restricts subsidised consumer access and sales volumes.

Authorisations

There is currently provision for a drug to be given a restricted benefit or authority required listing for one or more of the following reasons:

- to limit PBS usage to the indications, conditions or settings seen as being appropriate for clinical or cost effectiveness reasons—clinical or cost effectiveness authorities;
- to limit PBS usage so that it is in accordance with TGA approved indications—medical authorities; or
- to contain costs where the drug has an average treatment cost of \$32 or more per month and is assessed by the PBAC as having a cheaper alternative under the PBS —economic authorities.

For all authority required drugs the prescribing physician is required to obtain prior approval for prescription. This approval can be obtained over the telephone from the DHFS. Approximately 15 per cent of listed pharmaceutical substances are currently subject to some type of authorisation.¹³

Provision for Economic Authorities was introduced in the 1988–89 Budget as a cost containment measure. Since December 1994 the requirement for this type of authority has been at the discretion of the Minister and as at April 1996 Economic Authorities are not required for any drugs.

The PBAC indicated that for other types of authorities the overriding objective is to ensure that drugs made available under the PBS represent value for money and that decisions frequently take account of both medical and economic factors:

In many cases the reason in relation to ‘medical’ or ‘economic’ is not fully black or white and there may be elements of both. [Purely medical grounds relate to products] ... which would be listed as they now are irrespective of price. [A]n example of a purely economic reason [is where] the single unit packaging makes the product more expensive than multidose products [or where] the product is ‘better’ than [another product] but many times more expensive. The listing is limited to a situation where the benefits are considered worthy of the additional cost (PBPA correspondence 11 December 1995).

Companies, however, assert that the primary motive behind the use of authorities by the PBAC continues to be cost containment even though Economic Authorities are no longer being used.

¹³ Based on information supplied by the PBB detailing the number of pharmaceutical substances relative to the total number of these substances listed on the PBS. Does not reflect prevalence in terms of scripts subject to authorisations.

Monitoring and PBS abuse prevention

The Health Insurance Commission (HIC) began to monitor prescribing trends and drug utilisation in 1993 in an effort to detect misuses of the PBS. Priority areas are incorrect prescribing of pharmaceuticals subject to authority and specified purpose restrictions, the misuse of the safety nets and excessive prescribing of selected, high cost pharmaceuticals.

In addition, the HIC has tightened the requirements for pharmacists to check the entitlement of cardholders to concessional rate pharmaceuticals. The HIC itself is required to check people's actual entitlement status.

Education for appropriate pharmaceutical use

The Australian Pharmaceutical Advisory Council (APAC) and the Pharmaceutical Health and Rational use of Medicines (PHARM) Committee are involved in ensuring that pharmaceuticals are used by patients in a judicious, appropriate and safe manner so that optimal health outcomes result. This is consistent with the second arm of the NMDP. Expenditure in 1993–94 on pharmaceutical education related to appropriate use of pharmaceuticals was \$3 million.

4.6.4 Indirect cost controls

The numbers of general practitioners (GPs) and retail pharmacists have been the subject of specific Government rationalisation programs which have indirect implications for PBS expenditure. A recent development in indirectly controlling the cost of the PBS is the use of price/volume agreements between the PBPA and companies.

General practice

General practice reforms were introduced in the 1991–92 and 1992–93 Budgets to reduce the excess supply of GPs in Australia. Such measures may have had some impact in containing costs of the PBS since GPs act as the gatekeepers in the supply of pharmaceuticals to patients.

Community pharmacy

The number of pharmacies is regulated. Pharmacy numbers have an impact on retail drug prices and hence consumer demand because the profitability of low volume pharmacies is taken into account by the DHFS when deciding on an appropriate pharmacy dispensing fee.

The Government's rationalisation of retail pharmacy was discussed in more detail in Chapter 3.

Price/volume agreements

Price/volume agreements enable the PBPA to negotiate a lower price when all other negotiation strategies have proven inadequate. A company agrees to supply a drug at a price slightly higher than the PBPA was aiming for, on the understanding that once a certain volume is reached, the price received falls, thus containing costs. There can be multiple 'price steps' in a price volume agreement (see Chapter 9).

4.7 Policy issues

The growth in health expenditure has become a source of concern for the Commonwealth Government. COAG has identified a number of problems in Australia's health system, due largely to a policy focus on the needs of service providers rather than consumer needs, and poor integration between various health services (COAG 1995b). The PBS is an example of a health service with poor links to other health services (see Chapter 9).

A number of PBS related issues raised by participants may have an adverse impact on the pharmaceutical industry. They can be broadly categorised as the use of Government monopsony power to suppress PBS prices, problems with the PBS listing processes (such as delays, a lack of transparency and the application of the cost effectiveness criteria); and the current piecemeal approach to the containment of pharmaceutical costs. These issues are analysed further in Chapters 8, 9 and 10.

5 FACTOR F

The Factor f scheme is a key element of the Pharmaceutical Industry Development Program adopted by the Commonwealth Government in 1987 to encourage the growth of the pharmaceutical industry in Australia. The scheme is designed to compensate companies for the effects of low prices of pharmaceuticals supplied under the Pharmaceutical Benefits Scheme (PBS). In return for higher notional prices on some of their PBS products, companies are required to increase their research and development (R&D) expenditure, as well as their domestic manufacturing and export activity in Australia.

Since the inception of the Factor f scheme in 1988, companies have committed \$1.9 billion in export value added, \$1.9 billion in domestic value added, and \$538 million on R&D expenditure. In addition, they have undertaken \$604 million of investment expenditure. The Government has allocated approximately \$1 billion in funding.

5.1 Background to the Factor f scheme

In the early to mid 1980's, Australia's place in the international pharmaceutical industry was seen to be under threat. Numerous commentators noted a widely held industry perception of the Australian operating environment as 'hostile'. It was argued that this perception, combined with international business rationalisation (described in Chapter 6), led to some disinvestment in the Australian industry, a general decline in activity, a running down of production facilities, an increasing deficit on the pharmaceutical balance of trade and the threat of more departures.

The Department of Industry, Science and Technology (now, Department of Industry, Science and Tourism) (DIST) noted that Eli Lilly closed its manufacturing facilities in Australia and confined activities to sales and marketing, Ciba-Geigy and Upjohn ceased local production, and Roche and Riker closed their research and development (R&D) facilities (sub. 56, p. 26). Furthermore, the Bureau of Industry Economics (BIE) noted declines in activity by Merck, Sharp & Dohme and Parke Davis through shifts of varying degrees from local manufacturing to imports (BIE 1991, p. 45). However, at the same

time, Alphapharm was emerging as an industry player, specialising in the supply of generic products, and Astra was actually expanding (BIE 1991, p. 45).

In the 1980's, the main elements contributing to the industry's 'hostile environment perception' were low prices on the Pharmaceutical Benefits Scheme (PBS) and an idiosyncratic and slow regulatory system. Industry was also highly critical of the patent system at the time.

In a bid to change the perception of Australia as a hostile environment and encourage companies to stay in Australia and undertake further investment, the Commonwealth Government announced, in September 1987, the establishment of the Pharmaceutical Industry Development Program (PIDP).

5.2 Pharmaceutical Industry Development Program

The three main elements of the PIDP announced by Ministers Button and Blewett were:

- to replace the Pharmaceutical Benefits Pricing Bureau with an independent Authority;
- to require the Authority to take into account the level of an individual company's Australian pharmaceutical activity when setting or making recommendations on prices; and
- to provide for extensions to patent life on pharmaceuticals for human use (Button & Blewett 1987a, p.1).

Unlike its predecessor, the independent Pharmaceutical Benefits Pricing Authority (PBPA) must give due consideration to the level of an individual company's Australian pharmaceutical activity when recommending PBS prices. This requirement, named Factor f because it is sixth in the list of factors that the PBPA is required to take into consideration when recommending prices (see Chapter 4), led to the establishment, in mid 1988, of the Factor f scheme. The scheme was later included as the mechanism through which an arm of the National Medicinal Drug Policy, the maintenance of a viable pharmaceutical industry, was to be achieved (see Chapter 2).

Payments under the Factor f scheme have no specific legislative basis. The Government approves funding for the Factor f scheme as part of its program appropriations to DIST. The only element of the PIDP given any legislative basis was the granting of four year administrative extensions to pharmaceutical patents (see Chapter 15).

5.3 Objective of the Factor f scheme

During the course of this Inquiry, the Commission noted that participants had different understandings about the objective of the Factor f scheme. They have expressed a range of views on what the scheme was meant to be, what it is and what it should be. This section sets out these views and relevant Government statements about the scheme. Finally, it outlines the Commission's view of the appropriate objective of the scheme.

5.3.1 Participants' views

Some participants put the view that the objective of the scheme was to remove the impediment of low PBS prices to the normal development of the industry. For example, CSL stated that:

... it is important to recall the origin of the Factor f scheme and place its objectives into context. The fact that the scheme was targeted or 'tied' and has been so successful in generating new, internationally competitive activity, has given it the appearance of an industry assistance or development plan. This is not what Factor f was, or is today. Its fundamental purpose is to provide some compensation for low prices in a market which is distorted by Government monopsony power.

The Factor f scheme was, and remains, a pragmatic initiative to partly counter the negative impact on the pharmaceutical industry of Government health and welfare policies, particularly the subsidy of medicines to consumers through the exercise of its monopsony power over pharmaceutical pricing. These Government induced market distortions were (and still are) the major contributors to a hostile investment environment preventing normal industry development (sub. 118, p. 2).

Merck, Sharp & Dohme agreed:

While the Factor f scheme is part of the Pharmaceutical Industry Development Plan, its essential character is not that of an industry development scheme. Given the right operating environment, the pharmaceutical industry requires no greater assistance than any other industry sector.

The Factor f scheme is fundamentally a price correction scheme—it aims to minimise the pricing distortions resulting from the Government's monopsony position in the market. To our knowledge, no other industry sector works in such a controlled marketplace (sub. 122, p. 1).

Glaxo Wellcome stated that:

The Factor f scheme has been used by Government to balance the provision of cheap drugs under the PBS with the need to develop a viable and internationally competitive pharmaceutical industry in this country. In this sense, it exists to

partially offset the negative impact of a different set of Government policy relating to health and welfare (sub. 144, p. 4).

Some participants, while sharing the view that the scheme's objective was compensation for price suppression, argued that such compensation was partial and temporary. As Pfizer stated:

... we reiterate that Factor f is a stop-gap approach and does not adequately—or for the long term—address the fundamental distortion created by the PBS.

Whilst participation in Factor f has clearly stimulated greater investment in Australia and value adding by Pfizer, it continues to be our strong submission that it is more appropriate to deliver incentives to investment and value adding activities directly through fair and reasonable prices (sub. 133, p. 4).

In its first submission to the Inquiry, DIST stated:

The Factor f scheme was introduced in 1988 to compensate pharmaceutical companies for the low PBS prices obtainable by the Government through exercising its monopsony purchasing power. It was perceived by industry as an interim measure until the longer term pricing environment could be considered by Government (sub. 56, p. 29).

Other participants, however, claimed that the scheme was designed to go beyond removing an impediment and restoring activity lost due to price suppression under the PBS. This alternative view was supported by DIST in a later submission and several other participants. DIST considered that the Commission's Draft Report did not capture the original intent of the Factor f scheme:

[The Commission] fails to take into account the intention of the scheme as announced by Ministers in 1988—to create an environment for the industry which would encourage greater R&D and investment in manufacturing capacity on an internationally competitive basis. The scheme should be evaluated on the basis of whether the Government has received 'value for money' in encouraging this activity. I do not see the rationale of the scheme as being solely to restore activity in the industry to a theoretical 'free market' level (sub. 154, p. 2).

A similar view was put by Parke Davis which stated:

Whilst the question of PBS pricing may still be a significant issue, as it was in 1988 when Factor f was introduced, the development, and importantly, location of a 'value adding' R&D based pharmaceutical/OTC industry may be a more appropriate objective. On this basis such a scheme should not be considered solely on a PBS patent basis (sub. 121, p. 4).

Interestingly, low prices did not feature in Parke Davis's list of examples of major impediments to industry development (sub. 121, p. 2).

Apart from differences over the objectives of the Factor f scheme, participants also had differing views about whether raising prices would be sufficient to create a viable pharmaceutical sector.

Astra argued that, for Australia to become a net exporter of pharmaceutical products, in addition to raising prices to the levels of other countries in the Organisation for Economic Co-operation and Development (OECD) for locally manufactured products, there needed to be an incentive package to encourage local R&D plus incentives to maintain the development and production of any new chemical entity within Australia (sub. 141, p. 20). In this respect, the Institute of Drug Technology (IDT) considered that PBS price compensation should not be the only justification for an industry scheme. It stated:

We recognise that as long as the industry development program is linked only to PBS compensation, companies such as IDT will remain ineligible. Accordingly it may be appropriate to implement a program of industry development for pharmaceutical companies not eligible to receive Factor f type compensation. This might take the form of a scheme of grants or low interest loans similar to those currently administered by the [Industry Research and Development] IR&D Board, but falling outside the current guidelines for industrial research and development. For our industry, regulatory and quality compliance costs for example may fall outside the IR&D Board guidelines but could become eligible for Government support of some kind (sub. 156, p. 1).

Finally, some participants considered that Factor f should offer extra support for Australian based companies. For example, Faulding proposed:

The scheme should emphasise support for the growth and development of a fully integrated truly Australian pharmaceutical industry. This will help to minimise leakage to overseas via foreign based multinationals, maximise the benefits to the Australian economy and public and maximise the return on investment for the Australian Government.

... The development of a fully integrated Australian pharmaceutical industry will not happen quickly but it will never occur whilst small start up Australian ventures must compete for funding support with large, well established foreign companies. The loss of Australian innovations and R&D to foreign owned companies for commercialisation is stark testament to this fact (sub. 129, pp. 4–5).

5.3.2 The Government's stated objectives

The Ministers' press release of September 1987, which announced the elements of the PIDP, including the Factor f scheme, stated that the objective of the overall program was to:

... encourage the growth of the pharmaceutical products industry in Australia.

The Ministers said that the growth of the industry would be consistent with Government policy to encourage technologically advanced, outward-looking industries with minimal levels of assistance. The industry has strong links with Australia's science and technology base. It is highly skill intensive, dependent on research and development for continued growth and conscious of the need for greater export orientation.

The objective was to create an environment which would encourage a significant increase in research and development performance by the industry, together with increased investment, production and export performance, and strengthened employment opportunities (Button & Blewett 1987a, p. 1).

With respect to the rationale for the new pricing criterion, Factor f in particular, the Ministers stated that:

... the [Pharmaceutical Benefits Pricing] Bureau's guidelines for setting prices under the PBS had not required local pharmaceutical manufacturing activity to be taken into account. In recent years, the pharmaceutical industry had not developed significantly and the Government had been concerned that unless action was taken to redress industry problems, the industry would undergo severe disinvestment (Button & Blewett 1987a, p. 3).

In a subsequent press release announcing the acceptance of Glaxo as the first company into the scheme, the Ministers emphasised higher prices:

In announcing this, ... (the Ministers) said the company would be allowed to increase prices progressively over the next five years.

As a consequence, Glaxo's average Pharmaceutical Benefits Scheme (PBS) pharmaceutical prices will increase from around 55 per cent to around 70 per cent of world prices.

Subject to the company achieving the export and R&D performance outlined in its proposal, the value of price adjustments for Glaxo products will be around \$74 million over the five year period.

Under the development program, the Government provides higher prices for PBS products from companies which make significant commitments to Australian manufacturing, product development and exports.

These higher prices are part of an industry development package that also includes extended patent terms (Button & Staples 1989, Attachment, p. 1).

The original 1988 Factor f guidelines¹, which focused on pricing issues, provide the clearest statement that the scheme was intended to remove an impediment to

¹ The present Guidelines for the scheme maintain these original principles, with the exception being that the price cap of a 'normal competitive market' has been replaced by 'average prices of pharmaceutical products in the European Community (Factor f Pricing Guidelines, 1992).

the development of the industry. The four ‘fundamental principles’ of the scheme were that:

- prices for drugs listed on the Pharmaceutical Benefits Scheme (PBS) should not be an impediment to the significant development of the industry;
- higher prices should only be recommended if they are likely to contribute to the development of significant internationally competitive activity in Australia;
- PBS prices should not exceed the prices which could be expected in a normal competitive market; and
- a net benefit to the economy should result from any price increases granted on the basis of Australian activity (Button & Blewett 1988, Attachment, p. 1).

Along with the previous Government’s statements about the Factor f scheme, it is also useful to consider the objective of the scheme in the context of general Government statements about the role of Government in industry policy. The previous Government indicated that its role should be to provide a competitive environment for business, to facilitate competition, and to direct policy at addressing systemic problems and impediments to industries’ normal development (Keating 1994, p. 58). It did not justify any intervention beyond the latter. Hence, while recent Government pronouncements did not preclude industry development programs, they have not actively encouraged them.

5.3.3 The Commission’s view

It is apparent that the way the Factor f scheme was described by Government in its early days has led to confusion about its objectives and rationale. A careful reading of the source documents, and consideration of participants views, suggests to the Commission that its rationale was, and continues to be, to promote the development of the sector by partially compensating for low PBS prices in order to regain competitive activity argued to have been lost to Australia as a result of the structural impediment represented by these prices.

The Commission points out that industry development and the removal of impediments to achieving a level of activity closer to that which would exist in an unconstrained market are not mutually exclusive goals. The issue turns on what is the desired end point of the Factor f scheme—restoring activity lost due to low prices under the PBS or something different from, or more than, that. The lines between the two are not always clear.

DIST drew a subtle distinction between the rationale for the scheme and its objective:

I guess the way we look at it is that ... the intermediate objective of the scheme is to compensate for lower prices and through that mechanism to improve the environment,

but ... the ultimate objective—the reason that you’re doing that—is to achieve a better environment for industry development and it is obvious in a sense by the way you’re doing it. You’re not compensating equitably—you’re doing it to achieve an industry development objective—so I guess there is a little bit of mental gymnastics in this scheme and that is why we get people talking in a fairly mixed up way sometimes ... about why the scheme exists, because between its ... rationale and its operation there is a difference (transcript, p. 780).

The Commission agrees with DIST that improving the environment for industry development is an aim of the Factor f scheme, but considers that the scheme should not go beyond the removal of the impediment to the industry’s normal development represented by low PBS prices.

Apart from removing impediments to its efficient operation, the Commission considers that there is no reason to favour support for the pharmaceutical industry over that for any other industry. This is consistent with the Commission’s view on appropriate industry policy principles (see Chapter 17) and the trend away from sectoral assistance that has been occurring in Australia for over a decade. The Commission considers that any evaluation of the Factor f scheme should be conducted in this context.

5.4 Administration of the Factor f scheme

Under the Factor f scheme, notional price increases are granted for specific products sold on the PBS. Payments are made ex-post as a quarterly lump sum by the PBPA.

While the PBPA is responsible for PBS price recommendations and review, it has separated out consideration of Factor f issues from the other factors that it considers (see Chapter 4). The PBPA is serviced by two Secretariats—one in Department of Health and Family Services (DHFS) which considers health related PBS pricing matters, the other in DIST to consider industry development matters.

The separation of these Secretariats, which occurred some years after the establishment of the PBPA², underlines a view prevailing in the Authority that health and industry considerations are separate issues in PBS pricing.

² Initially, the Factor f Secretariat was located within the then Department of Health, Housing and Community Services. However, on 1 January 1991, it was transferred to the Department of Industry, Technology and Commerce (DITAC), now Department of Industry, Science and Tourism (DIST).

The Factor f Secretariat is headed by an Executive Officer and includes a number of case officers who have responsibility to liaise with participating companies. As well as making quarterly payments and keeping records, the Secretariat monitors performance, seeks information regarding under-performance or any other significant variation in activity, prepares an annual monitoring report for consideration by the Authority and generally provides advice on the operation of the Factor f scheme (PBPA, sub. 74, p. 4).

Administration of the Factor f scheme by the Secretariat is guided by *Factor f Pricing Guidelines*, *Factor f Monitoring Procedures* and the *Factor f Procedures Manual* (PBPA, sub. 74, p. 4).

The Factor f scheme has been administered in two phases. Phase I commenced on 1 January 1988 and concluded on 30 June 1995. Phase II commenced on 1 July 1992 and will conclude on 30 June 1999.

5.5 Phase I

The Commonwealth Government allocated \$198 million to Phase I. In total, the Government spent \$157.7 million (PBPA, correspondence, 22 March 1996).

5.5.1 Performance guidelines

The Government introduced the first guidelines for Phase I of the Factor f scheme on 25 May 1988. These were amended on 19 November 1990. The guidelines outlined four ‘fundamental’ principles for companies’ eligibility to Phase I. According to these principles, if PBS prices represented an impediment to industry development, higher prices could be recommended if they contributed to internationally competitive activity in Australia and if that activity resulted in a net benefit to the Australian economy. Higher prices could not exceed the prices expected in a ‘normal competitive market’.

In addition, quantitative and qualitative performance guidelines were designed to set criteria that companies were required to meet to qualify for entry to the scheme. The intention of the qualitative performance guidelines was to ensure eligibility of companies which could not meet the quantitative requirements of the scheme but were nonetheless making a significant contribution to internationally competitive production in Australia.

5.5.2 Eligibility criteria

Under Phase I, there were four quantitative eligibility criteria which companies had to meet:

- achieve a ratio of exports to imports of one half within three full company financial years of acceptance of the Authority's offer of price increases;
- increase exports by 33 per cent in real terms within three full company financial years of acceptance of the Authority's offer of price increases;
- spend a minimum of 3 per cent of turnover on R&D; and
- increase spending on R&D by 33 per cent in real terms within three full company years of acceptance of the Authority's offer of price increases.

The R&D criterion could be waived if a company established a major, internationally competitive plant for the manufacture and export of active ingredients (PBPA sub. 74, p. 5).

To qualify under the qualitative criteria, a company had to satisfy the PBPA that it was substantially increasing its activity in Australia and the activity was internationally competitive. The stated intention was 'not to bypass the stringency or intent of the quantitative requirements, but rather to provide some flexibility in those cases where a company's development strategy was no less ambitious' (PBPA 1990, p. 175).

5.5.3 Payments system

Payments under Phase I were subject to a maximum of 25 per cent of the increased Australian value added activity. However, payments varied according to the type of activity undertaken.

Payments for value added on exports were calculated as 25 per cent of the aggregate increase in value added³ on the company's exports out of Australia. The PBPA had discretion to alter the payment rate, and actually lowered one company's entitlement.

Value added payments on domestic sales were calculated as 25 per cent of the aggregate increase in value added on either new products, or existing products where additional value adding was to occur. However, unlike value added on exports, value added on domestic sales was calculated on an individual product

³ For both exports and domestic sales, notional price increases granted under the Factor f scheme and increases in value added as a result of normal price changes were not taken into account when calculating value added.

basis. Further, any changes to value added due to changes in volume of the product sold on the domestic market were not used in the calculations.

Payments for expenditure on R&D depended on whether a company was claiming the 150 per cent tax concession for R&D. If the company was claiming the concession, then payments were calculated in the same manner as value added for exports. If the company was not claiming, then payments were calculated as 50 per cent of the increase in post-tax expenditure relative to the base year. The PBPA had discretion to vary the standard entitlement and did so on one occasion. The BIE (1991) calculated that the effective payment rate was virtually the same regardless of whether the company was claiming the 150 per cent tax concession or not.

Companies nominated PBS products to which a notional price increase would apply. The overall entitlement was converted into a notional price increase for PBS sales. It was generally expected that notional price increases would apply to products with a high local value added content but this was not a requirement. Factor f products were subject to approval.

There were ‘caps’ on the size of notional price increases for companies. First, notional prices could not exceed the world average price. Second, year on year payment increases could not exceed 10 per cent of total PBS product sales. One of the Phase I participants was affected by the 10 per cent cap and missed out on more than \$700 000 (BIE 1991, p. 59).

5.5.4 Monitoring

The 1990 Guidelines stated that performance in domestic value added, export value added and R&D would be monitored annually by the PBPA to ensure that the relationship between the price increases and the likely benefits was being maintained. Further, profitability would be monitored to ensure that it did not become ‘excessive’ compared with similar industries.

The PBPA had the capacity to investigate cases where a company’s overall average value adding on domestic sales was falling and, if necessary, to revise payments. This was to prevent companies from lowering their value adding on non Factor f linked products while increasing it on Factor f linked products.

5.5.5 Who participated?

According to the PBPA, all of the ten companies which met the eligibility criteria were admitted to Phase I of the scheme (see Box 5.1). Nine companies were admitted under quantitative guidelines. The other was admitted under the

qualitative guidelines, making significant commitments to R&D and investment. They were sent a letter of offer by the Government to confirm performance targets and funding (sub. 74, p. 7). Two companies were unsuccessful in their bids to attract funding, and two companies were approved to enter the scheme but did not accept the Government's offer (PBPA correspondence, 14 November 1995).

Box 5.1: Phase I participants

Bristol-Myers Squibb Pharmaceuticals	ICI Australia
CSL	Merck, Sharp & Dohme
Cyanamid Australia	Schering-Plough
F H Faulding	Sigma Pharmaceuticals
Glaxo Australia	SmithKline Beecham

Source: PBPA sub. 74, p. 10

5.5.6 Achievements

During Phase I, there was a significant increase in investment, production and R&D. In addition, numerous linkages were formed between companies and Australian medical research bodies. Further, some subsidiaries of multinational enterprises (MNEs) claimed that the Factor f scheme had significantly changed the views of their foreign head office about the attractiveness of Australia as an investment location. This is discussed further in Section 5.7.7.

While Phase I of the Factor f scheme is likely to have contributed to a higher level of pharmaceutical activity, it is important to note that there have been other significant economic reforms over this period that have increased the efficiency and competitiveness of the Australian operating environment. These include:

- labour market reforms to increase productivity and contain wages growth;
- a lowering of inflation, inflation expectations, and real wages;
- depreciation of the Australian currency; and
- the start of microeconomic reform in infrastructure such as telecommunication, banking, ports, shipping and aviation.

There are also other features of the Australian operating environment that are advantageous to pharmaceutical investment (see Chapter 7). These enhance Australia's attractiveness as a location to service regional and/or global markets. Hence, higher investment and production over Phase I could be attributed, at least in part, to companies' strategic decisions to operate in Australia in an environment of rationalisation and globalisation.

Indeed, the strong growth rates of some companies that did not participate in the scheme (see Appendix J) is evidence that there are factors beyond the Factor f scheme influencing companies' decisions to locate and invest in Australia.

It is difficult to separate out activity attributed solely to Phase I from activity attributed to other reforms in the economy and other features of the Australian operating environment conducive to pharmaceutical investment.

These qualifications should be noted when considering the overall level of activity committed and achieved during Phase I as shown in Table 5.1.

Table 5.1: Phase I activity increases—actual compared to forecast

<i>Category of activity</i>	<i>Actual</i>	<i>Forecast</i>	<i>Ratio of actual to forecast</i>
	<i>\$m</i>	<i>\$m</i>	<i>%</i>
Export value added	387.3	494.3	78
Domestic value added	314.4	442.6	71
Research and development	160.7	146.9	109
Total	862.4	1 083.8	80

Source: BIE 1995, p. 36

Six of the ten companies participating in Phase I met all of the eligibility. Three companies admitted under quantitative guidelines were unable to meet at least one of the following:

- export/import ratio;
- expenditure of 3 per cent of turnover on R&D; and
- increase exports by 33 per cent.

These companies had their payments suspended during the scheme. One company formally withdrew.

The PBPA listed the reasons for under-performance as technical difficulties, difficulties in gaining registration, marketing approval delays, and difficulties in commencing and completing research projects (PBPA, sub. 74, p. 15).

The Australian Pharmaceutical Manufacturers Association (APMA) listed highlights of Phase I achievements (sub. 31, p. 31). These are provided in Box 5.2.

Box 5.2: Phase I achievements

The APMA listed the following highlights of Phase I activity:

- commitment by Merck, Sharp & Dohme in 1992 to invest \$75 million on a dedicated plant for a major new product and to expand and upgrade existing facilities;
- announcement of a strategic alliance between Glaxo and Faulding in 1990 to develop a sustained release morphine analgesic for the management of severe pain. The product is to be manufactured by Faulding using raw material supplied by Glaxo and marketed world wide by both companies;
- Glaxo was awarded the 1991 Australian Business Magazine Value Added Export Award for outstanding success achieved by value adding to Australian commodity based products. The company also announced in 1991 the exploratory development of an anti-influenza compound developed by Biota Holdings and CSIRO;
- Merck, Sharp & Dohme reached \$100 million in exports in the 12 months to February 1993 and announced an agreement to supply a major product to France;
- in 1988 Glaxo announced the commitment of \$55 million for the construction of new solid dose and blow-fill-seal manufacturing plants at its Boronia site, and in 1992 the company opened a new \$10 million product development centre designed to produce new formulations and new presentations for use by Glaxo world wide;
- CSL announced that it would invest \$13 million in world class manufacturing facilities and \$14 million in research into vaccines and biosynthetic hormones;
- Bristol-Myers Squibb committed to a \$9 million plant expansion and upgrade and to a \$27.5 million research program; and
- SmithKline Beecham expanded its existing antibiotic manufacturing plant as well as its warehouse and laboratory premises.

Source: APMA sub. 31, p. 31

A detailed example of increased performance by one company under Phase I is provided in Box 5.3.

Box 5.3: Increased performance by one company under Phase I—a case study of SmithKline Beecham

Factor f Phase I was an initiative of Beecham Research Laboratories negotiated prior to the merger with SmithKline & French in 1991.

Key features of SmithKline Beecham's performance in Phase I^a were:

- capital investment at the Dandenong site of \$26 million;
- doubling of exports from \$8 million in 1987–88 to \$19 million in 1992;
- achieving an export to import ratio of 0.60 in 1992 compared to 0.47 in 1987–88 (base year);
- increasing eligible R&D expenditure from zero in the base year to \$1.7 million in 1992; and
- adding a further 60 skilled jobs at the Dandenong plant.

For SmithKline Beecham, benefits of participation in Factor f Phase I were to:

- provide a catalyst for the development of export opportunities;
- provide a clear message to head office that the Australian Government was prepared to support the industry, offering a hierarchy of investment opportunities in Australia and the region
- ensure that every sourcing decision during the Factor f scheme was taking Australia into account as a beneficial location for manufacturing;
- allow SmithKline Beecham to get involved to a significant degree in discovery research activities in Australia and make use of the considerable scientific expertise here; and
- raise the status and profile of the Australian operations within the world pharmaceutical industry, who came to see Australia as competitive with other countries.

^a To 30 June 1993, only Beecham Research Laboratories' products, R&D and production were used to calculate Factor f performance.

Source: SmithKline Beecham sub. 13, pp. 6, 26

5.5.7 What did it cost?

In total, the Government spent \$157.5 million on Phase I (PBPA correspondence, 22 March 1996). Annual payments increased from \$1.3 million in 1988–89 to \$43.8 million in 1992–93, and then declined in the remaining two years of the scheme. This payment pattern, outlined in Table 5.2, reflects the time taken to install new capacity to meet activity targets. Payments increased until 1992–93 as companies installed additional capacity to meet their production commitments and then declined as some companies completed their Factor f agreements.

Table 5.2: Factor f payments for Phase I, \$

<i>Financial year</i>	<i>Payment</i>
1988–89	1 326 418
1989–90	12 900 303
1990–91	16 675 556
1991–92	26 285 625
1992–93	43 786 457
1993–94	36 240 630
1994–95	20 235 979
1995–96	271 884
Total	157 722 852

Sources: PBPA sub. 74, Attachment B; PBPA correspondence 22 March 1996.

Details of payments to individual companies are not publicly available.

5.6 Evaluation of Phase I

There have been two main Government initiated evaluations of Phase I: an economic evaluation by the BIE (1991) and an audit by the Australian National Audit Office (ANAO 1993). In addition, there have been two independent assessments examining the impact of the scheme.

5.6.1 BIE 1991 review

At the time the Factor f scheme was announced, the Government also announced its intention to have a five year review by the BIE to evaluate the

scheme's 'effectiveness as a means of achieving the Government's objectives' (Button & Blewett 1987, p. 5). The BIE completed this review in 1991.

While the BIE Report described the industry, rationale for the Factor f scheme, its operation and other non-price regulations, it largely focused on the scheme's efficiency and effectiveness in meeting its objectives.

The BIE viewed the objective of the scheme as increasing activity to the level that would have prevailed in the absence of PBS price suppression. It calculated the effective payment rate (equal to the 'real' rate of subsidy of additional activity) for each eligible activity as the Factor f payment divided by the additional activity.

As shown in Table 5.3, the effective payment rates calculated by the BIE were consistently lower than 25 per cent (BIE 1991, p. 71). The lower effective payment rates for exports and R&D reflected the PBPA's discretion to decrease the payment rate below 25 per cent. The much lower effective payment rate for domestic sales reflected the way in which this is calculated. In particular, in contrast to calculations of export value added which took account of the total value of increased sales, calculations of domestic value added did not take account of any increased volumes of products already produced in Australia in the base year. This resulted in a much lower effective payment rate.

Table 5.3: Effective Factor f (Phase I) payment rates, by activity

<i>Activity</i>	<i>Proposed additional activity \$m</i>	<i>Proposed Factor f payment \$m</i>	<i>Effective payment rate^a %</i>
Value added on exports	533.4	128.4	24.1
Expenditure on R&D	117.3	24.4	20.8
Value added on domestic sales	211.0	17.7	8.4
Total	861.7	170.5	19.8

a The effective payment rate is calculated as the Factor f payment divided by the additional activity.

Source: BIE 1991, p. 71

With regard to effectiveness, the BIE concluded that, overall, around 85 per cent of increased activity had probably been induced by the Factor f scheme. While the scheme had induced around 90 per cent of the additional export and domestic sales value added, it had only induced around 50 per cent of the additional R&D. In addition, the BIE concluded that it was likely that the scheme had under-compensated some companies because of the 10 per cent

price cap rule and the tight quantitative eligibility criteria but over-compensated exports and actives production.

In relation to efficiency, the BIE calculated that for Factor f to be welfare enhancing for the Australian community as a whole each Factor f dollar spent would have to bring between \$0.85 and \$1.50 in benefits (taking into account the distortionary effects of raising taxes as well as the clawback of Factor f money in tax). Overall, the BIE could not determine if the scheme had been welfare enhancing. It concluded that the larger the increase in net investment and the greater the spillover benefits, the more likely it was that the scheme had generated more benefits than costs.

As a result of its review, the BIE made a number of recommendations to modify the scheme, summarised in Box 5.4.

Box 5.4: Recommendations of the BIE 1991 review

The BIE's recommendations included:

- consideration be given to reducing the effective rate of compensation;
- Factor f price increases should be actual, not nominal (except where this would significantly disadvantage a company competing against products with a suppressed price);
- the upper limit of price increases should be the European Community average;
- the 10 per cent cap on annual price increases should be removed;
- Factor f payments for all value added on domestic sales activity be calculated in the same way as for value added on exports;
- hospital sales be deemed eligible; and
- qualitative proposals be more sympathetically considered, where this would lead to internationally competitive activity, and that this change be actively communicated to companies.

Source: BIE 1991, p. xix

5.6.2 ANAO 1993 Audit

The ANAO audit on administration of Phase I was tabled in May 1993. While the ANAO considered that, overall, the scheme had been satisfactorily administered, it suggested several changes. These recommendations are summarised in Box 5.5. ANAO noted that only 45 per cent of the promised

increased activity had actually taken place by 30 June 1992 and that some companies were not meeting their performance targets.

During the course of the audit, Department of Industry, Technology, and Commerce (DITAC) (now DIST) developed a new financial management system for Phase II of the scheme. This made redundant many of the ANAO recommendations relating to previous administration procedures. However, other recommendations were incorporated specifically into the new financial management system for Phase II (PBPA sub. 74, p. 9).

Box 5.5: Recommendations of the ANAO 1993 audit

The ANAO recommendations included:

- the preparation of an information package for potential applicants;
- periodic review of procedures for assessment and approval of applications to avoid delays;
- a standard contract between the Department and companies;
- legal advice be sought over non-compliance and payments;
- integrated policy guidelines and procedures to ensure that the approval of progress payments takes into account the pro-rata level of performance targets (rather than on a case by case basis);
- guidelines for withholding payments where performance guidelines are unlikely to be met;
- advice to participants on the new policy and procedures as soon as they are determined;
- policy guidelines on time extensions (and that companies be notified of these guidelines, to be included in the information package—which the Department did not agree to);
- audit certificates should be obtained for all base year and annual monitoring reports, and payments should be withheld until they have been supplied;
- the format of quarterly activity reports should be amended to include information on sales and turnover imports;
- a standard form for annual monitoring returns; and
- the Department should amend its computerised management information system to provide additional aggregate and other information to monitor company performance more regularly.

Source: ANAO 1993, pp. ix–xiii

5.6.3 Recent independent assessments

In 1993, the National Institute of Economic and Industry Research undertook a review of the Factor f scheme on behalf of the APMA (Brain 1993). It estimated the economy-wide impacts of the Factor f scheme using the IMP model to estimate the multiplier effect. According to the results, each \$1 million of Factor f payments would increase gross domestic product by \$10 million and total employment by 150.

Any interpretation of Brain's results should bear in mind that the estimated multiplier effect does not account for resource constraints. Hence, it may over-estimate the effects of the scheme on the economy. In particular, the model assumes that growth in one sector does not constrain growth in another, even though both sectors may be competing for the same resources. For example, if the pharmaceutical industry employs more of scarce Australian skilled labour, it may adversely affect other industries. This may be the case even in times of high unemployment, because not all unemployed workers will possess skills required in these industries. To the extent that resources are brought in from overseas and are net additions to the resources in Australia, Brain's estimated multiplier effect becomes more plausible.

In 1994, the Centre for Strategic Economic Studies at Victoria University published a review of the performance of Australia's Elaborately Transformed Manufacturing (ETM) industries. It observed that, while exports of ETMs had risen generally, industries assisted by specific Government policies had risen more significantly.

While the effects are difficult to quantify, there is clear evidence that many of the industry specific policies designed to boost the export orientation of various sectors have played an important part in the improved ETM trading performance.

... The relatively strong export performance of those groups for which specific export facilitation policies have been in place must be taken as *prima facie* evidence of success of those policies (Sheehan, Pappas & Cheng 1994, pp. 23–24).

5.7 Phase II

On 22 March 1992, in response to the BIE Review, the Government announced an expansion of the Factor f scheme into Phase II running from 1992 to 1999. It allocated a further \$820 million in Factor f payments over the life of the

scheme. A limit was imposed on total annual expenditure, equal to 10 per cent of domestic sales, ex-manufacturer, of PBS products in any one year.

The Government accepted the BIE recommendations on an EC average price cap, the removal of the 10 per cent cap on individual company annual price increases, domestic value adding, the inclusion of hospital products and qualitative guidelines.

In response to the BIE recommendation to create a body to discuss policy issues affecting the industry, the Government established the Industry/Government Consultative Forum under the PIDP with DIST to provide the Secretariat. This Forum is discussed in more detail in Chapter 15.

The Government did not accept the BIE's recommendations on actual price increases or reduction in the rate of assistance.⁴

5.7.1 Performance guidelines

Under Phase II, the four general principles used in Phase I to guide decisions on granting higher prices still applied. However, the price cap of the 'normal competitive market' was changed to 'the average prices of pharmaceutical products in the European Community'.

In addition, to participate in Phase II, companies were required to submit detailed information to the PBPA, including:

- plans for new and expanded R&D and production;
- how these proposals are integrated with the long term strategic direction of the whole company; and
- forecast data for activity over the period of the proposal and audited data for activity in the base year.

Like Phase I, there were performance guidelines for Phase II that set out quantitative and/or qualitative criteria that companies were required to meet to become eligible for the scheme. Companies meeting these criteria were also required to demonstrate that the proposed activity was internationally competitive and would provide significant net benefits to Australia.

⁴ In Phase II, the PBPA was not required to pay the maximum 25 per cent payment rate. This provision also existed in Phase I.

5.7.2 Eligibility criteria

Under Phase II, eligibility criteria differed according to whether participants were ‘new’ or ‘continuing’ from Phase I.

New participants

The quantitative criteria for new participants to the scheme required companies to:

- increase value added on Australian pharmaceutical production by 50 per cent over a three year period; and
- achieve a level of R&D spending equal to 3 per cent of turnover and maintain R&D spending at 3 per cent of turnover for the remainder of the scheme.

Companies had to undertake to meet one of these criteria within three years of entry into the scheme and the other within five years.

The intention of the qualitative guidelines in Phase II was the same as Phase I⁵ but the actual criteria were more explicit. With the same global caveats regarding international competitiveness and significant net benefits, the PBPA could also look at:

- new active ingredient production;
- new investment in production plant, facilities or equipment;
- expenditure on new R&D projects;
- new production for export and domestic sale;
- commitment to best manufacturing practice through measures such as benchmarking, quality programs and workplace reform;
- establishment of Australia as a centre for operations in the Asia-Pacific region; and
- other internationally competitive activity (PBPA 1992, p. 8).

After meeting the requirements for entry, the companies negotiated performance targets with the PBPA. These targets were set at the time of approval.

⁵ That is ‘not to bypass the stringency or intent of the quantitative requirements, but rather to provide some flexibility in those cases where a company’s development strategy was no less ambitious’ (PBPA 1990, p. 175).

Continuing participants

Continuing participants from Phase I, provided they met all performance requirements under Phase I, did not have to meet the quantitative criteria under Phase II. However, they did have to demonstrate their continuing commitment to expanding internationally competitive activity by meeting negotiated performance targets or milestones. Continuing participants were also able to keep their existing base year.⁶

If a continuing participant had not met all of its performance requirements under Phase I, its eligibility criteria and base year for Phase II were negotiated with the PBPA, subject to Ministerial approval. These negotiations took account of proposed activity under the extended scheme and actual performance under past guidelines (PBPA 1992, p. 10).

All continuing participants were judged on whether the:

- company is substantially increasing its level of production and R&D activity in Australia;
- company's proposed performance targets reflect the increased activity proposed by the company;
- proposed activity is internationally competitive; and
- proposed activity will produce significant net benefits for Australia (PBPA 1992, p. 10).

If the PBPA considered the proposal acceptable, a payment rate would be discussed with the company before being recommended for Ministerial approval. If the PBPA considered the proposal insufficient, additional activity or higher performance targets were discussed with the company.

5.7.3 Payments system

As for Phase I, payments under Phase II are subject to a maximum of 25 per cent of eligible domestic and export value added activity.

The PBPA has the discretion to lower the payment rate. In the case of domestic value added, it has lowered the payment rate for six of the seven new participants to 20 per cent. The other new participant and all continuing participants receive the full 25 per cent payment rate for domestic value added

⁶ Generally, the base year for continuing participants was the year before they were admitted to Phase I.

(BIE 1995). For export value added, all participating companies receive the maximum 25 per cent.

For R&D, companies are entitled to the lesser of 50 per cent of the increase in after tax expenditure or 25 per cent of the increase in total expenditure. As in Phase I, the payment rate is therefore dependent on whether the company is eligible for the 150 per cent R&D tax concession.

There were two main differences between the rules limiting price increases under Phase I and Phase II.

First, the price increases are capped by the average price of the product in the EC in Phase II rather than world prices as in Phase I. European prices are established by either an Intercontinental Medical Statistics' certificate, proof supplied by an overseas head office or reference to similar product prices where the exact product is not sold in the EC.

Second, the price cap, which restricted notional price increases to a maximum of 10 per cent in any year, was removed in Phase II.

The BIE (1995) has calculated the effective payment rates as the ratio between forecast Factor f entitlements and forecast additional eligible activity for domestic value added, export value added and R&D. Its results are presented in Table 5.4.

Table 5.4: Effective Factor f payment rates—Phase II

<i>Activity</i>	<i>Forecast additional activity \$m</i>	<i>Forecast entitlements \$m</i>	<i>Effective payment rate %</i>
Value added on exports ^a	1 479	368	24.9
Value added on domestic sales	1 589	367	23.1
Research & development	377	77	20.4
Total	3 445	812	23.6

a The payment rate on export value added differs slightly from 25 per cent because the final year payment for one participant has been capped.

Source: BIE 1995, p. 33

5.7.4 Monitoring

Under Phase II, all participants were required to sign a contract with the Government detailing targets and entitlements. Performance is monitored by the PBPA.

Companies must submit quarterly performance reports and an audited annual performance report consolidating their quarterly reports. The annual performance report must contain information on progress towards meeting the eligibility criteria, any investment commenced or completed during the year, profitability and commentary on the year's activity, including explanation for any under-performance.

In addition, the companies are subject to review after three years in the scheme. At this time, they must submit revised forecasts of activity for the remaining years of the scheme. This gives the PBPA and companies an opportunity to review performance and negotiate revised performance levels and price increases for the remainder of the proposal. According to the Guidelines, the three year review should not have precluded companies from lodging new or supplementary proposals. However, supplementary proposals were precluded due to funding constraints.

Companies may become subject to review at any time if performance is significantly below forecast levels.

There is provision in the scheme for companies to make up for under-performance in the early years by over-performance in later years. Similarly, there is provision for companies to use early over-performance to offset later under-performance. This 'catch up' provision recognises that there are external factors affecting a company's performance in any given year.

The rules for catch up depend on activity type. In general, over-performance in production for domestic sales can only be used to offset later under-performance in production for domestic sales. However, over-performance in production for export and expenditure on R&D can be used to offset any performance shortfall in each other. There are, however, two companies which can use any over-performance to offset any under-performance (sub. 74, p. 8).

5.7.5 Who participated?

Under Phase II, eleven companies were admitted into the scheme. These companies are listed in Box 5.6.

Box 5.6: Phase II participants

3M Pharmaceuticals (Australia)	Glaxo Australia
AMRAD	Merck, Sharp & Dohme (Australia)
Astra Pharmaceuticals	Pfizer

CSL
F H Faulding

Fisons

Source: PBPA sub. 74, p. 10

Upjohn
Wellcome Australia

Ten companies were admitted under the quantitative criteria, while the other company was admitted under the qualitative criteria. Four companies (CSL, Faulding, Glaxo and Merck, Sharp & Dohme) were continuing participants from Phase I.

On the basis of proposals, seven other companies were considered by the PBPA to be eligible for inclusion to Phase II of the scheme but were not accepted because all available funds had been committed (PBPA 1994, p. 15). There were two supplementary submissions from participating Phase II companies but these were rejected for the same reason. Three of the rejected applicants have lodged appeals in the Federal Court against their exclusion. These appeals are still pending (APMA sub. 31, p. 32).

The PBPA has maintained that all details of the selection process for Phase II are to be kept strictly in confidence.

5.7.6 Who did not participate?

The Factor f scheme has been used by a relatively small number of pharmaceutical companies operating in Australia. Of the 120 or so companies selling products on the PBS, only 17 have participated in the Factor f scheme over both Phases I and II and only 11 are currently participating.

While the Factor f companies comprise about 70 per cent of total PBS sales, there are some sizeable companies that have not participated in the scheme. In fact, among the largest 20 suppliers in Australia, there are 12 non-participants (PBPA 1995, p. 19). Notable examples include Eli Lilly, which is one of the largest companies in the global industry, and Roche which has a manufacturing presence in Australia.

Some of the companies that have not participated in the Factor f scheme did not apply for entry. However, there are some companies that did apply but were rejected either on the basis of their proposals or due to a lack of available funds. In addition, there are other companies which may have qualified under Phase II but did not apply when it became clear that all funds had been committed.

There is some evidence that the rejection of applications to the Factor f scheme has caused projects to go overseas which were otherwise destined for Australia (APMA 1994a). As an example, SmithKline Beecham indicated it lost a business opportunity to supply a non penicillin product to Japan due to the shortfall of funds under Phase II (sub. 115, p. 4). The experience of one company that qualified under Phase I but did not qualify under Phase II is provided in Box 5.7.

Box 5.7: The experience of one company that did not qualify for Phase II—a case study of SmithKline Beecham

In its first submission to the Inquiry, SmithKline Beecham stated that the non-entry into Phase II was a significant factor in the failure to secure increased export activity in the form of a number of sourcing proposals which would have benefited the Australian economy. The most significant of these being supply of Tagamet for Japan. The proposal alone would have delivered increased export sales of \$137 million over five years, representing \$33 million in value added processing. As a result to secure this supply from Australia, the decision was taken to remain with joint manufacture in Japan.

In December 1995, however, SmithKline Beecham announced a decision to use its Dandenong manufacturing plant to supply all South East Asian markets, Japan, Australia and New Zealand with oral penicillin. In a subsequent submission to the Inquiry, SmithKline Beecham stated that due to the problems experienced under Phase II of the scheme, for SmithKline Beecham Australia to survive it had to convince the Corporation that Australia was a sound investment location. With assistance from DIST this was achieved.

After that, the choice between Dandenong and Singapore of the manufacturing site for the region was based on productivity, capacity and long term Government policy.

The decision was in favour of Dandenong because the initial Phase I investment gave the support needed to put in place a larger and more productive supply centre than might have been the case.

Sources: SmithKline Beecham sub. 13, p. 7; sub. 115, p. 4.

At the same time, there are some companies that have not been admitted to the Factor f scheme under Phase I or Phase II but nonetheless may have increased activity based on leverage and signals generated by the scheme. In its submission, Eli Lilly stated that its:

... local activities have grown in recent years and are expected to continue because of Factor f, despite rejection of its application. This activity would not have occurred at all but for Factor f, and is well below what could have been achieved if [its] application had been successful (sub. 142, p. 3).

5.7.7 Achievements

During Phase II, companies have committed themselves to significant increases in domestic value added, export value added and expenditure on R&D. These comprise an increase in exports of around \$2.7 billion with an increase in export value added of approximately \$1.5 billion, an increase in domestic value added activity of \$1.6 billion, an increase in R&D of \$377 million, and an increase in investment expenditure on new facilities of \$427 million.

As for Phase I, it is important to bear in mind that, beyond the Factor f scheme, there have been significant economic reforms over the period of Phase II that are likely to have contributed to a higher level of investment and output by pharmaceutical companies (see Section 5.5.6). Again, there are also features of the Australian operating environment that are advantageous to pharmaceutical investment and likely to have attracted activity in the current environment of rationalisation and globalisation (see Chapter 7).

Given these qualifications, Phase II activity to 30 June 1994 is provided in Table 5.5.

Table 5.5: Phase II activity increases—actual compared to forecast

<i>Category of activity</i>	<i>Actual (to 30 June 1994) \$m</i>	<i>Forecast (to 30 June 1994) \$m</i>	<i>Ratio of actual to forecast %</i>
Export value added	194.7	163.5	119
Domestic value added	532.1	517.4	103
Research and development	83.2	73.0	114
Total	810.0	753.9	107

Source: BIE 1995, p. 37.

In total, companies have exceeded their targets, although the data for individual companies are mixed. Some companies are under-performing against targets, while others are over-performing. Given the flexibility provided in the catch up provisions, these results do not necessarily reflect performance over the life of the scheme.

The achievements of a new entrant to the Factor f scheme under Phase II are shown in Box 5.8. The achievements of a continuing participant over Phase I and II are provided in Box 5.9.

Box 5.8: Achievements of a new entrant under Phase II— a case study of Astra

Astra qualified for and participated in Phase II of the Factor f scheme. Involvement in the scheme has resulted in a number of investments in Australia and increased activity which Astra believes to be welfare enhancing.

In particular:

- exports have increased from \$8 million in 1990 to \$65 million in 1995; and value added on domestic sales has increased from 46 per cent in 1992 to 54 per cent in 1995;
- new technology investment has been developed such as form fill seal plastic technology, tablet production for sustained release dosage forms, and in production of polypropylene cartridges;
- preclinical research has increased from a base of \$1.5 million in 1993 to \$4.4 million in 1995, and clinical research has increased from a base of \$0.3 million in 1992 to \$0.9 million in 1995; and
- to date, total expenditure on Factor f related equipment is \$14.6 million and on production equipment is \$88 million.

According to Astra:

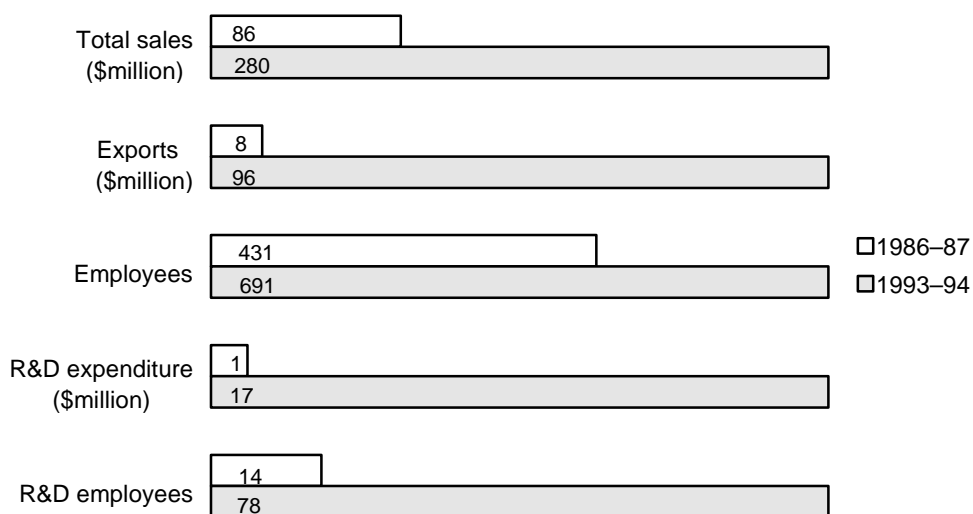
- increased value added on exports and domestic products has increased employment in their production department from 196 people in 1992 to 286 people in 1995, and in their medical department from 25 people in 1992 to 32 people in 1995. Virtually all of the new positions are directly attributable to production of Factor f products. The increase in employment in the medical department excludes spin off increases in employment from research activities;
- increased expenditure on R&D has significantly increased preclinical and clinical research in this country. For example, the Queensland Pharmaceutical Research Institute pre-clinical research centre in association with Griffith University uses leading edge technology and has formed a strong bond between academia and industry. Further, this has resulted in technology transfers to local researchers and is helping to direct worldwide attention to Australia as a potential research location; and
- increased capital expenditure has benefited external service providers financially and probably enhanced their ability to compete internationally.

Source: Astra sub. 141, pp. 7–9.

Box 5.9: Achievements of a continuing participant over Phases I and II—a case study of Glaxo Wellcome

Glaxo Wellcome stated that any evaluation of the impact of the Factor f scheme on Glaxo Wellcome's contribution to the Australian community should take into account the considerably narrower and limited activities prior to inception of the scheme.

This is demonstrated by comparing some key facts and figures relating to its operations pre and post Phase I of the Factor f scheme, particularly in the more discretionary investment area of manufacturing, R&D and exports.



Source: Glaxo Wellcome sub. 144, p. 2

Like Phase I of the Factor f scheme, Phase II appears to have positively influenced the views of foreign head offices of Australian MNE subsidiaries about the attractiveness of Australia as an investment location for new entrants and continuing participants. The benefits of this as claimed by the local operation of a continuing participant are outlined in Box 5.10. In addition, the existence of a scheme may have also positively influenced the investment decisions of some non-participating companies.

Under Phase II, companies have been active in developing collaborative arrangements with research organisations and other companies. AMRAD noted that:

One of the more successful outcomes of Factor f has been the establishment of important linkages between Merck, Sharp & Dohme-AMRAD, Merck Sharp & Dohme-CSL, Glaxo-Faulding, Glaxo-Biota and Pfizer-IDT, which all have significant R&D components and have added substantially to the growth in local value added activities of international significance (sub. 117, p. 7).

Box 5.11: CSL alliances under Factor f

The quality and long term significance to Australia of alliances between CSL and other companies under the Factor f scheme are demonstrated in four case studies:

The Human Papilloma Virus Project

CSL has announced major collaboration with Merck & Co. (US) and Uni Quest to develop a vaccine to prevent and treat HPV infection. CSL provided significant funding to originators of the work at the University of Queensland and both have established pre-eminent intellectual property positions. This formed the basis of a partnership with Merck & Co. (US) that will take two products to international markets.

The Helicobacter pylori Project

CSL is developing a vaccine to eradicate infection implicated in development of peptic ulcers and gastric cancer with advantages over current therapies making it a most cost effective solution. Validation at the University of New South Wales is developing a strong package of intellectual property which CSL is enhancing through additional collaborative work with Universities of Queensland and New South Wales.

The Combination Paediatric Vaccine Project

CSL is developing an extended combination paediatric vaccine. It has negotiated a strategic alliance with Merck, Sharp & Dohme and Merck & Co. (US) to develop a vaccine protecting against five childhood diseases. CSL will do R&D on the new vaccine combinations, manufacture DTP components, formulate final products and dispense and pack the new combination vaccines for distribution in Australia. Merck will manufacture and supply other vaccine components. Merck, Sharp & Dohme will export. Clinical trials are to be conducted at the Royal Children's Hospital in Melbourne.

The Adjuvanted Influenza Virus Vaccine Project

CSL and other leading manufacturers of influenza vaccines have sought to develop a product with enhanced protective immune responses and safety levels of current vaccines. CSL has formed a major research effort supplemented by collaborations at University of Melbourne and the CRC for Vaccine Technology. CSL established close working relations with Isotec AB and subsequently acquired a controlling interest in this innovative Swedish company. Technology emerging from this relationship has enhanced other CSL projects and CSL's attractiveness as a development partner.

Source: CSL sub. 39, pp. 9–11

5.7.8 What will it cost?

The estimated budgetary costs of Phase II on a year by year basis are shown in Table 5.6. Payments are expected to steadily increase until 1997–98, when two participants complete their Factor f commitments.

Table 5.6: Factor f payments for Phase II, \$

<i>Financial year</i>	<i>Payment</i>
1992–93	8 243 319
1993–94	46 082 930
1994–95	74 775 852
1995–96 ^a	135 131 102
1996–97 ^a	180 018 363
1997–98 ^a	198 637 405
1998–99 ^a	137 919 309
1999–00 ^a	28 485 263
Total^{ab}	809 293 543

a These figures are subject to revision and should be regarded as indicative only.

b This figure is based on the PBPA Factor f Secretariat's most recent forecast of activity to be undertaken under the Factor f scheme. This figure does not take account of payments worth \$3.82 million as a consequence of underperformance in earlier years.

Source: PBPA, correspondence, 22 March 1996 and 26 March 1996.

5.8 Factor f costs and achievements in total

Total Factor f budgeted payments and commitments over Phase I and II of the scheme are provided in Table 5.7.

To achieve their Factor f targets, participants carried out \$224 million in additional investment under Phase I, and are likely to carry out \$380 million (revised downward from \$427 million) under Phase II. Around 1000 new jobs have been directly created.

Over the period 1988 to 1995, the Government has paid Factor f entitlements of \$287 million.

Table 5.7: Factor f budgeted payments and commitments, \$ million

<i>Payment and commitments</i>	<i>Export value added</i>	<i>Domestic value added</i>	<i>R&D</i>	<i>Total</i>
Payments				
Phase I	128	24	18	170 ^a
Phase II ^b	368	367	77	812
Total	496	391	95	982
Commitments				
To 30 June 1994 (Phases I and II)	582	847	244	1 673
Total Phases I and II	1 900	1 900	538	4 338

a Actual payments were \$158 million.

b Assuming the companies meet all their activity targets.

Sources: BIE 1995, pp. 33, 36–37; PBPA sub. 74, Attachment B; and PBPA correspondence 22 March 1996 and 26 March 1996

5.9 Factor f payments in context

The Factor f scheme is the single largest item of specific sector outlays to manufacturing industry, costing the Government \$136.7 million in 1995–96. This represents 87 per cent of Government industry specific outlays. However, it should be noted that Government specific outlays exclude Government assistance through tariffs and export facilitation arrangements.

A comparison of the Government's budgetary outlays to the pharmaceutical industry with manufacturing generally is provided in Table 5.8. This shows that Factor f is growing in importance relative to the general trend of reduced outlays to industry. However, the rationale for the Factor f Scheme, to compensate for the effects on activity of low PBS prices, is different to the rationale for intervention in all other cases.

Pharmaceutical companies are not precluded from participating in other general Commonwealth or State industry development schemes and R&D support measures. Details of these schemes and the extent of pharmaceutical company involvement are discussed further in Appendix F.

Table 5.8: Commonwealth budgetary outlays to the pharmaceutical industry and manufacturing generally, 1989–90 to 1995–96, \$ million

	<i>1989–90</i>	<i>1990–91</i>	<i>1991–92</i>	<i>1992–93</i>	<i>1993–94</i>	<i>1994–95</i>	<i>1995–96</i>
Pharmaceutical industry assistance (Factor f scheme)	12.9	16.7	26.3	51.9	80.0	94.5	136.7
Other industry-specific programs, sub total ^a	49.4	48.5	72.8	167.0	142.1	126.9	157.2
Total manufacturing	698.2	643.7	722.2	773.6	788.2	819.7	863.6

a Including Factor f scheme.

Source: IC 1995a pp. 140–142

5.10 Major issues

This Chapter has outlined the mechanics, costs and results of the Factor f scheme. The more fundamental questions are addressed in Chapter 10, including:

- how effective Factor f has been in achieving its objectives;
- how efficiently it has met its objectives; and
- how well the Scheme was administered.

The rationale and recommendations relating to future Government intervention in relation to the PBS are contained in Chapters 11 and 12 respectively.

6 GLOBAL PRESSURES

Over the period from the 1950s to the mid 1980s the operating environment of the pharmaceutical industry was relatively stable. Over the last few years however, pressures on the industry have led to rapid and widespread change. This change will have far reaching consequences for the global industry, its structure and operations. The Australian industry, as a subset of the international industry, will be affected by these international forces. This Chapter reviews the industry changes and their future impact, both internationally and on the Australian industry.

6.1 Introduction

Although the Australian pharmaceutical sector is only a small part of the global industry, it is fully integrated with it. A large number of the major pharmaceutical multinational enterprises (MNEs) have a presence in Australia and many are expanding their exports from Australia, particularly to the Asia Pacific region.

The significant presence of MNEs in Australia means that the local industry is likely to be affected by developments in the international operating environment and by changes in the structure of the global industry. Periods of rapid global change will pose significant threats and opportunities for Australia. The local industry can capture opportunities by exploiting its inherent strengths and adjusting to overcome its weaknesses. The alternative is marginalisation in the event of a failure to respond to global developments.

This Chapter attempts to identify major global developments likely to influence the future of the Australian pharmaceutical industry. The major trends can be categorised as those influencing demand for pharmaceutical products (see Section 6.3) and those likely to affect supply (see Section 6.4). The industry's response to these trends is examined in Section 6.5. Chapter 7 examines strengths and weaknesses of the Australian industry and Australia's operating environment and discusses the implications of global developments for the Australian industry.

6.2 Early development of the industry

Before examining recent trends in the international pharmaceutical industry, it is useful to look at the industry's past development.

The period from the 1950s to the mid 1980s is generally considered to be one of steady growth and prosperity for the global pharmaceutical industry. During this period, the structure of the international market for pharmaceuticals was relatively stable. According to Ballance, Pogany and Forstner (1992, p. 183) there were few new entrants into the ranks of major producers and no company could claim more than 4 per cent of the world drug market. Companies changed in size according to the relative success of their research and development (R&D) and marketing programs, but there was relatively little takeover or merger activity.

The corporate structure of pharmaceutical companies was also relatively stable. While the distribution of production activities between the centre (head office) and the periphery (regional offices or local subsidiaries) varied between companies, there was a general tendency for companies to adopt multilevel structures.

The head office generally undertook basic research and provided intragroup services. Regional or country operations developed specific strategies for local operations, albeit in the context of centrally determined plans. Table 6.1 shows how activities were typically distributed.

Regular company success in developing, marketing and capturing the returns from product innovation (through patents) contributed to consistently high commercial earnings for pharmaceutical companies. According to Ballance, Pogany and Forstner:

The pace of product development was frantic until the mid 1970s. On average, the world's pharmaceutical firms introduced 83 new chemical entities per year in 1961 to 1974. Later the annual number of new drug discoveries declined, but by the late 1980s it had stabilised at about 50 per year (Ballance, Pogany & Forstner 1992, pp. 85-6).

This suggests that efforts to improve company profitability were channelled mainly into discovering and marketing new products. Company structures were probably well suited to this pattern of activity.

The traditional structure of the international pharmaceutical industry was also influenced by the unique requirements and circumstances of distinct geographical markets.

Table 6.1: Typical corporate structures of the pharmaceutical industry from the 1950s to the mid 1980s

<i>Centralised</i>	<i>Decentralised</i>
Basic research and product development was located in central laboratories, research strategies were also centrally directed.	Linkages to specialised basic research agencies, although these were rare.
Clinical trials and collation of information generally required to show the safety, efficacy and quality of new chemical entities	Regulatory approval , responding to the requirements of regulatory agencies.
Primary manufacturing of active ingredients , centralised in plants as operations require the processing or synthesis of large volumes of material creating large quantities of waste.	Secondary formulation of prepared pharmaceuticals. Involves importing active ingredients and formulating and packaging products for market.
Preparation of product information , specifications, technical data required for approval and for preparation of materials for doctors and catalogues.	Detailing , direct communication with doctors, product support as well as developing advertising strategies if permitted.
Intragroup services , such as finance, administration, troubleshooting, medical and technical services.	Public and legal relations were decentralised to the extent that countries' legal environments differ.

Source: Collins 1993, pp. 53–57

Historically, individual regulatory regimes, the need to tailor marketing arrangements to the requirements of particular markets and barriers to trade made a strong production presence in each country important. In a survey of seven of the largest companies in the industry, Kenne, Linden and Schackman found that:

In the sixties and seventies, the surveyed companies found it all but impossible to do business in a major country market unless they had their own plant, headed by an autonomous manager who was sensitive to local issues. What made a local presence necessary was protectionism and local political pressures in the form of import licensing, import duties, registration and pricing (Kenne, Linden & Schackman 1990, p. 31).

Considerable resources were committed by the industry to complying with regulatory arrangements in each market. In addition, local in-house expertise was needed to steer drugs through the approvals and pricing processes, to conduct clinical trials and to maintain standards of production.

Local production facilities were feasible because of the typical two stage production process—active extraction and synthesis, and formulation. Active production could be located in the MNE's home market or close to essential raw

material inputs in order to capture economies of scale, whilst formulation in local markets allowed value to be added behind trade barriers.

Recent developments

The mid 1980s marked a turning point for the international pharmaceutical industry. Since that time, ongoing mergers and acquisitions have significantly reduced the number of companies in the industry, increasing the market share of the largest operators. The corporate structures of the companies have also changed (see Section 6.5).

According to Glaxo:

In the past year we have seen a spate of acquisitions and alliances, announcements of reorganisations, staff reductions and some dramatic examples of vertical integration as companies jostle for position in the new environment, particularly as it affects the important US market (Glaxo 1994, p. 6).

Indeed, many in the industry expect that rationalisation will continue. For instance, RP Scherer said:

The international pharmaceutical industry is going through a revolutionary phase, which when completed, will dramatically alter the way the industry is structured worldwide. It has been hypothesised that perhaps only ten major pharmaceutical companies will remain by the year 2000. Certainly many companies which are currently in existence with manufacturing operations in Australia will disappear within the next five years (sub. 29, p. 3).

A question that arises is what factors have been driving these changes? While it is not possible to relate particular factors to specific outcomes, it is possible to identify a range of factors that may have contributed to changes in the structure of the pharmaceutical industry.

6.3 Demand side changes

Demand trends have been an important influence on the structure of the international pharmaceutical industry. Changes in demand can directly affect company fortunes (for example, changes in demand may influence drug prices and therefore revenue). Company structures also respond to demand conditions—for instance local production by MNEs may be necessary to adapt products to suit the requirements of particular customers.

The major factors determining demand for pharmaceuticals include:

- social and economic changes affecting health needs and expectations; and
- government intervention aimed at containing the growth in health care costs.

6.3.1 Demographic and economic changes

The world's population is growing and ageing. In industrialised economies, the median population age is expected to increase from 35 in 1990, to between 39 and 45 by the year 2010 (Ballance, Pogany & Forstner 1992, p. 202). The proportion of the population over the age of 65 is likewise expected to rise. While the median age in developing countries is not expected to increase, numbers of elderly people will still rise in line with population growth.

While total demand for pharmaceuticals is growing in response to population growth, more significantly, the ageing of populations in developed economies is increasing demand for the treatment of chronic and degenerative diseases. Much of the treatment for these ailments is of a preventative or alleviating nature, rather than curative.

The level of pharmaceutical expenditure is positively related to a nation's income (OECD 1993). Continued global economic growth is expected to increase the expenditure on health care and pharmaceuticals. In addition, new markets are emerging, particularly in the Asian region. Strong growth in consumption of pharmaceuticals is expected to continue in Asia, as a result of rising incomes, an expanding middle class and a shift away from traditional medicines towards western medicines.¹

The growth in demand, resulting from demographic and economic development factors, is putting pressure on the financial resources of governments and insurers, which typically have a key role in funding drug purchases (see Chapter 2). Governments and insurers have responded to this pressure by putting in place three broad cost containment mechanisms:

- controls over the prices or profits of drug companies (Section 6.3.2);
- controls over usage of drugs by consumers (Section 6.3.3); and
- total health cost management measures (Section 6.3.4).

But such approaches, by restricting returns to pharmaceutical companies, may put added pressure on companies to maintain profits through other means (such as rationalisation).

¹ See for example, Booz Allen & Hamilton (1995, p. II.B-18).

6.3.2 Price and profit control mechanisms

Price and profit controls have been used for some time by governments in an attempt to contain the pharmaceutical component of their health care budgets. A range of approaches have been adopted, including:²

- government determination of companies' prices through negotiation (used in France, Spain, Italy, New Zealand and Australia);
- direct profit controls (used in the UK);
- encouraging doctors to prescribe cheaper medicines and pharmacists to dispense cheaper generic equivalents; and
- limits on reimbursement of consumers by compulsory government health insurance funds (used in Germany, Denmark and the Netherlands).

As well as these formal mechanisms, a number of market-based and regulatory developments are adding to the downward pressure on prices. These include: reference prices³ amongst therapeutic clusters, sourcing from low price countries and benchmark pricing.

First, a number of European countries have recently established reference prices for therapeutic clusters of drugs.⁴ Companies remain free to price their products in excess of the reference price, but additional costs are borne by the consumer. Reference pricing places pressure on the suppliers of branded drugs to match the prices of generic substitutes, and increases consumer awareness of price differentials among drugs. Both of these effectively lower drug prices.

Reference pricing has proved to be a very effective mechanism for limiting growth in pharmaceutical costs. In Germany, for example, the system has resulted in a 66 per cent reduction in annual outlays by the Health Insurance Funds since 1991 (Bundesministerium für Gesundheit 1995, p. 3).

The second mechanism placing downward pressure on prices arises from the development of a single market in the European Union (EU). This has led to greater harmonisation of drug evaluation and a convergence in drug prices. Under the new arrangements, distributors in high-price countries (such as the Netherlands) are able to source drugs from low-price European countries (PPBH 1994, p. 49).

² These approaches are described in more detail in Appendix D.

³ The meaning of the term reference prices in Europe varies slightly from that adopted in Australia under the PBS (see Chapter 4).

⁴ For example, Germany, the Netherlands, Denmark, Sweden and Switzerland.

Third, the increasing internationalisation of the world economy has raised awareness among purchasers (such as governments and insurers), of prices paid to pharmaceutical producers in other markets, generally referred to as benchmark pricing. A number of countries, particularly in Asia, now expect to secure prices for pharmaceuticals at comparable levels to other markets (see Chapter 8).

6.3.3 Volume control mechanisms

Governments are increasingly introducing policies directed at influencing doctors' prescribing behaviour and consumers' purchasing patterns. A number of mechanisms have been adopted:

- differential reimbursement rates, or levels of patient copayment, thus reducing the cost burden upon the government or insurers;
- provision of pharmaceutical cost information to physicians, targeted at increasing doctor awareness of the cost of drugs prescribed and cheaper treatment options;
- restricting coverage of insurance schemes to particular drugs and limited indications, for example through positive and negative lists;
- authorisation requirements in which doctors must seek insurer approval before prescribing certain high cost drugs; and
- provision of educational material to consumers aimed at encouraging rational use of drugs.

These policies are described in more detail in Appendix D.

6.3.4 Total health cost management measures

Apart from measures aimed at reducing costs, pharmaceuticals and other health services are increasingly being assessed for cost effectiveness or reviewed in the context of general disease management programs. These approaches are adopted with varying degrees of sophistication within government health programs or elsewhere by private health insurers. As noted by the then Department of Industry, Science and Technology (now the Department of Industry, Science and Tourism) (DIST):

There are moves around the world, in both government and the private sector, to relate health costs and outcomes in order to provide improved health outcomes at lower overall cost. These moves focus on disease management, which is in

contrast to the traditional approach of cost containment in specific areas such as pharmaceutical expenditure.

This trend is most prevalent in the US as the US health care system facilitates the development of complete treatment programs for specific therapeutic areas with the aim of establishing risk-sharing and capitated agreements between suppliers and payers (sub. 56, p. 10).

One impact of the introduction of total health cost management measures is that they may put downward pressure on company sales volumes and prices. A partially offsetting factor is that the measures boost demand for drugs which are shown to have a positive impact on overall health costs—for example demand for cholesterol reducing drugs may cut coronary care costs in the longer term.

Three major approaches have been implemented: the establishment of Health Maintenance Organisations (HMOs), purchaser–provider splitting and cost effectiveness analysis.⁵

In the US, HMOs have been established as insurers for a broad range of health care services. The HMOs are a key element of a general shift towards managed care. Neimeth (1995, Slide 13) has forecast that managed care arrangements will soon replace fee-for-service payments as the major payment system in the US. Because the HMOs are exposed to the full health costs of their patients, they will choose the most appropriate treatment mix to minimise these costs.

For pharmaceuticals, cost saving measures have been achieved through the development of Pharmaceutical Benefit Management companies (PBMs) and mail order pharmacies, which manage pharmaceutical purchases and programs for large users such as HMOs. These programs may limit access to pharmacies (often to in-house providers) and also the range of drugs available. It has been estimated that by 1997, 40 per cent of the US population will be members of PBMs and by 2001 this will increase to 50 per cent (Kanavos 1994, p. 57).

The purchaser–provider model aims to encourage doctors to prescribe drugs cost effectively by making them accountable for the cost of the drugs they provide. For example, under the UK's National Health Service, general practitioners and District Health Authorities (as the purchasers of health care on behalf of patients) have been able to contract with service providers (such as pharmacists, hospitals, specialists and nursing homes) for the cost effective supply of health goods and services (GAO 1994, Appendix IV:5). In Germany, individual doctors are provided with drug budgets according to region and speciality, and are investigated by the health funds if expenditure exceeds the budget by more than 15 per cent (GAO 1994, Appendix II:5.1).

⁵ These approaches are described in more detail in Appendix D.

A third approach that has been implemented in public schemes is the application of cost effectiveness analysis in listing decisions.⁶ It aims to provide a framework in which the cost and the therapeutic value (benefits) of drugs can be balanced and therefore potentially represents an improvement over previous simple cost-plus assessment.

6.4 Supply side changes

A number of trends affecting the supply of pharmaceuticals also have the potential to influence the structure of the pharmaceutical industry. Key trends examined in this section are:

- rising costs of developing new drugs;
- technological developments, particularly in the formulation stage of production;
- measures to improve market access (such as trade liberalisation and harmonisation of drug assessment procedures); and
- explicit targeting of the pharmaceutical industry by countries through industry assistance measures.

6.4.1 Cost of a new product pipeline

The patents on many of the drugs discovered in the 1950s, 1960s and 1970s have now expired or will expire in the near future. The continued prosperity of the international industry is therefore partly dependent on developing new drugs (Collins 1993, p. 29).

A problem for the international industry is that the rate of introduction of new chemical entities (NCEs) (the basis for new products) appears to have slowed. At the same time, the cost of developing new drugs (through R&D) has risen dramatically (see Figure 6.1). These trends are likely to add to the commercial pressures on companies to develop new ways of discovering chemical compounds and to spread the cost and risks of undertaking R&D.

According to Ballance, Pogany and Forstner (1992, p. 94), three factors have led to rising drug development costs. First, tighter government approval controls were imposed during the 1960s and 1970s. This had the effect of increasing the cost and time taken to assess the safety and efficacy of drugs. Second, drug

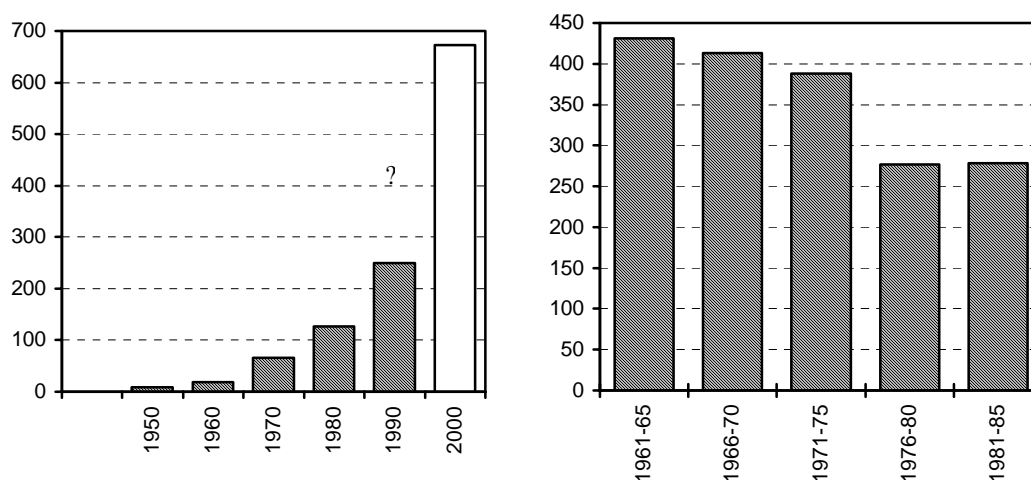
⁶ Canada, Germany, France and Australia currently undertake some form of cost effectiveness analysis. The Australian approach is discussed in Chapter 10.

disasters (such as Thalidomide) pushed up product liability costs for companies and forced them to undertake more rigorous and expensive clinical trials. Third, traditional methods of undertaking R&D (the iterative manipulation of NCEs with therapeutic effects) has become less effective, requiring newer, more complex techniques to be utilised.

Figure 6.1: Research and development, costs and success

The cost of developing a new drug, decade beginning 1950 to 1990, US\$ million

Number of new chemical entities introduced, 5 year totals, 1960 to 1985



Source: Collins 1993, pp. 33, 130

Apart from increasing the cost of R&D, these trends have also contributed to a lengthening of the product development period and increased risks regarding future returns.

Returns to research, and the ultimate cost of developing new products are also affected by government policies relating to protection of intellectual property. In the past, establishing a local manufacturing capacity was often a condition for awarding patents in developing countries (Collins 1993, p. 54). This encouraged a proliferation of local manufacturers in different markets. More recently, the conclusion of the Uruguay round of the General Agreement on Tariffs and Trade (GATT) Trade Related Intellectual Property (TRIPs) agreement, whereby most countries have adopted a minimum 20 year period of patent protection, effectively extended the coverage and terms of intellectual property protection for MNEs.⁷ This is likely to lessen pressures on MNEs to manufacture in countries with weak patent protection. The worldwide increase

⁷ The TRIPs agreement and other intellectual property issues are discussed in Chapter 16.

in patent terms and coverage is an essential element in offsetting the increasing cost and risk of R&D.

6.4.2 Technological developments

Many in the pharmaceutical industry considered that, until relatively recently, opportunities for exploiting economies of scale were largely confined to the active extraction and synthesis stages. Scale was deemed to be less important for other stages, such as formulation because they used fairly simple technologies. According to Collins (1993, p. 55), the relative simplicity of the formulation stage meant that manufacturing facilities could be economically located in small-scale establishments scattered around the world.

Recent technological developments, particularly in the formulation process, have increased the level of sophistication of the technologies employed. In particular, the introduction of more sophisticated and safer drug delivery systems (such as sustained release, wet and multiple active formulations) have increased production costs.

Technological developments and other factors, such as improvements in market access have prompted some companies to re-examine the strategy of locating formulation plants in major country markets (see Section 6.5).

Technological change has also occurred within research laboratories. Researchers are increasingly using computers to simulate the pharmacological and toxicological impact of drugs. For example the Australian Academy of Science submitted that:

One [development] strategy involves the design and synthesis of new compounds which block or mimic targets identified through basic research in biology and medicine. This strategy ... applies modern computer graphic technology to the detailed three-dimensional structures of biomolecular targets (sub. 60, p. 2).

6.4.3 Market access

Trade liberalisation and harmonisation of drug assessment procedures have promoted competition in pharmaceutical markets by reducing or eliminating barriers to international trade in pharmaceuticals.

In the past, the existence of high tariffs on pharmaceuticals impeded trade and therefore competition in some markets. Companies often responded to tariff barriers by establishing local manufacturing operations. Recent tariff reductions

for pharmaceuticals derive from two global events, the Quad countries⁸ agreement made during negotiations in the Uruguay GATT round and the formation of multinational trading blocs.

Although there was no specific commitment on pharmaceutical import tariffs made in the Final Act of the GATT, a major feature of the Uruguay GATT round was the agreement by the Quad countries to eliminate all tariffs on pharmaceutical products (see Appendix D). Since then, other countries have also committed to eliminate tariffs (Singapore and Austria) in accordance with the Quad countries agreement or to reductions on pharmaceutical import tariffs (Mexico, India and Indonesia). In all cases, these commitments are not 'bound'.⁹

A number of trading blocs, such as the EU, North American Free Trade Agreement (NAFTA), Association of South East Asian Nations (ASEAN) and Australia and New Zealand under the Closer Economic Relations (CER) agreement, have also agreed to reduce or eliminate tariffs amongst members. These blocs and agreements have begun to eliminate tariff and non-tariff barriers to international trade thereby reducing the segmentation of pharmaceutical markets and by reducing the incentive for companies to decentralise formulation processes.

In addition, variations in evaluation processes between countries caused many pharmaceutical companies to establish local operations in order to facilitate the market evaluation of their drugs. As discussed in Chapter 14, the international harmonisation of market evaluation of pharmaceutical products is shortening, simplifying or even eliminating the process of drug assessment necessary to gain market access. These changes will in turn mean more flexibility in companies' production and marketing decisions.

6.4.4 Intercountry competition for development

A number of countries have incentives in place to attract local investment by multinational pharmaceutical companies.¹⁰ Development incentives are primarily provided by central governments, although regional and local governments can also provide incentives. Broadly, incentives are designed to

⁸ The EU, US, Japan and Canada.

⁹ Non-bound commitments are undertakings that can be reversed without other countries having the right to appeal to the World Trade Organisation. Australia has a continuing unbound commitment to zero tariffs on pharmaceuticals.

¹⁰ Appendix D identifies the key elements of industry support programs for the US, UK, Japan, Sweden, Singapore, Ireland and Canada.

attract or retain investment by the major multinational pharmaceutical companies (see Box 6.1).

Box 6.1: International development incentives

Appendix E outlines the industry development incentives adopted in Ireland, Canada, Singapore, Japan, Sweden, New Zealand, the US and the UK. Development incentives are generally not targeted specifically towards the pharmaceutical industry. Instead the incentives most commonly adopted, such as R&D tax concessions, favour the pharmaceutical industry because of its high levels of research expenditure. Countries with the relatively generous R&D assistance mechanisms are Singapore, Ireland, Canada and Australia.

Health care environments also play an important role in determining the relative attractiveness of particular locations. There is a wide variation amongst countries in the nature of price, volume and reimbursement constraints adopted. Japan and Sweden operate pricing regimes which explicitly provide price premiums for innovative breakthrough drugs.

Appendix E shows the changes in total trade shares for a similar selection of countries. The data indicated that large relative gains in exports had been made in recent years by Sweden, Ireland and, to a lesser extent, Japan.

Some participants claimed that such incentives played an important part in their location and investment decisions. For example ICI stated that:

In the global competition to attract pharmaceutical manufacturing and exports, the winners over the past decade have clearly been relatively small countries, who have been able to offer large long term exemptions on corporate profits associated with new ventures (sub. 50, p. 2).

Other participants claimed that while incentives have little impact in attracting new investment, they are crucial in retaining current activities:

... I think it's just too late for [Australia]. The concept of "Here's an incentive. Why don't you do more. Let's build up" ... we have missed that. We're in a phase now where all our head offices need is incentives and reasons to even continue what we're doing now ... We're talking about survival mode (Roche, roundtable, p. 86).

6.5 Improving efficiency

As noted in Section 6.1, the focus of the pharmaceutical industry has historically largely been on expansion through developing new products. Reducing costs was important, but this was not the major competitive strategy.

The demand and supply side trends described in previous sections are likely to have contributed to recent changes in the balance of competitive strategies, with the pursuit of efficiency improvements through structural change becoming increasingly important. For instance, government price and profit controls have squeezed company profits. In order to maintain profitability, companies have had to pay relatively more attention to their manufacturing costs. Companies have responded in different ways to this pressure:

- industry rationalisation (for example through mergers and acquisitions);
- specialisation (for example through strategic alliances); and
- diversification (for example through vertical integration).

6.5.1 Industry rationalisation

Rationalisation in the pharmaceutical industry has taken three principal forms: consolidation through mergers and acquisitions; the closure of some manufacturing facilities; and the restructuring of corporate offices.

Demand and supply side trends have encouraged industry consolidation through mergers and acquisitions within the pharmaceutical industry (horizontal integration). For instance, mergers or takeovers are one way of acquiring a new product pipeline. Acquisitions may also be a way of increasing the ability of companies to spread R&D costs and risks.¹¹ Table 6.2 lists recent major mergers between large pharmaceutical companies.

The merger and acquisition activity in the industry has recently changed in nature. Previously, it largely involved companies acquiring smaller rivals. More recently, the focus has shifted to mergers between medium sized (and even large) companies designed to ward off acquisition by larger competitors. (Green 1995).

Merger activity in the industry has led to some consolidation, but it has not altered the competitive dynamics of the industry. In 1978, the top four companies accounted for only 13 per cent of industry sales (Ballance, Pogany &

¹¹ As discussed in Section 6.5.2, strategic alliances are another way that companies can obtain access to R&D and other production capabilities.

Forstner 1992, p. 113) and by 1994, the four largest companies in the industry accounted for 15 per cent of total industry sales. However, the level of competition in the industry is still considered to be high (see Chapter 2).

Table 6.2: Major mergers and acquisitions in the pharmaceutical industry, 1990 to 1996

<i>Year</i>	<i>Merging companies</i>		<i>Merged company</i>
1990	Rhone-Poulenc	Rorer	Rhône-Poulenc Rorer
1990	Kai	Pharmacia & Leo	Pharmacia
1990	Roche	Genentech	Roche
1990	Sankyo	Lultpold-Werk	Sankyo
1991	Sanofi	Sterling Winthrop	Sanofi-Sterling
1992	Bristol Myers	Squibb ER	Bristol-Myers Squibb
1993	Merck	Medco (a PBM)	Merck
1994	SmithKline Beecham	Sterling Winthrop ^a	SmithKline Beecham
1994	American Home Products	American Cyanamid	American Home Products
1994	Eli Lilly	PCS (a PBM)	Eli Lilly
1994	Rhône-Poulenc Rorer	Institut Mérieux	Rhône-Poulenc Rorer
1995	Glaxo	Wellcome	Glaxo Wellcome
1995	Upjohn	Pharmacia	Upjohn & Pharmacia
1995	Hoechst	Marion Merrell Dow	Hoechst/MMD
1995	Fisons	Rhone-Poulenc Rorer	Rhone-Poulenc Rorer
1995	Roche	Syntex	Roche
1996	Ciba-Geigy	Sandoz	Novartis

^a In 1994 Sanofi-Sterling sold their OTC division (the former Sterling-Winthrop) to SmithKline Beecham.

Sources: Ballance, Pogany and Forstner 1992, p. 184; Green 1995; Economist, The 1996

A number of factors are likely to have underpinned moves by some pharmaceutical companies to close small scale regional manufacturing facilities. First, industry integration, through mergers and acquisitions since the mid 1980s has created considerable excess manufacturing capacity through duplication of facilities (see Box 6.2).

Second, supply side trends such as technological developments, trade liberalisation and the move towards single markets through the harmonisation of

regulatory processes have opened new opportunities for reducing costs by reducing local formulation capacity in each market (see Section 6.4).

Box 6.2: Plant size and rates of capacity utilisation in Western Europe

There is a significant mismatch between European demand for pharmaceuticals and the industry's current manufacturing capacity. In 1990, pharmaceutical formulation plants in the region were operating at very low rates of utilisation—50 per cent to 60 per cent of capacity. This was far below the corresponding rates in North America.

By the late 1990s, large integrated pharmaceutical companies will probably only need around ten strategically located manufacturing plants to supply local demand and to retain a global presence. Of these, no more than three to five should be in Europe. Such a development would imply a substantial reorganisation of the European industry.

Source: Ballance, Pogany and Forstner 1992, p. 122

Rather than closing all regional plants and centralising production in one location, it appears that some companies are establishing headquarters and plants to produce for regional markets and manage regional operations. Regional plants may specialise in producing particular drugs rather than a wide range of products. Regional plants may arise because of the possible trade-off between reaping economies of scale through centralising production and the flexibility and leverage (the 'local knowledge') that is gained by having dispersed production. A local production presence may help in tailoring products and marketing strategies, and in understanding and navigating regulatory systems.¹²

Similarly, regional headquarters are increasingly being established in major geographic areas (such as Europe and Asia). These offices are responsible for managing country operations within their regions. A prominent example of this is the hub and spoke structure recently established by Eli Lilly in Europe.

¹² An added reason may be that companies can take advantage of government industry development incentives.

6.5.2 Specialisation

Demand and supply trends are also likely to have contributed to an increase in specialisation, particularly within the R&D, formulation and marketing stages of pharmaceutical production. Specialisation has occurred in a number of areas:

- chemical conglomerates such as ICI have sold off their pharmaceutical subsidiaries (Zeneca);
- pharmaceutical companies have sold off non-core activities for example medical appliances, health care and cosmetic products, and veterinary pharmaceutical businesses; and
- within the ethical pharmaceutical area, companies have increasingly chosen to specialise in particular therapeutic classes.

Specialisation has been facilitated by the formation of strategic alliances between:

- large pharmaceutical companies;
- between pharmaceutical companies and small scale specialist companies, for example to supply new drugs on a global basis (for example see Faulding, sub. 85, pp. 5–6); and
- between pharmaceutical companies and specialist research institutes for the development of new drugs.

The formation of strategic alliances between companies is an alternative to full integration through merger or acquisition. Alliances can take the form of joint ventures covering activities in a particular market, country or therapeutic class. They also include agreements covering activities such as comarketing or cross-licensing of R&D.

Strategic alliances often cover R&D, the marketing and approval of drugs, or the manufacture of drugs. Box 6.3 illustrates how one company has developed a range of agreements, covering its research and marketing activities.

A range of factors are likely to have contributed to increased specialisation within the pharmaceutical industry.

The increased use of strategic alliances in the R&D stage of the pharmaceutical industry may have been motivated by the increasing cost and risks associated with conventional research. For instance, CSL said:

The rapid pace of technology change has meant that not even the large, international companies have the resources to address all development issues and this in turn has led to the emergence of a range of innovative technical and commercial alliances between the larger and smaller specialist companies. This

is especially the case in vaccines where there are now only four major global companies, each relying on a network of smaller alliance partners (sub. 39, p. 5).

Companies can seek to spread costs and risks by shifting from large scale centralised R&D to funding research in independent companies and research institutes. In some cases, funding is conditional on companies having the first right of refusal over the rights to use new products developed through R&D. In other cases, companies may have the right to a share of royalties from exploitation of R&D results.

Box 6.3: Merck's strategic alliances

Merck & Co. of the US has formed worldwide strategic alliances with other companies for different aspects of its business.

Astra Merck: Marketing agreement

Formally launched in 1994, as a joint venture between Merck and Astra AB (Sweden) Astra Merck markets Astra's breakthrough anti-ulcer medication Prilose, its cardiovascular drugs Plendil and Tonocard, and has US rights to most of Astra's future discoveries.

DuPont Merck: Prescription drugs research agreement

DuPont Merck is a research based joint venture specialising in the development of radiopharmaceuticals. A number of new products have been developed by the venture and are at the approval stage. In 1994, DuPont Merck established a generic research subsidiary.

Johnson & Johnson ° Merck: OTC research agreement

A joint venture between Johnson & Johnson and Merck for the development of OTC products and consumer health products worldwide. The venture has launched a number of new products in Europe and the US.

Source: Merck 1994, p. 24

Other companies may specialise in activities such as steering new drugs through clinical trials, marketing approval, active and secondary manufacturing and in marketing drugs to doctors and consumers.

A production agreement may be useful to capture specialist small scale manufacturing abilities, where a company's manufacturing facilities may be uneconomic. A marketing agreement enables the manufacturer, or patent holder, to utilise marketing skills developed by other companies, without the need to develop in-house skills.

Government industry development strategies may also have been a factor stimulating the use of alliances, particularly in the formulation stage. For instance, a number of countries have had industry policies which require local production to gain market access (see Appendix E).

6.5.3 Diversification

Vertical integration along the product development chain (research, development, clinical trials, approval, production, formulation and marketing) is a feature of the industry which dates from its initial development. However, recent mergers and acquisitions in the industry have extended integration into related activities such as pharmaceutical wholesaling, hospitals, health insurance and other areas of health care.

Most of the vertical integration into health care management has occurred in the US.¹³ A benefit of acquiring PBMs is that it provides pharmaceutical companies with access to detailed information about the consumption habits and preferences of patients and doctors. This information can assist companies in identifying potential new markets but has also led to concerns regarding the power of PBMs to influence doctors' prescribing behaviour (Neimeth 1995, pp. 24–25).

Diversification into health care provision is also likely to result in a broadening of the scope for management of overall health costs which could extend beyond the management of pharmaceutical care. This is because the integrated nature of operations will force management to make decisions to minimise prospective costs by choosing the least cost means of health care delivery.

A final avenue of diversification within the pharmaceutical industry has been the shift by ethical pharmaceutical manufacturers into generic production. This has largely occurred in response to the growing number of drugs which are now off patent and the policies adopted worldwide by governments to encourage generic prescribing and dispensing of drugs.

6.6 Conclusion

To date Australia has not been severely affected by industry rationalisation and specialisation. For example, Alphapharm said:

¹³ Major examples are: Merck's and Medco Containment Services; Eli Lilly's and PCS Health Systems; SmithKline Beecham's and Diversified Pharmaceutical Services; and Schering-Plough's and Integrated Therapeutics Group (APMA sub. 31, p. 12).

The industry structure in Australia has been quite stable for several years. There are the notable exceptions of the well publicised mergers or acquisitions, but generally the number and size of pharmaceutical companies operating in Australia has increased. This stands in direct contrast to world industry trends where rationalisations are hitting the industry hard (sub. 14, p. 3).

Similarly, referring to the late 1980s, Parry and Creyke argued that Australia had largely been insulated from international pressures because:

The initial focus [of corporate restructuring] is very much on Europe followed by North America and then Japan. Excluding Japan, the Asia Pacific market is a potentially important growing market rather than a major existing mature market with a generally high level of disposable income and per capita pharmaceutical consumption. Asia and the Pacific is not driving corporate rationalisation strategies nor is the region seen as a priority within the rationalisation process (Parry & Creyke 1991, p. 25).

Despite a number of recent plant closures (for example Beecham Australia's operations), the level of activity and investment in Australia's pharmaceutical industry has been steady, if not rising. This does not mean, however, that Australia is, or will continue to be, immune from change. The reality is that the domestic industry is dominated by MNEs and is integrated with the world market. The shake-out in Europe and North America is therefore likely to have major consequences for the Australian industry.

Changes in the international structure of the industry represent opportunities for countries like Australia. However, they also pose a threat. Australia could benefit from moves by companies to develop strategic alliances, and establish regional headquarters and production centres. However, it is also possible that alliances will be formed with researchers in other countries, or that regional headquarters and production centres will be established in other parts of the Asian region.

The outcome will depend upon the strengths and weaknesses of Australia and its relative attractiveness as an investment location. The next Chapter examines Australia's strengths and weaknesses and seeks to identify the major barriers to Australia taking maximum advantage of the opportunities that are emerging.

7 STRENGTHS AND WEAKNESSES OF THE AUSTRALIAN INDUSTRY

This Chapter uses survey information and participants' comments to identify the strengths and weaknesses of the Australian pharmaceutical industry. Based on the discussion in Chapter 6, this Chapter also identifies the leading opportunities and threats for the industry. The interaction of these factors will have an effect on perceptions of the attractiveness of Australia as an investment location.

7.1 Introduction

Many participants to this Inquiry pointed to the strengths of Australia as an investment location for domestic and international pharmaceutical companies. Potential investors are attracted by Australia's stable political and economic environment, its proximity to expanding markets in the Asia Pacific area, a well educated labour force and good economic infrastructure.

In the light of recent international developments (reviewed in Chapter 6) a question is whether these strengths will be sufficient to enable the Australian pharmaceutical industry to capitalise on emerging opportunities and respond flexibly and efficiently to emerging threats. There is a certain amount of urgency—other countries have undoubtedly identified these opportunities and are moving to exploit them. The challenge for Australian companies and governments is to take advantage of these opportunities while they are still available.

This Chapter draws on information submitted by participants and other sources to identify the strengths and weaknesses of the Australian pharmaceutical industry. Where applicable, international comparisons are used to illustrate relative advantages and disadvantages. An attempt has also been made to highlight the importance of various factors for major stages in the production of pharmaceuticals. Section 7.2 focuses more closely on the sources of information used by the Commission and the approach used to analyse this material.

7.2 The Commission’s approach

Strengths and weaknesses determine an industry’s relative competitive position. They can operate at an individual company level (where it needs to be considered that one company’s weakness may be another’s strength) or in the context of the general operating environment facing a whole industry. As it is not practical to analyse and aggregate the strengths and weaknesses of individual companies in the pharmaceutical industry, the emphasis here is on identifying the strengths and weaknesses that broadly apply to the industry.

Two recent surveys undertaken by the Australian Pharmaceutical Manufacturers Association (APMA 1995a) and the then Department of Industry Science Technology (now Department of Industry Science and Tourism, DIST 1995b) provide a starting point in the assessment of strengths and weaknesses of the Australian industry (see Box 7.1 and Table 7.1).

Box 7.1: Perceptions of the Australian pharmaceutical industry’s strengths and weaknesses

A survey of the Australian pharmaceutical industry commissioned by APMA (1995a) sought information on the economic activities of Australia’s industry. It also sought to identify factors that have influenced (positively and negatively) the domestic development of the industry. It complemented a 1993 survey commissioned by DIST (1995b).

The surveys asked companies to comment on government policies and other factors that influence the development of pharmaceutical businesses in Australia. To assist respondents completing the questionnaire a list of indicative ‘industry specific’ and broader ‘environmental’ factors was included:

Environmental factors

- research and development environment;
- economic environment;
- political environment;
- overall health system environment;
- location of Australia in Asia Pacific;
- quality of labour (management, technical and production);
- patents and intellectual property; and
- Australian taxation.

Industry specific factors

- Factor f scheme;
- drug evaluation and registration;
- Pharmaceutical Benefits Scheme (PBS) listing and prescribing process;
- PBS prices and controls;
- policies towards over the counter drugs; and
- policy towards generics.

Source: APMA 1995a

The six highest ranked positive and negative factors in 1995 and their respective 1993 rankings, are summarised in Table 7.1.

Table 7.1: Factors influencing pharmaceutical business development in Australia

<i>Negative factors</i>	<i>% of</i>			<i>Rank</i>		<i>Positive factors</i>	<i>% of</i>			<i>Rank</i>
	<i>respondents</i>						<i>respondents</i>			
	<i>1995</i>	<i>1995</i>	<i>1993</i>				<i>1995</i>	<i>1995</i>	<i>1993</i>	
PBS pricing	89	1	1			Quality of labour/management	83	1	3	
PBS listing/prescribing restrictions	80	2	5			Location proximity to Asia	66	2	4	
Australian taxation	71	3	6			Australian R&D environment	60	3	2	
Generics policy	69	4	9			Factor f	52	4	1	
Drug evaluation/registration	49	5	2			Economic environment	49	5	6	
Overall health system/environment	46	6	-			Overall health system/environment	46	6	5	

Source: APMA 1995a, pp. 20, 21

The Commission has also used comments from submissions to augment the broad conclusions of the APMA and DIST surveys.

Potential strengths and weaknesses identified by the surveys or raised by participants can be separated into factors that affect the supply of pharmaceuticals (for example the quality and quantity of inputs to production) and those factors that affect demand (for instance the sophistication of the domestic market and links between producers and consumers).

The role of government is discussed separately in each section because it plays such a pervasive role in influencing both supply and demand conditions.

7.3 Underlying strengths and weaknesses—factor conditions

Many participants cited the availability of skilled research and development (R&D) personnel and infrastructure, and an educated workforce as major requirements for pharmaceutical companies operating in Australia. Governments have an influence on factor conditions in industry through industry development mechanisms, intellectual property regimes, taxation and educational arrangements.

7.3.1 Research and development

The importance of R&D to the domestic and international pharmaceutical industry is discussed in Chapter 2 and Chapter 6. The earlier discussion highlighted important global trends influencing the development of the international pharmaceutical industry. Trends relating to R&D included the rising costs associated with developing and bringing new pharmaceutical products to market and increasing specialisation within pharmaceutical research. An implication of these trends is that future investment in R&D is likely to go to those locations possessing particular strengths in research.

Most respondents to the APMA and DIST surveys (see Section 7.2) rated the Australian R&D environment as a positive factor affecting the development of the industry. However, the survey did not distinguish between different elements of the R&D environment.

Important elements of the R&D environment include skilled personnel (for example, scientists and engineers), research infrastructure (equipment and facilities that support research), and opportunities in particular research areas arising from unique local conditions (for example, the existence of native plants and animals).

R&D personnel costs and quality

Many participants claimed that one of Australia's strengths is the availability, low cost and quality of R&D personnel. For instance, the Australian Society for Medical Research claimed that:

Australia has a strong reputation for health and medical research, producing 2 per cent of the world's medical research output. The salaries for research personnel (and associated on-costs) are also generally less than for people with equivalent qualifications and experience in the US and Europe, offering a potential advantage for a company conducting research in Australia (sub. 36, p. 2).

Similarly, SmithKline Beecham stated:

The costs involved in undertaking discovery, preclinical and clinical research in Australia are either less or extremely competitive with the US and European Union countries, whilst still providing comparable Good Clinical Practice quality (sub. 13, p. 18).

Studies of Australia's R&D capabilities generally focus on the national picture rather than specific industries like the pharmaceutical industry. For instance, a recent Bureau of Industry Economics (BIE) (1996) report attempted to benchmark Australia's science system against those in other countries. It looked at the availability of R&D personnel, costs of employing research staff and their productivity (see Box 7.2).

Box 7.2: Bureau of Industry Economics study of Australia's science system

A recent study by the Bureau of Industry Economics (BIE) found that Australia has a high concentration of personnel engaged in R&D, particularly compared to Asian countries. In Australia there are about 50 research scientists and engineers for every 10 000 people in the labour force. While this ratio is low when compared to the US and Japan (76 and 75 respectively), it is much higher than other Asian countries such as South Korea (37), Singapore (30), China (6), Indonesia (6) and Thailand (5). The BIE also found that fewer of Australia's R&D personnel worked in the business sector (compared to most developed and developing nations)—most were employed in universities and public science agencies.

The BIE also argued that the supply of new entrants (graduates and immigrants) to Australia's science and technology workforce appears to be sufficient to maintain current capabilities and to allow for some expansion. Both wages and R&D costs per employee appear to be relatively low (BIE 1996, p. xxi).^a

There is also some evidence to suggest that the output (productivity) of Australia's R&D personnel is high by international standards. For instance, using partial measures of R&D productivity^b the BIE found that Australia produces more R&D outputs than would be expected, given Australia's levels of public and private expenditure on R&D and the number of research personnel employed by the public and private sectors.

a The BIE found that R&D costs per employee were the tenth highest amongst 16 member states of the Organisation of Economic Cooperation and Development (OECD). Reasons attributed to this were the low wages of Australian academics and engineers and the fact that most local R&D is not considered to be capital intensive.

b The BIE looked at measures of scientific output (published scientific papers, citations of these papers and patent statistics) and related these to R&D spending and the stock of R&D personnel. See BIE (1996) for a full discussion.

Source: BIE 1996

National studies of R&D capabilities support the view that Australia is well endowed with relatively cheap and efficient R&D personnel. While there are no similar studies for the pharmaceutical industry, the limited evidence supports the findings of national studies.¹ For instance, work by DIST has found that the cost of employing pharmaceutical researchers in Australia was lower than Singapore, South Korea, Taiwan, the US, and European countries, but more expensive than Indonesia and Malaysia (DIST 1995a, p. 10).

¹ An unresolved issue is whether the dominance of the public sector in funding R&D activities and employing research personnel in any way alters the picture of Australia being an attractive investment location for private pharmaceutical companies.

A number of participants raised specific concerns about the adequacy of Australia's R&D resources. Faulding claimed that Australia has a limited supply of people skilled in the core competencies of chemistry, formulation, engineering and possesses few experts in regulation and intellectual property (sub. 85, p. 7).

Similarly, the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists submitted that:

Australia has a serious shortage of clinical pharmacologists. They are essential if Australia is to be an increasingly active player in drug development.

... establishing a number of new training positions for clinical pharmacologists [is] in the interest of increasing the competitiveness of the Australian pharmaceutical industry (sub. 6, pp. 3–4).

Research infrastructure

R&D infrastructure is another important input to pharmaceutical research. The term research infrastructure is generally used to describe scientific equipment (such as microscopes and computers) and facilities (such as offices and laboratories) but it can also cover the experience and knowledge embodied in public research organisations.

The major components of Australia's R&D infrastructure are located in universities and associated institutes, the Commonwealth Scientific and Industrial Research Organisation and other bodies such as Cooperative Research Centres. The academic and hospital associated medical research institutes form a particularly large component of Australian research. Industry linkages allow pharmaceutical companies to use research infrastructure and expertise possessed by these bodies.

A common perception within the general scientific community is that Australia's research infrastructure is inadequate.² In this Inquiry, the adequacy of medical research infrastructure received relatively little comment. However, participants were generally critical of the level of funding for the maintenance and expansion of Australia's infrastructure base. For instance Astra stated:

Infrastructure for Australian research is inadequate and usually focused in small groups (sub. 20, p. 21).

The Australian Association of Medical Research Institutes claimed that insufficient funding of medical research was contributing to the ageing of Australia's research infrastructure (transcript, p. 1063).

² See for example, the concerns expressed in the National Board of Employment Education and Training report (NBEET 1993) on research infrastructure in higher education.

A difficulty with assessing the adequacy of Australia's R&D infrastructure for the pharmaceutical industry is that most studies focus on the national picture.

The study by the BIE (1996) found that between 1986 and 1990, Australia's spending on public research fixed assets (12.6 per cent of total public research spending) was below the Organisation for Economic Co-operation and Development (OECD) average of 15.2 per cent. But this does not in itself tell us that infrastructure spending in Australia is inadequate. The BIE attributed part of the difference to the lower capital intensity of research in Australia, as relatively less research in areas like nuclear power generation, aeronautics and space exploration is conducted in Australia than in comparable countries.³

The importance of using research infrastructure through establishing links with industry is discussed below.

Australian research activities

Australia's strengths in research are also related to those fields where local researchers have built up and acquired knowledge. Some areas of local expertise amongst companies based in Australia are discussed in Box 7.3.

An important area of local expertise is in clinical trials. Clinical trials are generally undertaken in hospitals and are therefore dependent upon the cost and quality of patient monitoring services provided by hospitals. The Society of Hospital Pharmacists argued:

Pharmaceutical companies rely heavily on public hospitals for the safe and scientific conduct of clinical trials and these now form a significant workload for hospital pharmacy departments, particularly in major teaching hospitals (sub. 42, p. 7).

According to the Society of Hospital Pharmacists, the advantages of conducting clinical trials in Australia include:

- the high standard of health care with moderate cost in Australia; and
- high standards of medical research (sub. 42, pp. 7–8).

There are also a number of emerging opportunities for researchers in Australia. These include Australia's natural products base and the establishment of linkages and strategic alliances between companies and institutes (see Section 7.4).

³ See BIE (1996, p. 88) for a detailed discussion.

Box 7.3: Strengths of companies operating in Australia

AMRAD	AMRAD has developed expertise in biotechnology products. Its strengths are in managing clinical trials and the commercialisation, production and marketing of biotechnology products. AMRAD has established linkages with 11 Australian research institutes. AMRAD Pharmacia Biotech was established in 1993 to distribute Australian biotechnology products to markets in Asia, Europe, the US and within Australia.
CSL	CSL has expertise in R&D related to antibiotics, vaccines, recombinant proteins, hormones and products derived from human bioplasma. The thrust of CSL's research is to develop pharmaceutical products of biological origin. CSL undertakes activities ranging from basic research and clinical trials to approval and marketing within Australia. CSL has established a number of links to market its developments overseas.
Faulding	Faulding undertakes R&D in delivery systems which involve reformulating new and existing drugs. Faulding has developed a number of sustained release formulations of off patent drugs—for example, Kapanol. Marketing of Faulding's products is undertaken through linkages with Glaxo Wellcome, Dainippon, Bristol-Myers Squibb and Sanofi Winthrop.
Glaxo Wellcome	Glaxo Wellcome's strengths are in clinical research, marketing and education particularly focused on the opiate intermediates and opiate alkaloids manufactured in Tasmania.
SmithKline Beecham	SmithKline Beecham is a leader in the supply and development of products in the therapeutic classes of anti-infectives, central nervous system, gastro-intestinal and vaccines. SmithKline Beecham's R&D is focused on joint research ventures with Australian universities in the areas of insular cortex research, dementia, Hepatitis C, Alzheimers disease, immunity/viral research and schizophrenia.

Sources: AMRAD 1995b; CSL sub. 39; Faulding sub. 85; Glaxo Wellcome sub. 143; SmithKline Beecham sub. 13

Some participants claimed, however, that the R&D conducted in Australia is not fully utilising the capabilities of the Australian medical research community. For example, AMRAD argued that:

Most of the untied R&D conducted in Australia by foreign owned companies is directed towards late stage clinical development and pre-manufacturing formulation development. ... this type of R&D does not utilise the world class pre-clinical and clinical research base which is available in Australia and is largely directed to supporting future manufacturing activities or for marketing expansion of existing products (sub. 117, p. 7).

Commercialisation

Having large numbers of research personnel and efficient research infrastructure is no guarantee that Australia will be seen as an attractive location for investment by the pharmaceutical industry. The ability to convert research into marketable products (referred to as commercialisation) is also important.

Some participants commented that Australia has missed opportunities to commercialise medical research. For instance AMRAD said:

Despite Australia's reputation in research discovery, Australia has not capitalised on this strength. Prior to the late 1980s there has been a distinct lack of local companies specialising in the patenting and development of new chemical entities. As a result discoveries have been developed overseas and therefore the benefits of these discoveries have been lost to multinational companies (sub 24, p. 7).

There is a general perception that Australia has performed poorly in commercialising ideas or products created through research in a wide range of areas.⁴ The Industry Commission's Research and Development Inquiry (IC 1995b) examined some of the possible reasons advanced to explain the perceived poor commercialisation performance.⁵

A number of initiatives have been put in place in an attempt to improve Australia's commercialisation track record. Initiatives include government support for industry and public sector research linkages (for example, cooperative research centres), strategic alliances between private companies, and equity ties between researchers and companies. Initiatives relevant to the pharmaceutical industry are discussed in more detail in Chapter 2 and Appendix F.

⁴ For a discussion of commercialisation issues, see Industry Commission (1995b, pp. 609–632).

⁵ Reasons explored by the Commission included the lack of market focus and interaction between public and private research bodies, and the wrong mix and direction of R&D funding (IC 1995b, pp. 611–621).

R&D alliances

Chapter 6 noted that the rising cost and risks of developing new pharmaceutical products is a stimulus to international companies forming R&D alliances with other companies and research institutes. Research alliances are a useful way for companies to tap into local expertise, and often involve partners sharing resources and resultant rights to intellectual property. Similarly, from the perspective of the researcher, the formation of an alliance provides funding for further development stages and eventual approval and marketing of a prospective new drug.

In Australia, alliances have been developed between pharmaceutical companies and researchers with expertise in biopharmaceutical R&D and formulation.⁶

Biotechnology applications are considered to be the leading area for prospective new drugs (Kavanos 1994, p. 14). Companies such as AMRAD have succeeded in establishing linkages with both academic researchers and multinational enterprises (MNEs). They have thereby succeeded in bringing a number of new biotechnological products to market (sub. 24, p. 10).

There are also opportunities for establishing linkages which capture emerging Australian expertise in areas of drug design, formulation, active synthesis and extraction. The strategic linkages adopted by Faulding are a prominent example:

Links have concentrated on particular areas of R&D including formulation, biology, statistics, modelling and clinical research. Links have increased in recent years due to strategic decisions to expand Faulding's portfolio of drug delivery technologies. Linkages are essential in order to speed both the research and development phases ... building in-house competence and resources in all areas would be too expensive and slow (sub. 85, p. 5).

7.3.2 Labour skills

Although the pharmaceutical industry is not generally considered to be labour-intensive, the quality and cost of labour will still have an impact on the development of the industry. The APMA survey (1995a) ranked quality of labour (along with management) as the most commonly cited positive influence on business development in Australia (cited by 83 per cent of respondents). Labour skills and management capabilities were highly valued in the manufacturing and export areas by participants. For example, SmithKline Beecham said that a skilled labour force:

⁶ See Chapter 2 for a more detailed discussion of research alliances.

... allows Australian manufacturing to operate with a lower aggregate head count...

In the area of pharmaceutical construction, Australian contractors are low cost, high quality suppliers. They are currently capturing extensive regional work in their own right ... (sub. 13, p. 18).

While these comments show that Australia is generally considered to have a well educated, skilled and cost effective labour force, the significance of this as a strength for the pharmaceutical industry will also depend on the nature of workplace arrangements. Arrangements that promote industrial stability, allow the flexible use of labour and provide incentives for productivity and continuous improvement will help Australia capitalise on its inherent strengths.

The pharmaceutical industry has embraced total quality management regimes and is organising its workplaces through workplace agreements. The then Minister for Industry Science and Technology stated that the industry:

... has a demonstrated willingness to embrace reforms by working in partnership with unions and adopting Total Quality Management and similar internationally recognised production and accreditation standards (Cook 1995, p. 1).

Some participants argued that one positive impact of these developments had been to reduce the rate of industrial disputation in the pharmaceutical industry. For instance, the Australian Council of Trade Unions stated that:

The Australian pharmaceutical manufacturing industry has such labour stability that it could be seen as a model of cooperation for other industries (sub. 55, p. 6).

7.3.3 Quality and cost of Australian management

Management plays an important role in influencing the performance of companies. While the quality of management will be influenced by many factors, two key influences are educational attainment and experience.

As noted above, in the APMA survey (1995a), the quality of management was frequently cited as a positive factor influencing the development of Australia's pharmaceutical industry. Several participants also said that one of Australia's strengths was the high quality and low relative cost of management. For instance, DIST stated that:

With a very large pool of tertiary trained managers and technicians, Australia is well placed to provide international companies with the skills and management support they need to develop their business worldwide. Australia's total management pool is eight times larger than Singapore's and four times larger than Hong Kong's. Australian executives often have 10 to 15 years more commercial experience than their counterparts elsewhere in Asia.

International salary surveys highlight Australia's advantage in salary costs for senior managers in Asia (DIST 1995a, p. 17).

However, recent reviews of management in Australia have been less glowing. For instance, the Karpin report (1995) identified a number of deficiencies in Australian management and management education.

7.3.4 Construction and equipment

Pharmaceutical companies must comply with high standards of purity in their production processes. For instance, in order to comply with ventilation standards, high quality air conditioning units, capable of preventing infectious airborne contaminants from circulating throughout the building and environment, must be installed during the construction of the plant.

Pharmaceutical companies are therefore dependent on specialist engineering companies and high quality construction companies in the construction and design phases of new plants. While CSL claimed that these skills are relatively rare in Australia and must be imported, these skills are beginning to develop (sub. 118, p. 23).

Much of the specialist equipment employed in pharmaceutical plants is not produced in Australia. While a small number of companies are capable of producing machines to customer specifications, lower cost off-the-shelf equipment must be imported from overseas. A number of manufacturers in the US and Europe specialise in producing this equipment.

7.3.5 Government policies and programs

Factor f

As discussed in Chapter 5, the Factor f scheme commenced in 1988 in an effort to overcome the negative effect on industry activity in Australia of low Pharmaceutical Benefits Scheme (PBS) prices. However, the Factor f scheme was viewed as a strength by some participants and a weakness by others.

Recipient companies generally argued that Factor f had been crucial in creating a positive image of the Australian operating environment amongst overseas executives, and that the funding was responsible for recent decisions to invest in Australia. However, some of these companies criticised the short term nature of Factor f assistance:

Factor f is a stop-gap approach to addressing the fundamental distortion in the operating environment created by the PBS. It is inappropriate as a long term assistance measure (Pfizer sub. 79, p. 3).

Other companies complained about the selective nature of the assistance provided by Factor f. For instance, Sigma stated:

The Factor f scheme rewarded ... multinational companies who could transfer operations to Australia .. [yet] gave Australia no absolute sustainable competitive edge because the recipients of Factor f could move to a more favourable environment if the opportunity arose. The scheme did little or nothing for Australian companies who did not have significant pre-existing export sales (sub. 19, p. 9).

The industry has also expressed some concern as to the future of the Factor f scheme. For example, Fisons submitted that:

The Factor f scheme has been the single most important Federal Government initiative in recent times. However, ... there is now considerable uncertainty as to the future of the industry in Australia and with respect to Factor f, as to the Australian government's intentions beyond the end of the scheme in mid 1999.

Four years might seem like a long way off but the pharmaceutical industry's and Fisons' planning horizons are typically very much longer than this. [This] uncertainty is damaging (sub. 35, p. 9).

The success of the scheme in terms of inducement of investment and value adding activities is described in more detail in Chapter 11.

General industry assistance

Aside from the specific assistance provided under the Factor f scheme, the pharmaceutical industry is also eligible for assistance under government programs encouraging:

- R&D;
- export enhancement; and
- location in Australia of regional headquarters (RHQs).

The pharmaceutical industry's use of the available industry assistance programs varies. Reflecting the research intensity of the industry, R&D assistance programs are widely used (see Appendix F).

As discussed in Appendix F, the industry has not yet made use of the regional headquarters program and only selective use of export enhancement measures. As the industry continues to restructure and the export focus of the Australian industry increases, greater utilisation of these schemes may occur.

Inconsistency of health and industry policies

The pharmaceutical industry—by virtue of the importance of public health as a social issue, and the cost to government of drug subsidies and market power provided by many pharmaceutical innovations—is subject to extensive government regulations. The impact of these policies is partly acknowledged through the compensation received by the industry through Factor f.

The uncertainty and contradiction between Australian government policies towards the pharmaceutical industry received considerable attention in submissions to this Inquiry. For example, Pfizer stated that:

Changes, inconsistencies and discontinuity in government policies destabilise the investment environment and make long term planning (and headquarters endorsement of investment proposals) very difficult. The pharmaceutical industry has very long term planning horizons and for this reason requires a stable, predictable and fair operating environment before committing to major investments, particularly in R&D (sub. 79, p. 23).

Similarly, Fisons stated that:

Uncertainty ... is now beginning to inhibit [Fison's] management from seeking further investment from its parent company. Fisons is reviewing its world wide manufacturing operations and is questioning the future of the industry in Australia and the government's commitment to it. The inconsistency of policies which on the one hand call for and support a viable pharmaceutical industry (National Medicinal Drug Policy, Factor f) and on the other seem bent on doing the opposite (PBS pricing policy, PBS listing delays, tax and tax audit, generic substitution) has drawn adverse comment (sub. 35, pp. 10–11).

Some participants (for example, Pfizer sub. 79, p. 23) claimed that a source of this conflict was the division of responsibility between the Department of Human Services and Health (DHS, now the Department of Health and Family Services) and DIST. For example, the Australian Health Industry Development Forum said:

A clear case in point is the conflict between the policies/schemes of DHS which may inhibit innovation and investment in R&D and manufacture ... and the policies/schemes of DIST which are formulated to assist the industry in investment in R&D, manufacture and export. Some such as Factor f are even designed to counter the adverse effects of DHS programs (sub. 197, p. 2).

7.3.6 Patent regime

The patent regime in Australia has received considerable comment from the pharmaceutical industry and is discussed in detail in Chapter 16. The industry perceives that this is a crucial factor determining business success. For example, Pfizer stated:

The value of the pharmaceutical industry's R&D is recognised through the granting of patents for innovative advances. These patents represent the core of the industry, which is founded on intellectual property rather than the basic manufacture of goods. The value of this intellectual property must be recognised, and protected by the Government (sub. 66, p. 2).

In the APMA and DIST surveys, patent protection was listed as both a positive and negative influence on business development (APMA 1995a, p. 23). The major concerns were:

- patent term, and the lack of extensions to accommodate delays in the listing and registration processes (effective patent terms);
- inadequate protection of commercial data submitted to regulatory authorities in applying to receive patent protection; and
- although Australia currently does not have generic springboarding, various calls for springboarding in the past have been met with considerable hostility.

However, positive comment was received regarding:

- Australia's recognition of overseas patents and compliance with international standards such as the GATT Trade Related Intellectual Property agreement (TRIPs); and
- actions by the Government to enforce patent holders' rights.

Participants stated that the level of protection for intellectual property has improved. For example Glaxo Wellcome stated:

... a positive change over recent years was the move to 20 year patent terms for pharmaceuticals, albeit subject to a two year springboard period, in advance of the recent changes to unqualified 20 year terms in accordance with GATT/TRIPs (sub. 143, p. 2).

However, there was some remaining dissatisfaction. For instance, the APMA stated that:

... Australia lags behind the rest of the world, and countries within the EU and the US have better patent protection than we do here. ... the really fundamental thing is we want a level playing field and we don't want to be at a disadvantage when compared to other comparable countries (transcript, pp. 393–394).

7.3.7 Taxation arrangements

The APMA survey (1995a) ranked 'Australian taxation' third in the list of negative factors cited by pharmaceutical companies as impeding business development and new investment (APMA 1995a). In its submission, the Proprietary Medicines Association of Australia (PMAA) stated:

There is no doubt that business finds the Australian taxation laws and administration complicated and difficult, by comparison with many other parts of the world. Unless the Government can make a real effort to make real and substantial improvements, it is certain that new investment in Australia will be held back (sub. 71, p. 40).

Participants' concerns centred on the administration of transfer pricing and wholesale sales tax (WST) arrangements. The following discussion draws on the detailed description of taxation arrangements and participants views contained in Appendix G.

Transfer pricing arrangements

International transfer prices (hereafter, transfer prices) refer to the prices charged for international transactions between related parties (for example a subsidiary and its parent company). Transfer pricing arrangements are significant for taxpayers and tax administrators because they largely determine income and costs, and hence taxable profits, of the related parties in different tax jurisdictions.

In common with other OECD countries, the Australian Taxation Office (ATO) has adopted the arm's length principle as a method for arbitrating transfer pricing arrangements.⁷

A significant number of companies were extremely critical of the administration of transfer pricing arrangements by the ATO. For example, ICI stated:

It is particularly detrimental to Australia's image as an investment centre, to have a national tax authority (the ATO), which has built a substantial reputation amongst international R&D based companies for its aggressive and unreasonable attitude in investigating transfer prices (sub. 50, p. 1).

While companies had several specific problems with the ATO's administrative approach, the main difficulties were:

- it is costly and leads to delays;
- interpretation of legislation is unclear; and
- its approach is inconsistent with OECD guidelines and other government policies.⁸

⁷ This principle requires that goods and services traded between related parties transact at the price that would have been paid in a comparable transaction by independent parties acting at arm's length under comparable circumstances.

⁸ See Appendix G for a more detailed discussion of participants' concerns.

First, some companies highlighted the substantial costs and delays, particularly associated with the resolution of disputes with the ATO in transfer pricing audits. The APMA estimated the costs to members to have been in the tens of millions of dollars over the last ten years (sub. 119, p. 18). The Commission has received evidence of audits taking in excess of 10 years to resolve.

However, Eli Lilly through its recently completed Advance Pricing Arrangement (APA)⁹ considered that it has gained an understanding on how to work effectively with the ATO (transcript, p. 375). On the APA process, Eli Lilly stated:

... the ATO gained valuable insight into the overall structure, assets, functions and risks of a multinational pharmaceutical company as well as how transfer pricing policies and practices operate within a global corporation. This allowed the ATO to better understand the nature of the industry and finalise the terms and conditions of an APA for Lilly Australia. We believe this process has created a level of certainty that is essential if Lilly Corporate is to make substantial investment decisions about its Australian operation (Eli Lilly correspondence 5 March 1996).

There are resource costs to companies and the ATO in negotiating APAs. The ATO indicated that, on average, APAs take about nine months to negotiate (transcript, pp. 1042–1043). However, APAs do not appear to be widely used by the Australian business community.¹⁰ As far as the Commission is aware, only one APA has been concluded with a pharmaceutical company.

Second, companies have complained that the ATO's interpretation of the law is unclear. They claim that a lack of clarity and certainty over the ATO's position on transfer pricing matters is inhibiting effective self assessment and may lead to issuance of penalties for incorrect assessments. The APMA stated:

... the ATO draft rulings have done very little to resolve the uncertainties, thus inhibiting effective self assessment.

The draft rulings are not only lengthy and complex but contain very little practical assistance to taxpayers.

One of the many concerns which our members have is that non-compliance with a tax auditor's interpretation of those rulings will result in enhanced penalties (sub. 119, pp. 18–19).

⁹ An APA is initiated by a company and negotiated with the ATO. It determines, in advance, how matters of significance in a company's transfer pricing arrangements are to be treated.

¹⁰ In 1995, only five APAs have been agreed between multinationals and the ATO (Lawson 1996, p. 5).

Third, companies criticised the approach of the ATO as being inconsistent with the OECD transfer pricing guidelines and other government policies, particularly in relation to the PBS. In particular, despite the requirement in the OECD guidelines that tax administrations take account of the effects of government policies when evaluating transfer prices, the companies claim that the ATO has ignored the effects of the PBS on company profits.

In response to these criticisms, the ATO claimed that it is at the forefront of developments on the OECD guidelines and that its approach is consistent with these. It noted that companies wanting to minimise risk and uncertainty have the option of negotiating an APA. It expressed a commitment to continual compliance improvement initiatives and more open and consultative arrangements (sub. 92, sub. 193, and transcript, pp. 1030–1043).

The ATO also noted that its main differences with industry related to the effect of the PBS on company profitability and choice of methodology. It acknowledged that the time, resource and financial costs associated with resolution of transfer pricing disputes with companies under audit were unacceptable and that it would be taking steps to resolve these problems (transcript, pp. 1037, 1043). At the public hearings, the ATO stated:

An audit as we understood them in the past, could range over several years. I have already indicated that I am not happy with that and we are looking at audit products and audit techniques with a view to shortening that cycle (transcript, p. 1043).

The ATO foreshadowed that it would re-establish an Industry/ATO Working Party with high level representation to achieve consensus on matters of significance in their transfer pricing arrangements. This process has been supported by the APMA.

Despite these developments, the Commission considers that there are still significant differences in opinion between many companies and the ATO on key aspects of transfer pricing arrangements particularly in relation to PBS pricing policies. This has led to uncertainty and conflict. Resolution of these differences through audit appears to be excessively lengthy and expensive and both the companies and the ATO seem to be approaching audits in an adversarial manner. However, the ability to negotiate APAs may help alleviate some of these concerns.

The Commission recognises the ATO's responsibility to ensure profits generated by activities undertaken in Australia are accurately assessed and hence the need to focus attention on industries such as pharmaceuticals where there is potential to manipulate profit realisation through transfer pricing arrangements.

However, the Commission believes the ATO needs to clarify its interpretation of the law sufficiently to reduce uncertainty for taxpayers. Based on the evidence, the Commission considers that the existing lack of clarity could be having a negative effect on decisions for pharmaceutical investment in Australia and could impede development of the industry.

The Commission notes that the ATO has established a Working Party to resolve the current level of uncertainty and conflict and the APMA's commitment to this process. The Commission also notes that the ATO has expressed a commitment to address the problems in its audit program.

Wholesale Sales Tax exemption

The other significant taxation issue raised by industry relates to the WST exemption for drugs and medicines.¹¹ The ATO has issued a draft ruling on its interpretation of this exemption. The effect of the draft ruling is to limit the WST exemption to therapeutic goods listed on the Australian Register of Therapeutic Goods (ARTG) which the ATO determines have been 'principally marketed' as a drug or medicine. In January 1994, the ATO indicated that it would issue a final ruling to clarify its position. However, a final ruling has yet to be issued.

The industry is concerned that the ATO's classification of 'drugs and medicines' is inconsistent and conflicts with the classification of a 'therapeutic good' in the *Therapeutic Goods Act* 1989 which also imposes a marketing test. Some participants claimed that the ATO's marketing test did not take account of the mandatory marketing requirements of the *Therapeutic Goods Act*. For example, Herron stated:

The ATO Ruling states that a product, 'must show on its packaging or labelling the kind of definite effect which could be expected regarding the particular ailment. The product must have more than general soothing effects'. We are unable to detail more completely the indications of this product [Siberian Ginseng] due to limitations of the Advertising Code (sub. 192, p. 1).

The industry claimed that inconsistency between the ATO's interpretation of the law and the *Therapeutic Goods Act* had led to inconsistency in Government policy and imposed administrative costs on industry.

If all drugs and medicines were subject to WST or all therapeutic goods on the ARTG were exempt from WST, the conflict that is perceived by industry

¹¹ This is contained in Item 78 in Schedule 1 to the *Sales Tax (Exemptions and Classifications) Act*.

between Government policy on therapeutic goods regulation and WST exemption would not arise.

However, the PMAA has recommended that the ATO adopt an interpretation of the law that exempts all goods on the ARTG from sales tax (sub. 71, p. 41). This view was reiterated by a majority of participants in the over the counter (OTC) sector. If this was not possible, the PMAA has argued that legislation should be brought in that ‘takes the matter beyond doubt’ (PMAA, sub. 71, p. ii).

At a more specific level, the industry’s main problems with the draft sales tax ruling in its present form were that:

- it is ill defined;
- it can be subjectively interpreted; and
- the stated exclusions on broad categories of products (for example, Vitamin E creams) do not take proper account of the medicinal purposes for which some individual products are manufactured and marketed.

With respect to the lack of clarity and subjectivity of the ATO’s position in the draft ruling, the PMAA stated:

Industry is faced with the untenable position of not knowing whether the ATO will agree with a classification decision until individual products come under scrutiny ...

The result is the need to request ATO confirmation of all classifications. This exercise would be costly and administratively difficult for industry. It can also lead to protracted negotiations with the ATO, as there is no guarantee that due consideration will be given, as the over-riding philosophy of the ATO is to protect revenue collections (sub. 71, Attachment 10, p. 9).

With respect to the ATO’s blanket exclusion of broad categories of products from the WST exemption, Blackmores provided the example of its Vitamin E cream which was only meant to be applied to the part of the body that has been injured or affected by a skin condition and stated:

The problem is that there is a temptation to read the exclusion so that any goods which can possibly be described as one of the listed exclusions will be excluded from exemption. This widely expands the exclusion so as to make otherwise exempt drugs and medicines taxable, and will potentially exclude all creams and moisturisers used to treat serious skin conditions (sub. 91, p. 2)

This view was supported by Proctor & Gamble with respect to the effect of the blanket exclusion on all medicated face washes.

The industry claimed that if the ATO's position was confirmed in its final ruling, it would substantially increase direct costs in the form of higher taxes. There are difficulties in estimating the financial cost to industry as previously exempt goods become subject to tax.¹² Nonetheless, six companies were able to provide the Commission with estimates of the additional tax that they expected to pay. In total, these companies estimated they would pay at least an additional \$12 million in tax each year. It is not clear whether this cost could be absorbed by companies or passed on to consumers in the form of higher prices.

More importantly, in the absence of a final ruling, the industry claimed that uncertainty over the ATO's position had already increased administration and compliance costs. The National Pharmaceutical Distributors Association and the PMAA considered that their members carried a considerable tax risk.

In response to the PMAA's recommendation that the ATO adopt an interpretation of the law that exempts all goods on the ARTG from sales tax, the ATO noted the different purposes of therapeutic goods and sales tax legislation. According to the ATO, the purpose of the former is to ensure safety and efficacy of certain goods before they become publicly available; the purpose of the latter is to raise revenue by determining which goods are subject to sales tax and which are exempt (sub. 193, p. 6). The ATO stated that:

... creating a link between the two pieces of legislation would not necessarily produce an appropriate result in all cases from a policy perspective (sub. 193, p. 6).

On the more specific problems identified by industry, the ATO indicated that it had not 'invented' the marketing test. Rather, this test was an important feature of sales tax legislation and that to exempt all goods on the ARTG from WST would require legislative amendment. The ATO also indicated that it does take account of the special features of individual products identified by industry.

The ATO stated that one of the purposes of the draft sales tax ruling was to receive constructive comment from industry which it will use to prepare a final ruling. It recognised that some guidelines in the draft ruling would have to be clarified and refined prior to the final ruling and indicated that it would be consulting with industry in the meantime (sub. 193, p. 6).

The Commission recognises the ATO's responsibility to interpret the intent of the sales tax legislation and the need for classification restrictions that ensure WST exemptions are confined to the goods and services for which they were

¹² First, the ATO has not yet finalised which products would become subject to tax. Second, it is difficult to determine the effect on sales if companies decided to pass higher taxes on to consumers in the form of higher prices.

intended. The classification of therapeutic goods under the ARTG may be too broad for the purposes of WST legislation as interpreted and administered by the ATO.

The Commission notes that, in most cases, the ATO considers WST exemption on a product by product basis. A product will be considered exempt from tax or taxable depending on the outcome of a marketing test administered by the ATO. However, with respect to stated exclusions to the WST exemption, the ATO has used a blanket approach to broad classes of products without administration of a marketing test. In the Commission's view, this could have the effect of excluding products from the WST exemption that are in fact principally marketed as drugs and medicines and generally located for retail with other drugs and medicines.

The Commission considers that the ATO needs to clarify its interpretation of sales tax legislation sufficiently to enable effective self assessment and reduction of uncertainty for taxpayers with respect to WST exemptions.

7.4 Underlying strengths and weaknesses—demand conditions

As noted in Chapter 2, governments around the world have a pervasive effect on the demand for pharmaceuticals. For equity and welfare reasons, most governments seek to ensure consumer access to pharmaceuticals by subsidising supply. But governments are also often concerned about the magnitude of government outlays on pharmaceuticals. Therefore they have put in place mechanisms to limit expenditure on drugs.

In Australia the Government subsidises the use of pharmaceuticals. In order to control its costs, it uses its market power to suppress prices. It has also installed mechanisms to control sales volumes (see Chapter 4). Participants generally viewed these mechanisms as key weaknesses affecting the development of the Australian pharmaceutical industry.

Comment was also received on a range of other factors that affect demand for pharmaceuticals such as generics policy, quality assessment and the performance of groups that influence pharmaceutical demand (hospitals, wholesalers and pharmacies).

7.4.1 PBS pricing

According to the APMA survey (1995a), PBS price control was the most frequently cited negative factor affecting business development. Indeed, this survey result was echoed by comments from participants in submissions and at public hearings. For instance, Glaxo Wellcome stated that:

The negative impact of the PBS on the investment climate and the consequent viability of a pharmaceutical manufacturing base in Australia has very significant repercussions for the realisation of the vision to commercialise Australian medical research for the benefit of Australia (sub. 144, p. 5).

The actual extent of price suppression in Australia is examined in detail in Chapter 8 and Appendix H. There is a clear perception in the industry that Australian prices are low by world standards and that low prices are a major disincentive to new investment in the local industry. For example, CSL stated that:

The comparatively low prices by international standards set by the Commonwealth Government for prescription pharmaceuticals and biopharmaceuticals is the major external factor inhibiting CSL's investment in R&D, manufacturing capacity and exports (sub. 39, p. 7).

As discussed in Chapter 8, participants also argued that the impact on companies of low PBS prices may be compounded by a number of international business practices, particularly country of origin and benchmark pricing.

7.4.2 PBS volume controls

A second element in PBS cost containment are the mechanisms adopted to contain the volumes or range of pharmaceuticals which are prescribed and dispensed. The major mechanisms adopted by countries include:

- cost analysis of prescriber behaviour used to recommend lower cost prescription patterns;
- limited formularies (such as positive and negative lists) which use cost-based principles of drug selection;
- therapeutic interchange—a form of substitution in which a range of drugs, not necessarily bioequivalent can be used as substitutes within therapeutic categories;
- the requirement to seek prior authorisation when prescribing certain medicines; and
- capitation agreements (Neimeth 1995, p. 26).

These mechanisms are discussed in greater detail in Appendix D.

Australia is not alone in having adopted these mechanisms. However, industry has submitted that there is a clear perception that PBS volume restrictions are tighter than those adopted elsewhere.

7.4.3 PBS listing process

A third element in the containment of costs on the PBS is the speed with which new drugs are admitted to the scheme. According to the APMA survey (1995a), the PBS listing process was the second most frequently cited negative factor affecting the domestic development of the pharmaceutical industry.¹³ Participants also raised a number of specific concerns about the PBS listing process. The problems included:

- coordination of the PBS listing process and the drug approval process;
- delays in the listing process;
- lack of transparency;
- price decision making by the Pharmaceutical Benefits Pricing Authority (PBPA); and
- the approach taken to economic analysis by the Pharmaceutical Benefits Advisory Committee.

While these problems and possible solutions are the focus of Chapter 9, it is important to note the extent to which the problems with the PBS listing process are viewed as an impediment to the future development of the local industry.

Problems with the listing process may affect the development prospects of the industry by imposing unnecessary administrative costs, causing excessive delays and creating undue uncertainty in the industry.

Many companies said that they were concerned about administrative costs and, more importantly, that the time lag between application and approval for listing on the PBS can reduce the returns from investments in pharmaceutical development and therefore the prospects for investment in the Australian industry. For example, SmithKline Beecham stated that:

Delays in the PBS process can lead to significant lost revenue, especially due to an inadequate patent term (sub. 13, p. 31).

¹³ According to Price Waterhouse, which conducted the survey, the question was understood to refer to the process of seeking access to the PBS for new products and delays in obtaining revisions to prices on the PBS.

Similarly, Pfizer (sub. 79, p. 16) sought an improvement in the PBS listing process as a means of ensuring against the erosion of effective patent life and excessive cost containment.

7.4.4 Small private market

Because of universal access to the PBS and the broad range of drugs available under it, Australia does not have a sizeable private prescription market. This has impeded the industry in securing a market for drugs outside the limitations of the PBS. For example, the APMA stated:

One of the key limitations to improved profitability and subsequent increased investment in Australia has been the inability of suppliers of prescription pharmaceuticals to develop a market outside the PBS. This means that, if new more expensive drugs fail to achieve listing on the PBS, they are not available to most consumers. ... The industry has attempted in recent years to expand this private prescription market into a viable alternative to the PBS but has not succeeded in gaining the necessary support from the retail pharmacy sector. The problem relates to the much higher mark-up and dispensing fee charged by pharmacists on private or non-PBS prescriptions (sub. 31, p. 37).

The private market for pharmaceuticals is discussed in greater detail in Chapter 4.

7.4.5 Generics policy

The recent introduction of generic substitution has increased company dissatisfaction with Australia's generics policy.¹⁴ The APMA survey (1995a) ranked Australia's policy towards generic substitution as the fourth most frequently cited factor impeding industry development. The APMA also stated that it:

... supports the role of the doctor to maintain the prescribing responsibility. It is important that the decision on the clinical intervention for the patient and selecting the appropriate course of treatment, is made in consultation between the doctor and the patient ... (APMA 1995d, p. 14).

Further, the Garvan Institute argued that generic substitution will reduce returns to Australian pharmaceutical companies and restrict the amount of R&D funding that is available for research institutes (sub. 33, p. 5).

Despite generic substitution being introduced in December 1994, there has been only an 8 per cent increase in the rate of substitution by pharmacists (DIST

¹⁴ Generic substitution allows pharmacists to substitute lower cost non-branded (generic) drugs where the doctors has prescribed a branded drug.

sub. 56, p. 10). Generics account for a relatively small share of the domestic market (9 per cent of prescriptions are substituted or written generically).

7.4.6 Market access and scheduling

Gaining timely access to the market for new drugs, given limited patent terms, is important for industry revenues. The Therapeutic Goods Administration (TGA) is an important part of this process and since 1991 has made considerable improvements in performance. For example, in the most recent APMA survey (1995a) the registration process was ranked as the fifth most frequently cited negative factor, compared to second in the 1993 survey.

Drug schedules are now largely consistent across the states. However, complete national uniformity of scheduling has yet to be achieved. For example, amendments to the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) are not uniformly adopted in all States with effect from the same day. In addition to timing differences, States may make amendments to the SUSDP before adopting it. The Australian Health Industry Development Forum said that:

... despite government efforts, national uniformity of scheduling has not been achieved. Only Victoria automatically adopts the SUSDP—other States may make amendments to the SUSDP before adopting it, resulting in a number of additional and unnecessary costs for industry (sub. 197, p. 9).

These issues are discussed in greater detail in Chapter 15.

7.4.7 Reputation for high quality

Several participants claimed that one of Australia's strengths is its reputation and standing in Asia and globally for high quality production and supply. In its submission, the South Australian Government stated that:

The widespread adoption of quality standards and the accreditation of the majority of companies in the industry will be important in retaining this image and in holding markets against competition from developing countries. Australia also has a reputation for being innovative and for having high standards of technical awareness (sub. 70, p. 7).

This reputation for quality is based, in part, upon the adoption of a Code of Good Manufacturing Practice amongst Australian producers (see Appendix D).

7.4.8 Intermediaries in supply

Most drugs are required to be sold through pharmacies (either with or without a doctor's prescription). Pharmacists' recommendations are an important element in providing and dispensing medicines. Although the Pharmacy Guild submitted that Australia's community pharmacy network is one of Australia's strengths and is efficient by world standards (sub. 181, Appendix II), other participants claimed that there are some significant problems.

Pfizer claimed that the pharmacy sector is currently 'over-regulated' and that this:

... encourages unnecessarily tight scheduling, limits on promotion, and higher mark-ups than would apply if competition prevailed. These factors result in a loss of economic benefits and access to OTC products for consumers (sub. 66, p. 33).

According to the APMA, pharmacy mark-ups are also impeding the development of a private prescription market for drugs:

... attempts to create ... the private prescription market ... have failed largely because the add-ons, in terms of pharmacy mark-ups in particular, and higher dispensing fees mean that the product is priced out of the market, or the returns to the manufacturer are no better than they could be on the PBS (roundtable, p. 230).

Wholesalers are an important intermediary between pharmaceutical manufacturers and the community pharmacy network. Australia's comparatively vast distances pose a relatively unique problem for wholesalers—they must deliver drugs to community pharmacies located throughout Australia, and must therefore deploy an extensive low volume network to cover rural areas.

There have not been any recent studies into the efficiency and effectiveness of wholesaling in Australia. However, there has been extensive recent rationalisation of the industry.

It is noteworthy that the considerable recent innovations in the US, including mail order and electronic mail order pharmacies, drug-marts and the integration of pharmacies into public health clinics have yet to occur in Australia.

Finally, the hospital sector is a major user of pharmaceuticals, accounting for 9 per cent of all human use pharmaceuticals dispensed in 1993–94 (Chapter 2).

7.4.9 Proximity to Asia

In the 1995 APMA survey (1995a), proximity to Asia was cited as a positive influence on business development in Australia by 66 per cent of respondents and ranked as the second most commonly cited positive influence. Its importance for pharmaceutical companies had increased since the 1993 DIST survey (1995b) when it was ranked fourth.

The importance of proximity to Asia is driven mainly by the continuing rapid growth in Asian markets. This derives from their increasing economic prosperity and a general trend towards the adoption of western medicines. For example, between 1975 and 1990 in Japan, per capita consumption increased from US\$92 to US\$277 (or a 201 per cent increase in real terms). Similarly in Taiwan and Singapore, per capita consumption increased by 150 per cent and 164 per cent respectively over the same period (Ballance, Pogany & Forstner 1992, pp. 230–233). In comparison, European growth rates have been slower—per capita consumption in Germany increased by 93 per cent, the UK by 82 per cent and France by 105 per cent.

The opportunities for the Australian industry offered by export growth in Asia are considered in Section 7.6.

7.5 Summary of strengths and weaknesses

The focus of the Chapter so far has been on assessing the strengths and weaknesses of the Australian pharmaceutical industry. In an attempt to bring the discussion together, key strengths and weaknesses have been summarised in Table 7.2.

Table 7.2: Strengths and weaknesses of the pharmaceutical industry

	<i>Strengths</i>	<i>Weaknesses</i>
Research and development	Good research infrastructure	Questions over adequacy of R&D infrastructure
	Research expertise	
	Research links	Shortage of some specialist skills
	Clinical trial capability	
Government programs	R&D assistance	Uncertainty about the long term availability of assistance (especially Factor f)
Government regulation	Efficient registration process	PBS pricing
		PBS listing process
		PBS volume constraints
		Policy inconsistency
		Scheduling inconsistencies
Other factors	Skilled local management pool Proximity of Asian markets Efficient manufacturing base	Failure to implement government commitments to extend patent life
		Difficulty in resolving taxation issues (transfer pricing and WST exemption)

In summary, the key strengths of the Australian pharmaceutical industry appear to be the ready availability of skilled and relatively inexpensive research personnel and opportunities for interaction with an extensive network of publicly funded research institutions. There are also specific and general government assistance programs available to the industry and a skilled local labour and management pool for manufacturing operations.

The main weaknesses perceived by the industry are the operation of the PBS—in holding down prices, restricting indications for which certain drugs can be prescribed and in creating delays in the release of new products onto the market—as well as the treatment of the industry by the ATO with respect to transfer pricing and WST.

An important conclusion to emerge from the discussion is that classifying features of the Australian pharmaceutical industry as strengths or weaknesses can be a very subjective exercise. In some cases certain factors were viewed as strengths by some companies and weaknesses by others—an example is Factor f. In many cases, there is insufficient information to allow the classification of particular factors as strengths or weaknesses.

In addition, there are likely to be other strengths and weaknesses of the industry in Australia that have not been covered in the discussion. For instance, the importance of Australia's relatively stable economic, social and political environment should not be underrated. Another strength is Australia's relatively good social and economic infrastructure (schools, roads, water and electricity). Other intangible factors such as 'quality of life' in a country can also be a factor influencing perceptions about a country's strengths and weaknesses.

7.6 Emerging opportunities and threats

This section considers where the greatest opportunities for development of the Australian pharmaceutical industry exist and where the threats to this development may arise. The major determining factors are the opportunities and threats in domestic and overseas markets posed by global rationalisation and specialisation.

7.6.1 Global rationalisation and specialisation

Chapter 6 outlined possible causes and forms of global rationalisation. Rationalisation has taken two primary forms. First, a number of the industry's centralised activities have increasingly been devolved, either through the multinational corporate structure or through the formation of external linkages with specialist enterprises and institutes. This trend has been particularly evident in the area of new product development.

Second, mergers and acquisitions and external industry changes have created a considerable degree of excess capacity in the industry's manufacturing plants. Globally, the previously highly decentralised formulation function is increasingly being centralised in regional production centres. Similarly, local management is being rationalised in favour of newly established RHQs.

According to DIST (sub. 56, p. 16) there are several examples of how Australia has benefited from global rationalisation:

- Australia has become the sole supplier for the Asia Pacific region (including Japan) of a number of Schering-Plough products;
- Merck, Sharp & Dohme is now the prime supplier of Merck products to New Zealand and South East Asia;
- Pfizer now supplies the New Zealand market following the closure of its New Zealand pharmaceutical operations in March 1995; and

- Bristol-Myers Squibb Australia has become one of the three key plants in the Asia Pacific region with the transfer of part of the Group's Canadian and Japanese manufacturing commitments.

However, Chapter 6 argued that the rationalisation process has yet to have a major effect on Australia and the Asia Pacific region. Therefore, Australia still has the opportunity to benefit greatly from global rationalisation, or equally to suffer a significant reduction in local industry activity.

Australia can take advantage of the current climate to secure and capitalise on its strengths in pharmaceutical R&D and areas of manufacturing. However, Australia will do so in competition with other countries in the region.

7.6.2 Export potential

Australia's strengths and the emerging market developments may represent a 'window of opportunity' for the Australian export industry. SmithKline Beecham submitted to the Commission that:

A big export opportunity is available if Australian plants can be justified given scalability and a sound business base. ... If Australia can build supply relationships with these regional markets now, exports will grow in parallel with their economies. This window of opportunity for Australia will be open for a short period only, whilst those less-developed regional competitors advance their level of manufacturing quality and sophistication (sub. 13, p. 9).

The prospect of rapid growth in Asia has focused multinational attention on the region. For many companies, Australia, as an established pharmaceutical market in which most companies have had a long term presence, represents a natural regional export base.

Blackmores, a leading Australian OTC producer, highlighted the opportunities available in Asia:

With Australia's reputation as a clean food producer, there are enormous opportunities to develop unprocessed and value added botanical products for domestic and export consumption, particularly in Asia (sub. 21, p. 1).

The PMAA and APMA also identified opportunities for increased exports of OTC and prescription products (see Box 7.4). They saw the lack of local knowledge of Asian regulations and consumer tastes as the major threat to Australian companies realising these opportunities.

7.6.3 Domestic activity

Some participants argued that there are also substantial opportunities within the Australian market. These opportunities stem primarily from marketing opportunities for new chemical entities and for new drug delivery mechanisms. These opportunities also exist in overseas pharmaceutical markets.

Some argued that there were prospects for Australia to develop the full stream of industry activities. For example, Faulding submitted that:

... companies such as CSL, Faulding, IDT, Alphapharm and Delta-West to varying degrees are dedicated to the development of a fully integrated Australian pharmaceutical industry (sub. 129, p. 8).

However, others argued that in the short term Australia cannot hope to capture the full stream of industry activities. The industry is increasingly sourcing inputs, intermediaries and management for individual markets globally. Australia has the opportunity to capture a share of global activity through capitalising on its expertise in niche markets. For example IDT stated in public hearings:

The Indonesians can make aspirin cheaper than [IDT] can. It's not a drug that [IDT] would want to make. [Aspirin] frankly is not a drug that [IDT] would want to make unless it was part of this kind of scheme. But [IDT's] particular specialisation is in the area of anti-cancer drugs and this company that approached [IDT] has a particular need in that area. So [IDT] does see the niche opportunities there and they're very significant (transcript p. 1097).

Abbott (sub. 48, p. 2) believes that there are major opportunities in capturing a greater share of the low volume batch formulation requirements increasingly being demanded by MNEs. This opportunity is likely to be dependent upon Australia's current strengths in the development of sustained release and solid state formulations and the recognised high quality of drug manufacturing in Australia.

Box 7.4: OTC and prescription export opportunities

The PMAA has recognised the increasing importance of export development to the future prospects of the local pharmaceutical industry. In 1993, the PMAA formed an International Trade Sub-Committee to assist the industry in developing its export potential. A study commissioned by the PMAA found that in 1993, exports to New Zealand and Asia were valued at \$71 million (for proprietary medicines) and \$247 million (total exports). It also forecast that exports of proprietary medicines would grow by 19 per cent per annum over the next three years.

The study also attempted to identify constraints on exports. Potential constraints identified were:

- regulations affecting imports in foreign countries, for example tariffs and product registration;
- local regulations governing exports (for example, export-only certification);
- commercial restrictions imposed on Australian subsidiaries of multinational companies preventing them from assuming responsibility for development of export business in proprietary medicines; and
- the limited ability of the Australian industry to reformulate and market products destined traditionally for the domestic market in a way which is acceptable to consumers in Asia.

According to the APMA, opportunities in the prescription sector are similar to those in the OTC market—growing incomes and a shift towards western medicines amongst Asian countries. The APMA submitted that:

... the Australian industry offers a proximity to the growing markets of South East Asia, with significant opportunities for export expansion as a result of relatively lower distances for transport of the goods and other inherent advantages of Australia's location in the Asia Pacific region such as time zones, and strengthening trade relationships through Asia Pacific Economic Cooperation (sub. 31, p. 28).

Sources: PMAA sub. 71, pp. 45–50; APMA sub. 31, p. 28

Australian pharmaceutical companies also have the opportunity to discover new therapeutic compounds by more extensive explorations of Australia's native flora and fauna. AMRAD stated that:

The history of the pharmaceutical industry is full of remedies derived from the natural world. ... only a small fraction of the Earth's species have been identified, let alone systematically tested for drug potential. While many of the world's leading pharmaceutical companies are combing the world's diverse habitats in search of new drugs, Australia, an area of extensive and often unique biodiversity, remains relatively unexplored by the pharmaceutical industry (AMRAD 1995a, p. 1).

Similarly, Prof. Peter Andrews submitted to the Commission:

The flora and fauna of Australia's reefs and forests represent one of the largest natural product reservoirs in the world (sub. 51, p. 5).

A final area of opportunity is to capitalise upon Australia's considerable expertise in clinical trials. According to participants, the development of markets in Asia represents an opportunity for Australia to become a regional centre of expertise in clinical trials supported by an efficient and respected

assessor of new products by overseas regulators. For instance, Dr Chris Sotiropoulos submitted that:

Australia is placed in a geographically unique position. The Association of South East Asian Nations requires a stable environment of strong intellectual ability to develop and test high technology products. ... In the global pharmaceutical market, Australia should represent the more reliable efficient centre for introducing rapid and efficient regulatory requirements for drug testing. Australia must become the regional leader in R&D and become a viable venue for clinical trials. ... [Otherwise] Australia will lose a vast opportunity on its door step, never to be regained (sub. 159, pp. 1–2).

Overall, the opportunities in the domestic market are most likely to lie primarily with specialist companies developing and marketing expertise in niche areas. It is important that the Australian industry is responsive to the needs of the global industry, through direct equity links, or through strategic alliances.

Table 7.3 summarises potential opportunities and threats faced by the Australian pharmaceutical industry. They have been classified according to where in the production chain they are likely to have the greatest impact.

7.7 Australia as an investment location

Many of the major multinational pharmaceutical companies have a significant presence in Australia and their choices about future directions are likely to play a large part in shaping the development of the domestic industry. As described in Chapter 6, pharmaceutical MNEs are moving to rationalise activity on a global and regional basis. This means that they are re-evaluating existing operations in particular countries and examining the attractiveness of other locations for new investment.

Table 7.3: Potential opportunities and threats for Australia

	<i>Opportunities</i>	<i>Threats</i>
Research and development	Multinational devolution of research Natural products base Clinical trials and market approvals for Asia	Failure to commercialise basic research through linkages with multinationals
Active extraction and synthesis	Specialised, small scale extraction and synthesis	Lack of strong comparative advantage, higher unit costs than in bulk processes
Formulation	Specialised, small scale formulation Increased exports through regional supplier status	Global plant closures
Marketing and management	Regional headquarters	Cultural gaps between Australia and Asian region

Most companies base their location decisions on a range of economic factors. These include, *inter alia*, the proximity and relative sophistication of markets, the availability and costs of raw materials and human resources, financial and construction costs and the quality of management. Companies will decide to invest in a particular location when their evaluation of these factors indicates that an investment in one location will give the project a sustainable competitive advantage over other possible locations.

In heavily regulated industries (like pharmaceuticals), locational decisions can also be influenced by the impact of government policy and the perceived willingness of government to provide companies with an attractive operating environment. In particular, companies are likely to be averse to policies which increase uncertainty.

Companies have claimed that government policies, covering the PBS, Factor f and taxation are major weaknesses for Australia and that they have raised the level of policy uncertainty. These claims are critical to this Inquiry and any assessment of the future of the Australian industry.

Given the case-by-case nature of investment decisions it is impossible to say whether, overall, Australia is a better location for investment by the pharmaceutical industry than other countries. However, there have been many comments from companies, some of which are supported by other evidence, suggesting that Australia compares favourably with other countries on many of the economic factors that influence locational decisions. The challenge for Australia is to ensure that the policy framework does not cancel out these advantages.

This Chapter has examined the strengths and weaknesses of the Australian pharmaceutical industry and the opportunities and threats posed by changes in the structure of the international industry. While it is difficult to make an overall assessment of Australia's strengths and weaknesses some clear points have emerged.

There are several factors that appear to be strengths for the Australian industry.

FINDINGS

Key strengths of the Australian operating environment are:

- the relative efficiency of Australia's research base in key aspects of pharmaceutical research and development (personnel, expertise and clinical trials) and the willingness of the Government to support research and development;
- Australia's proximity to growing markets in Asia; and
- recent improvements in the performance of the Therapeutic Goods Administration and the generally positive perception of the Therapeutic Goods Administration.

However, there are also several important weaknesses.

FINDINGS

Key weaknesses of the Australian operating environment are:

- Pharmaceutical Benefits Scheme pricing, process and listing constraints;
- the administration of transfer pricing and wholesale sales tax exemption policies by the Australian Taxation Office;
- uncertainty relating to the long term availability of Government programs such as Factor f; and
- inconsistency between Government industry and health policies.

There have been several positive changes in the Australian pharmaceutical industry over the last ten or so years. Many of the major international pharmaceutical companies have established operations in Australia, the nature of activity has changed, spending on R&D has risen and the industry has become more export oriented.

The discussion of international trends in Chapter 6 suggests that the structure of the pharmaceutical industry will continue to change. While predicting the precise direction of future trends and their impact on Australia is impossible, it appears from the discussion of strengths and weaknesses that the local industry is well placed to respond to potential future developments. If the international trend towards specialisation in research continues, Australia can exploit its

strengths in research personnel and infrastructure. But other industry strengths suggest that Australia could possibly develop a fuller range of activities (from actives synthesis to marketing of drugs) if the opportunities arise.

A major potential impediment for the industry appears to be the lack of attention that has been given to ensuring that the domestic policy environment reflects the global changes that have occurred. There have been some positive developments, for example, improvements to the administration of drug safety and efficacy regulation. However, fundamental problems still need to be resolved in a range of policy areas (such as the PBS, intellectual property regimes and the TGA). Whilst the Factor f scheme has partly addressed these problems in the short term, there is a widely held view that it has been unable to mask the need for more fundamental reform. This is reflected by uncertainty within the industry over the long term availability of the program.

Part B of the report takes up these issues in more detail. It examines the case for reform and seeks to provide some solutions to the major policy problems confronting the industry.

8 PHARMACEUTICAL BENEFITS SCHEME— PRICING AND AVAILABILITY ISSUES

This Chapter examines the impact of the PBS on company sales revenue and, as a consequence, the availability of drugs in Australia. The PBS affects companies' revenues by providing a subsidy to consumers and by the way the prices and market restrictions are negotiated under the scheme. PBS drug prices and market restrictions may also adversely affect the availability of drugs in Australia.

8.1 Introduction

Chapter 7 discussed factors that can affect the attractiveness of Australia as an investment location for pharmaceutical companies. In particular, it noted that features of Australia's policy environment have the potential to counteract any perceived natural advantages—such as strengths in research and development (R&D).

The policy environment in Australia is shaped by Government measures to achieve the appropriate balance between its health and industry objectives—ensuring timely availability of necessary drugs and a viable local pharmaceutical industry—and budgetary objectives—achieving industry and health policy objectives at lowest possible cost to the community.¹

The need to balance the interests of Government and pharmaceutical companies arises because of the direct relationship between the cost of drugs to Government and revenue from drug sales to companies through the Pharmaceutical Benefits Scheme (PBS).

The trade-off between budgetary and industry objectives is also influenced by other Government policies, such as the Pharmaceutical Industry Development Program (PIDP). Factor f, one element of the PIDP, is discussed in Chapter 11. Intellectual property arrangements for pharmaceutical products, another element of the PIDP, are discussed in Chapter 16.

¹ Government health and industry policy objectives are enshrined in the National Medicinal Drug Policy (see Chapter 2).

The focus of this Chapter is on the impact of the PBS on companies' revenues and the availability of drugs in Australia (the impact of the PBS on the level of local industry activity is discussed in Chapter 12).

The PBS affects companies' revenues and drug availability in three major ways. By providing a subsidy to consumers of drugs supplied through the PBS, it can boost total consumption and therefore company sales. This is called the subsidy effect (see Section 8.2).

The PBS can also affect companies' revenues through influencing the prices companies receive for products listed on the PBS.

Through the PBS, the Commonwealth Government is the dominant purchaser of pharmaceuticals in Australia. The Government attempts to exploit its monopsony position by negotiating low prices for drugs. This is called the price effect of the PBS (see Section 8.3).

The third way in which the PBS can influence companies' revenues is through imposing various market restrictions on certain drugs (see Section 8.4).

While it is possible to identify the ways in which individual factors (subsidy, price and market restrictions) affect companies' revenues, for policy purposes, it is the net effect that matters (see Section 8.5).

Apart from companies, the PBS also affects the community by influencing the availability of drugs (see Sections 8.6). The Chapter concludes with a discussion of the major pressures facing the PBS (see Section 8.7).

8.2 Subsidy effect

The operation of the PBS was described in Chapter 4. It noted that one of the aims of the PBS subsidy is to reduce the price of selected drugs to consumers. In theory, the subsidy should lead to an increase in drug purchases and a commensurate rise in companies' revenues. However, the magnitude of the subsidy effect is subject to some debate.

One possible way of examining the magnitude of the subsidy effect is to look at international comparisons of per capita prescription volumes (see Table 8.1).

International comparisons reveal that drug prescriptions per capita in Australia are similar to most other industrialised countries. This is despite differences in subsidy arrangements between countries.

Table 8.1: Number of prescriptions per capita dispensed through community pharmacies, 1991 to 1993 ^a

<i>Country</i>	<i>1991</i>	<i>1992</i>	<i>1993</i>
Australia	9	9	9
Canada	8	7	8
Ireland	9	9	9
New Zealand	7	7	7
UK	8	8	9
US	7	7	9

a Government-subsidised as well as private prescriptions dispensed through community pharmacies. These statistics are not strictly comparable because in some countries a significant number of prescriptions are distributed through alternative outlets such as hospital pharmacies and dispensing doctors.

Source: Feros, Riley & Associates sub. 181, Attachment 3, p. 3

However, there are a number of problems with using per capita prescriptions to show that drug purchases in Australia are not affected by the consumer subsidy. Most importantly, valid international comparisons would need to account for a range of factors, such as differences in income levels, Government policies (for example, the level of Government subsidy), methods of dispensing prescriptions, prescription sizes, the range of drugs available and doctors' prescribing habits. No implications can be drawn from the comparison of per capita prescriptions because of the failure to account for these factors.

A number of economic studies have attempted to examine the magnitude of the subsidy effect of the PBS. These studies have attempted to estimate the responsiveness of demand for drugs to changes in the price (called the 'own-price elasticity of demand' for prescription pharmaceuticals). The studies tend to suggest that the PBS has a positive but small subsidy effect.

A study by the Bureau of Industry Economics (BIE) (1985) found that total demand for subsidised drugs was relatively insensitive to price. It estimated that the own-price elasticity of demand for subsidised drugs was in the range -0.17 to -0.25. That is, a 10 per cent reduction in the price faced by consumers would be expected to lead to an increase in the quantity of subsidised drugs demanded of between 1.7 and 2.5 per cent.

In evaluating the BIE's study, the Industries Assistance Commission (IAC) (1986b, p. 87) noted that the volume of subsidised drugs under the PBS had not responded much to variations in consumer copayments. Nevertheless, the IAC considered that the increase in drug demand resulting from the PBS as a whole

could not be dismissed as insignificant—even if the own-price elasticity of demand was low. Rather, the IAC concluded that the large size of the price reductions to consumers caused by the PBS subsidy may have induced a significant absolute increase in the volume of drugs purchased.

Another study, by Johnston (1990), analysed changes in demand when the Australian subsidy arrangements were changed in 1986. Under these changes, the general copayment was doubled, the concessional copayment was increased by 25 per cent and a numerical safety net of 52 prescriptions per year was introduced (see Appendix B). Johnston estimated that the elasticity of demand to changes in the copayment arrangements was at least -0.25. That is, a 10 per cent increase in the size of the copayment would be expected to reduce the consumption of subsidised drugs by at least 2.5 per cent.

In assessing the effect of the PBS subsidy on companies' revenues an important consideration is that not all drugs receive a subsidy. Subsidising the consumption of PBS drugs should lead to a rise in drug purchases and a commensurate rise in the revenues of PBS drug suppliers. However, some of the increase will be at the expense of suppliers of non-subsidised products—suppliers to the non-PBS market may face a smaller market than would exist in the absence of the scheme.

On balance, the available evidence suggests that the PBS subsidy has a positive effect on total consumer demand for subsidised drugs and hence, companies' revenues. Even though overall price elasticities are likely to be low, the large size of the subsidy, particularly for concessional users, is likely to have led to increases in the volume of drugs purchased.

8.3 Price effect

Apart from increasing the overall demand for pharmaceuticals, the PBS aims to hold down the prices of drugs supplied by companies. While the industry and Government generally acknowledge that the PBS has suppressed drug prices in Australia below those overseas, the focus of debate has been on the extent of price suppression.

The Commission has examined two approaches to estimating the effect of the PBS on drug prices:

- company perceptions as to what their prices would be in the absence of the PBS; and
- international comparisons of prices (see below).

Assessing the magnitude of the price effect of the PBS is complicated by the existence of different categories of drugs.

8.3.1 Price suppression for different categories of drugs

The PBS may not have the same effect on all drug prices. In general, the price effect of the PBS will vary depending on the number of competing drugs in the market.

The pharmaceutical industry is generally considered to be competitive (see Chapter 2). However, patents and the ability of companies to differentiate their products, can give companies some monopoly power for certain products. World prices for certain products, particularly new products with few substitutes, will reflect the market power of companies.

A useful way of categorising drugs listed under the PBS is presented below:

- category 1 drugs—unique, breakthrough drugs that are the only effective form of treatment and where there is no direct substitute;
- category 2 drugs—drugs that are first in a new therapeutic class with equivalent efficacy to other drugs but with quality of life and/or safety improvements;
- category 3 drugs—me-too drugs in the same chemical family with no additional benefits; and
- category 4 drugs—out of patent products.²

The price effect of the PBS is likely to differ for each of these categories of drugs.

Category 1 drugs are the only drugs available to treat or cure a particular disease and therefore occupy a monopoly position in the market. For these drugs, the Government is in a relatively weak bargaining position and PBS prices are likely to be closer to their world average. Hence, companies may be able to earn monopoly profits for some time. However, because competition from other drugs is usually quick to emerge, there are generally only a few (possibly only four or five) drugs in this position in the market at any one time.

Category 2 drugs provide consumers with additional benefits not offered by alternative drug treatments. While these products may provide companies with some monopoly power, they face competition from suppliers of other products within chemical families and from different chemical families that can treat the

² This categorisation was suggested by Merck, Sharp & Dohme (sub. 174, p. 1).

same disease.³ For these drugs, the PBS has a greater potential to suppress prices below the world level.

Category 3 drugs are likely to have close substitutes and, hence, compete directly with other drugs. Producers may be able to exercise limited market power through targeting niche markets and the use of brand names. For these products, the PBS can be very effective in suppressing prices below world levels.

Category 4 drugs are subject to generic competition from chemically equivalent products. However, these drugs can maintain price differentials for a variety of reasons including consumer brand preferences—illustrating the importance of company reputations. While price competition is important for generic copies, originators of innovator brands often prefer to maintain high prices (at the cost of market shares) to preserve perceptions of higher quality.

The PBS may reduce prices for innovative brands in this category. However, there is no evidence that it suppresses prices for generic copies. Even for innovator brands, PBS price suppression can be illusory. That is, companies can voluntarily place brand premiums on their products but these will have to be funded by consumers out of their own pockets. Hence, brand premiums may represent a company's decision on a clear volume and price trade-off. In this case, competition should work to reduce costs to consumers and price suppression becomes less of an issue.

The implications of the price effect of the PBS on different categories of drugs is discussed in Section 8.5.

8.3.2 Company perceptions

Industry surveys and company submissions showed that companies believe that the PBS does suppress Australian drug prices below overseas prices.

In examining the price effect of the PBS, the BIE (1991) surveyed company perceptions of how drug prices might change in Australia if the Government did not control drug prices to either suppliers or consumers. The BIE noted that this was a hypothetical scenario and cautioned that the findings should be interpreted as being only broadly indicative of the likely price responses.

Overall, the BIE (1991 pp. 38–39) found that around 80 per cent of respondents thought that their own prices would be higher in a deregulated environment. In

³ For example, there are several classes of drugs (from different chemical families) used to treat hypertension some of which are more effective in particular patients than others.

turn, 80 per cent of these companies considered that prices would be between 5 and 20 per cent higher and the remainder more than 20 per cent higher.

In 1995 the BIE repeated this survey and reached a similar conclusion. Around 70 per cent of respondents thought their average price levels would be higher in a deregulated price environment. Of the 21 companies surveyed, 18 provided an estimate of the extent to which they thought prices would be higher—the average was 22 per cent, and the median was 18 per cent (BIE 1995, p. 13).

The BIE also noted that, where products were out of patent, respondents anticipated little, if any, price increase under a deregulated price environment (BIE 1995, p. 13).

8.3.3 International price comparisons

When making international price comparisons, it is important to consider three issues. Briefly, there are problems in choosing an appropriate benchmark country, selecting an appropriate basket of goods as the basis for comparison and identifying the appropriate prices to be used.⁴

Surveys of pharmaceutical companies have shown that companies believed that Australian drug prices would need to rise by between 80 and 100 per cent to reach average world prices or by around 40 per cent to reach the European Union (EU) average (BIE 1991). However, as noted above, companies believed that if the PBS was removed, Australian prices would only rise by around 20 per cent.

On this basis it could be concluded that companies do not expect that Australian drug prices would rise to world average levels in the absence of the PBS. Indeed, even the EU average would appear to be very much an upper limit to the price levels which might prevail in a deregulated pricing environment (BIE 1991, p. 39).

The upshot of this is that in any international comparison of drug prices, EU average prices are likely to provide the most useful guide to those that would exist in Australia in the absence of the PBS pricing system. Companies are unlikely to object to the use of EU prices as a benchmark for comparing prices since companies themselves did not think that Australian prices would reach EU average levels in the absence of the PBS. Therefore, the use of EU prices as a benchmark would not discriminate against those selling in the Australian market.

⁴ Methodological problems associated with international comparisons of drug prices are discussed in more detail in Appendix H.

In using international comparisons to assess the magnitude of the PBS price effect, the Commission examined two sources of information—price comparisons provided by companies and price comparison studies.

Company price comparisons

A number of companies submitted international price data for their products to support claims that PBS prices are significantly below those they receive in other developed countries. These included Merck, Sharp & Dohme (sub. 27, Schedule 4), SmithKline Beecham (sub. 13, Attachment 4), Glaxo Wellcome (sub. 143, p. 7 and sub. 144, p. 5), Astra (sub. 141, p. 16), Faulding (sub. 129, Attachment 1), Eli Lilly (sub. 142, p. 6) and CSL (sub. 118, p. 16).

Examples of relative prices for selected products are presented in Table 8.2 (see Appendix H for further details).

Apart from the information on prices of specific products, participants also provided anecdotal evidence suggesting that PBS prices for some products are increasing, particularly since the adoption of cost effectiveness analysis by the Pharmaceutical Benefits Advisory Committee (PBAC) in its decision making. For example, in discussions, participants suggested that certain classes of antiepileptic and antipsychotic drugs have been granted higher prices than they would have received in the past because of the results of cost effectiveness studies for these drugs.

Some companies acknowledged that PBS prices granted for some newer products were moving closer to world prices. For example, Glaxo Wellcome conceded that:

... for a number of our more recent products [Serevent and Flixotide] they may be getting listed at closer to world average prices (roundtable, p. 298).

AMRAD also conceded that ‘PBS prices are edging closer to international averages’ (sub. 24, p. 23).

However, the Australian Pharmaceutical Manufacturers Association (APMA) and Pfizer (sub. 133, p. 8) argued that perceived price increases may be limited to a small range of products.

For instance, the APMA said that:

... there’s a perception that some of the newer products have received higher prices and have got much closer to the European level. Well, that may be the case in some product categories, perhaps where the products have a unique feature or they’re not in a crowded therapeutic category. But in other instances where the therapeutic category has plenty of players at the moment, I’m not sure that those pricing levels have risen very much at all (roundtable, p. 9).

Table 8.2: Relative prices of selected pharmaceuticals

<i>Company</i>	<i>Pharmaceutical</i>	<i>Form</i>	<i>Aust. price as a % of European price</i>
Merck, Sharp & Dohme	Sinemet CR	50/200 mg 100 tablets	61
	Zocor	10 mg 100 tablets	76
	Renitec	5 mg 100 tablets	94
	Indocid	25 mg	42
SmithKline Beecham	Floxapen	Syrup 125 mg	73
	Amoxil	Syrup/suppression 250 mg	58
	Floxapen	Capsule 500 mg	43
	Tagamet	Effervescence	41
Glaxo Wellcome	Lamictal	100 mg tablets	75
	Becloforte inhaler	250 µg	40
	Flixotide	250 µg	80
	Zantac	150 mg tablets	33
Astra	Losec	20 mg	64
	Bricanyl	Turbuhaler 500 mg 200 d	42
	Imdur	60 mg	75
	Pulmicort	Turbuhaler 200 u/d 200 d	29
Faulding	Glyceryl	-	68
	Vancomycin	-	98
	Cytarabine	-	74
	Carboplatin	-	32
Eli Lilly	Prozac	-	96
	Ceclor	-	59
CSL	Clavulin	-	50

Sources: Merck, Sharp & Dohme sub. 27, Schedule 4; SmithKline Beecham sub. 13, Attachment 4; Glaxo Wellcome sub. 143, p. 7 and sub. 144, Appendix 1; Astra sub. 141, p. 16; Faulding sub. 129, Attachment 1; Eli Lilly sub. 142, pp. 6–7; CSL sub. 118, p. 17

Faulding considered that any general increase in PBS prices was confined to the late 1980s and early 1990s and was shortlived:

It is possible that after the last IAC inquiry (1987–88) some new products did launch at prices closer to world average prices. However since the introduction of the Generic Pricing policy and in particular the cost effectiveness guidelines, there has been no improvement in the Australian pricing situation versus world average prices. In fact, the situation has worsened for some therapeutic categories (sub. 85, p. 16).

In summary, evidence provided by companies suggests that prices of some drugs in Australia are relatively low but that the prices of some newer drugs are increasing.

The problem with drawing any firm conclusions from the evidence discussed in this Section is that product prices are drawn from a non-representative, self-selected sample limited to a few companies and their products. A number of studies have been undertaken since the late 1970s that attempt to examine the differences between Australian and overseas prices in a more rigorous manner. These can be divided into past studies (undertaken prior to 1995) and recent studies undertaken for this Inquiry.

Past price comparison studies

Various attempts have been made to draw general conclusions about prices by quantifying the difference between PBS prices and prices in markets overseas across a broad range of products. Although subject to some qualifications, these studies have found that unweighted Australian prescription drug prices have ranged between 41 and 86 per cent of various measures of world prices. These studies are summarised in Table 8.3 and described in more detail in Appendix H.

The conclusions of many of these studies should be qualified on the following grounds:

- most are quite dated (they may not account for recent increases in Australian prices or reductions in overseas prices);
- early studies often compared Australian prices with a broad range of overseas markets, including high price countries such as the US and Japan, without identifying the most relevant benchmark countries; and
- studies tended to group all products in terms of a single unweighted average price, not reflecting the expenditure pattern of the PBS or the real impact of the PBS on companies' revenues.

Trends in relative prices cannot be identified from these studies. The use of different baskets of goods, different benchmark countries and different time frames also results in a series of largely unrelated 'snapshots' of relative prices.

Price comparison studies prepared for this Inquiry

In response to a request for better quality price comparisons the Commission received information from the APMA, comparing Australian prices with world prices, and information from the PBPA, comparing Australian prices with UK prices. This information provided the most recent representative picture of

relative prices, as comparisons were made on the basis of average prices across a broad range of high cost drugs on the PBS within the last two years (see Table 8.4).

Table 8.3: International drug price comparison studies conducted prior to 1995

<i>Study</i>	<i>Year</i>	<i>Benchmark country</i>	<i>Basket of products</i>	<i>Unweighted price %^a</i>
Ralph Inquiry	1978	10 countries ^b	25 branded PBS drugs	'lowest'
Reekie	1982	US	major selling drugs	61
	1982	UK	of 9 multinational	71
	1982	Europe	drug suppliers	86
APMA	1982	12 countries ^c	58 drugs, 54% PBS	56
	1982	9 countries ^d	sales by value	71
Parry & Thwaites	1987	11 countries ^e	80 largest selling products in Australia	55
BIE	1991	EU	20 out of top 24 selling products in Australia	55
	1991	EU	80 largest selling products in Australia	70
Parry & Creyke	1990	'World average price'	80 largest selling products in Australia	50
APMA	1994	OECD ^f	top 50 products by consumption in New Zealand	41

a Unweighted Australian prices as a percentage of unweighted overseas prices.

b They are UK, NZ, South Africa, Germany, France, Italy, the Netherlands, Japan, the US and Canada.

c They are Austria, Belgium, Canada, Finland, Germany, France, Italy, Japan, the Netherlands, Spain, the UK and the US.

d Same countries as (b) but excludes Germany, Japan and the US.

e Same countries as (b) but excludes Italy.

f Organisation for Economic Co-operation and Development.

Sources: Ralph 1979; Reekie 1984; IAC 1986; Parry & Thwaites 1988; BIE 1991; Parry & Creyke 1991

Both the APMA and PBPA data also allowed relative prices to be weighted by Australian sales volumes. As discussed above, the use of unweighted prices is a major weakness of previous studies.

Table 8.4: Recent international drug price comparison information prepared for this Inquiry

<i>Study</i>	<i>Year</i>	<i>Benchmark country</i>	<i>Basket of products</i>	<i>Unweighted price %^a</i>	<i>Weighted price %^b</i>
APMA	1995	OECD	top 38 products by sales in Australia	71	54
APMA	1995	OECD	23 (19) products launched since January 1993 ^c	85	70
PBPA	1996	UK	69 (50) products by highest cost to Government as at January 1996 ^d	84	67
PBPA	1996	UK	36 (20) products launched since January 1993 ^e	92	83

a Unweighted Australian prices as a percentage of unweighted overseas prices.

b Weighted Australian prices as a percentage of weighted overseas prices. Prices are weighted by Australian sales volumes for each product.

c The product sample size was 19 for the weighted calculation.

d The 50 highest cost drugs as at January 1996 were used in the weighted calculation.

e The 20 highest cost drugs as at 1994–95, launched since January 1991 were used in the weighted calculation.

Sources: APMA sub. 31, p. 8; APMA 1995b; PBPA sub. 168

APMA information

The APMA provided price comparison data for Australia and a broad range of OECD countries (APMA sub.119, Attachment 4).⁵ Comparisons were undertaken for two categories of products—leading products and new products. The 38 leading products made up over 70 per cent of the 50 highest cost active substances listed on the PBS. New products referred to those products launched in Australia after 1 January 1993 and which each achieved annual sales of at least \$0.5 million by June 1995. The price data for Australia and overseas countries were weighted by volume to reflect the expenditure pattern of the PBS or the real impact of the PBS prices on companies' revenues.⁶

Like other studies, the APMA price comparison study is subject to limitations and not strictly comparable to earlier studies.

⁵ Subsequent revisions of information in the Pricing Report (APMA 1995) were also provided by the APMA for this inquiry (see APMA sub. 119, Attachment 4 and APMA correspondence 7 February 1996).

⁶ The weighting was by Australian sales volumes (as opposed to overseas sales volumes).

The international reference price for each drug was extracted only for those countries where there were sales of the identical product in terms of strength and dosage form. Where there was no equivalent product, the country was excluded from the calculation. Therefore, rather than a single consistent world average price, a moving basket of countries provides the reference price.

A wide range of countries were included in the overall basket.⁷ However, it included some which may be inappropriate benchmarks for Australia. The relatively ‘free market’ approach adopted in the US has led to relatively high prices in that market, which may distort the world average. Similarly, particular features of the Japanese market have led to Japanese prices being regarded as much higher than those in most of the rest of the world.

Where multiple brands of a product were available in a country, an arithmetic average was calculated to determine the price for that country. If higher priced brands have below average market shares, this will overestimate the weighted average price.

Despite these possible weaknesses, the APMA study represented a major improvement on previous studies because of the inclusion of weighted average price results. The significance of this can be gauged by comparing the differences for the unweighted and weighted price comparisons in Tables 8.3 and 8.4.

Key study results were:

- the unweighted average of the PBS prices of the 38 leading products is 71 per cent of unweighted world prices;
- the unweighted average of the PBS prices of 19 new products is 85 per cent of unweighted world prices;
- the weighted average of the PBS prices of the 38 leading products is 54 per cent of weighted world prices; and
- the weighted average of the PBS prices of 19 new products is 70 per cent of weighted world prices.

⁷ The basket of countries is made up of the US, the UK, France, Japan, Germany, Canada, Italy, Spain, the Netherlands, Belgium, Portugal, Greece, Austria, New Zealand, Turkey, Finland and Ireland.

PBPA information

The PBPA provided the Commission with unweighted price comparison data as at January 1996 for Australia and the UK for the 69 highest cost⁸ products sold on the PBS in 1995 and for 36 products launched since 1993 (sub. 168, p. 5).

The PBPA data avoided the problem of having to use a moving basket of countries because a single country is used as a comparator. However, it assumes the UK is a reasonable benchmark country for Australia.⁹

The Commission weighted the relative prices of the 50 highest cost drugs¹⁰ and the 20 highest cost drugs launched since 1993 by their 1995 Australian sales volumes to create weighted price comparisons.

Key study results were:

- the unweighted average of prices of the 69 highest cost products on the PBS is 84 per cent of unweighted UK prices;
- the unweighted average of prices of 36 products launched since 1993 is 92 per cent of unweighted UK prices;
- the weighted average prices of the 50 highest expenditure drugs on the PBS is 67 per cent of weighted UK prices; and
- the weighted average prices of the 20 highest cost drugs launched since 1991 on the PBS is 83 per cent of weighted UK prices.

8.3.4 The Commission's view

The information on relative prices provided in response to the Draft Report supports claims that drug prices under the PBS are lower than EU prices. The information also suggests that the gap is probably narrower for newer drugs.

Weighted price comparisons from the APMA and the PBPA cover a broad range of drugs which make up a significant share of Australian drug sales. They suggest that Australian prices are somewhere between 50 and 70 per cent of overseas prices for top selling drugs, but somewhere between 70 and 83 per cent for newer drugs.

The available evidence also suggests that the PBS is a cause of the difference between domestic and overseas prices. That said, it is not clear whether, in the

⁸ Highest annual cost to the budget.

⁹ UK prices are considered reasonably representative of average European prices.

¹⁰ These collectively made up 46 per cent of total expenditure under the PBS in 1995.

absence of the PBS, local drug prices would rise to the EU average. Because markets for drugs differ, it is impossible to say whether Australian prices would remain below or rise above EU prices. If Australian drug prices were to rise, companies' revenues would rise.

FINDING

The Commission finds that Australian drug prices are significantly below international drug prices. However, this difference appears to be decreasing over time.

8.4 Market restrictions

Apart from influencing drug prices, the PBS limits the overall market for drugs by imposing market restrictions on listed drugs. Restrictions, including limiting indications for which drugs are listed and applying authorisations to the listing of some drugs, were discussed in Chapter 4. This Section focuses on company concerns that market restrictions are used to contain Government costs, without due consideration for the Government's health and industry development objectives. Delays in the listing of some drugs onto the PBS may also restrict the market for drugs (see Chapter 9).

8.4.1 Limited indications

For a drug to be listed on the PBS, indications need to be specified. The indications for which a drug is listed determine the conditions for which the drug can be prescribed under the PBS and hence for which the consumer subsidy is available. This can influence the size of the market (or potential sales volume) for a drug.

Some companies argued that approved indications for some drugs are too narrow and that this has led to disparities between the Therapeutic Goods Administration (TGA) and PBS approved indications, as well as between indications for certain products in Australia and comparable countries overseas. For instance, the APMA said that:

This comes back to the ... terms of the limitations that are placed upon a product, even when it gets its listing on the PBS. Its range of indications may be severely limited and it is only available on the PBS within a very narrow indication (roundtable, p. 298).

Similarly, Glaxo Wellcome claimed that:

Almost all of Glaxo Wellcome's more recently introduced products are subject to PBS restrictions that lead to quite significant market access gaps [between conditions

approved by the TGA and the PBAC]. This is not the case with such products in comparable countries (sub. 144, p. 8).

Companies such as Glaxo Wellcome, Pfizer and Eli Lilly said that the PBAC is trading-off indications against prices negotiated under the PBS as a way of containing the overall costs of the PBS subsidy. For example, Glaxo Wellcome stated that:

There is a strong inverse relationship between the market access parameter and the pricing parameter, particularly in the case of products with significant market potential. This means that 'reasonable' market access will often come at the expense of a poor price, and a 'reasonable' price can be achieved only at the expense of limited market access (sub. 144, pp. 8–9).

Restricting indications can lead to consumers being denied the benefits of a drug. For example, the Glaxo drug Imigran has been submitted for PBS listing for the treatment of migraine attacks, but only where certain other therapies are considered inappropriate. As a result, if listed, Imigran will only be available to 15 per cent of patients for which its broader uses have been approved (sub. 144, Appendix 1).

In addition, limited indications can reduce companies' revenues from the sale of products. Two companies provided examples of drugs with relatively narrow indications (see Box 8.1). Other examples were provided to the Commission on a confidential basis. Companies did not provide any estimate of the revenue effects of narrow indications.

PBAC argued that limiting the indications of drugs under the PBS is justified on the grounds of cost effectiveness. As stated by PBAC:

Cost effectiveness ... gives a very clear indication from the clinical studies of what ranges of uses should be subsidised (transcript, p. 752).

The Australian Pharmaceutical Advisory Committee (APAC) supported this and argued that:

These things are peer evaluated by experts in their area and they would believe that the evidence for this indication is justified, but currently for this indication it is not (transcript, p. 327).

8.4.2 Authorisations

Authorisations are another way in which the PBS restricts the market for some drugs (see Chapter 4). Around 15 per cent of pharmaceutical substances listed on the PBS are restricted by authorisations. The market (or potential sales volume) for these drugs can be restricted by such authorisations.

Several companies argued that authorisations unnecessarily restricted the potential market for some of their products. Some companies, in discussions with the Commission, suggested that authorisations are used to restrict PBS costs for some products.

Box 8.1: Drugs listed with relatively narrow indications

Pfizer

Diflucan was launched in 1991 as an anti-infective with particular emphasis on immune-compromised patients (for example AIDS and chemotherapy patients). It received listing as an Authority Required item in 1992. Diflucan is not listed for its other approved and more general indication, vaginal candidiasis.

Zithromax is an antibiotic therapy which offers benefits across a wide range of common infective illnesses (for example, respiratory tract infections). In 1995 Zithromax received a listing for a single indication (urethritis and cervicitis due to *Chlamydia trachomatis*) and is unavailable in its general dosage form.

Glaxo Wellcome

Flixotide was listed in 1995 for withdrawal or reduction of oral corticosteroids in patients whose asthma is poorly controlled by maximal doses of other inhaler corticosteroids (about 3 per cent of asthmatics). Flixotide is approved for the prophylactic management of asthma in adults and children over four years (about 16 per cent of asthmatics). Its indication makes it available to 18 per cent of approved patients.

Serevent was listed in 1995 for patients with frequent episodes of nocturnal asthma who are receiving treatment with oral corticosteroids or maximal doses of inhaled corticosteroids (about 6 per cent of adults and 2 per cent of children). Serevent is approved for long term treatment of reversible airways obstruction in asthma (including nocturnal asthma) in patients aged four years or more who are receiving inhaled or oral corticosteroids, but not in patients whose asthma can be managed by occasional use of short-acting inhaled beta-2 agonist (about 17 per cent of adults and 6 per cent of children). Its indication makes it available to 33 per cent of approved patients.

Sources: Pfizer sub. 133, pp. 9–10; Glaxo Wellcome sub. 144, p. 5 and Appendix 1

The potential impact of restrictions on volumes was illustrated by an example provided by SmithKline Beecham. It claimed that the removal of unnecessary PBS restrictions on a drug called Tagamet led to a 322 per cent increase in sales volumes (sub 13, p. 29). Similarly, Eli Lilly argued that:

It is our view that Prozac's market share has been severely affected by supply constraints due to the authority required listing (sub. 142, p. 6).

Imposing authorisation restrictions on products can help ensure that drugs are used for their approved purposes. That said, imposing unnecessary restrictions can lower companies' revenues and reduce community access to beneficial treatments.

It is difficult to assess the extent to which authorisations are imposed unnecessarily. In discussions, the Commission was told that authorisations for some products have little effect on doctors' prescribing behaviour and company sales.

8.4.3 The Commission's view

Evidence presented to the Commission suggests that the PBS market for some drugs in Australia may be unnecessarily restricted by relatively narrow indications by international standards and authorisations on some pharmaceutical substances listed on the PBS. While the impact of these restrictions will vary from drug to drug, there is evidence to suggest that some restrictions may have been imposed unnecessarily.

Unnecessary restrictions limit company sales and reduce community access to pharmaceuticals.

FINDING

The Commission finds that limiting of indications for which some drugs are listed and the application of authorisations may have a significant impact on the sales volumes of some drugs.

Companies' sales revenues may also be adversely affected by unnecessary delays in getting their drugs listed on the PBS. This is discussed in Chapter 9.

8.5 Net effect

So far, this Chapter has examined three ways in which the PBS affects drug sales and availability (the subsidy and price effects and market restrictions). Evidence presented to this Inquiry and the Commission's analysis suggest that the PBS subsidy is unlikely to have a large impact on the overall market for drugs but its use of monopsony power and market restrictions has reduced prices and sales volumes for pharmaceutical companies.

The IAC (1986b) modelled the effects of the PBS on both demand for drugs and drug prices. It estimated how much the subsidy effect would have to increase sales to offset either a 25 per cent or a 50 per cent reduction in price. It concluded that the price effect is likely to outweigh the subsidy effect and that

this likelihood is greater the further prices are depressed. The low price elasticity of demand for drugs is likely to mean that this position still applies.

Based on the available information, the Commission believes that there is sufficient evidence to suggest that the negative impact on company sales of the price effect and to a lesser extent market restrictions, have outweighed the positive sales impact of the subsidy. However, there is insufficient information to estimate the magnitude of this effect.

That said, the overall impact is likely to vary for different products. For some drugs (such as innovative category 4 products) prices may be significantly below the appropriate (EU) benchmark. Similarly, limited indications have produced disparities between the approved indications of some drugs sold in Australia and overseas. In addition, the price effect of the PBS appears to be less significant for some new category 1 and 2 products. This suggests that the impact of the PBS may be spread unevenly between companies.

FINDING

The Commission finds that, overall, the Pharmaceutical Benefits Scheme has reduced pharmaceutical companies' sales revenues.

8.5.1 Ongoing information requirements

In Chapter 9, the Commission considers the case for creating an independent pricing authority. One of the proposed tasks for such a body would be to place a greater emphasis on overseas prices in any future decisions. In this context it is essential that appropriate data be available to policy makers. There is a need to monitor relative pharmaceutical prices and volumes in Australia compared to overseas markets in a more rigorous manner than has occurred in the past. As discussed above, the Commission considers EU drug prices and volumes to be the most appropriate benchmark for Australia.

A data base of Australian and EU drug prices and volumes would provide a valuable analytical tool for making pricing decisions. The existing or newly formed independent pricing authority could be best placed to maintain such a database (see Chapter 9).

Recommendation 8.1

The Commission recommends a data base of Australian and international pharmaceutical prices, volumes and market shares be established.

8.6 Impact of PBS on the availability of drugs

Companies have argued that low PBS prices, market restrictions and the PBS process itself (discussed in Chapter 9) have a detrimental effect on wider Government health and industry policy objectives. Although low prices and market restrictions may serve to reduce the cost of the PBS subsidy to the Government, at a certain point they may also lead to reduced availability of drugs in the Australian market.

The availability of drugs could be affected in a number of direct and indirect ways. As noted in Section 8.4.1, the existence of market restrictions, such as limited indications, directly reduces consumer access to drugs.

However, there are broader indirect effects as well. If companies expect that unacceptable prices or indications that are too narrow will be negotiated they may be reluctant to apply for PBS listing or delay application. Alternatively, they may decide to supply drugs on the private prescription market or enter into further negotiations.¹¹ In addition, delays inherent in the listing process itself may affect timely access to drugs (see Chapter 9).

The indirect effects of the PBS on availability of drugs may be accentuated if the low prices in Australia affect companies' revenues in overseas markets. One way that developments in Australia can affect companies' revenues overseas is through the practice of benchmark pricing.

8.6.1 Benchmark pricing

A number of participants claimed that it is increasingly common for companies not to market innovative drugs in Australia for fear that low PBS prices will become a benchmark that will 'flow on' to affect prices in overseas markets.¹²

As in Australia, overseas purchasers of drugs are facing rising pressure to contain costs. As a result, participants have argued that there is an increasing tendency for overseas drug purchasers to compare the price they pay to prices paid in other markets. Companies are less able to charge different prices in different markets ('price discriminate'). In response to the (real and threatened) benchmarking practices of overseas customers, companies indicated that they

¹¹ Another possibility is that a company may seek Government approval for a special patient contribution to cover the difference between the company's requested price and the price offered by the Government. This mechanism has only been approved in four cases to date.

¹² The Clinton Administration's 1994 proposed health reforms indicated a serious attempt to formalise a system of benchmark pricing which included Australia. However these reforms were not implemented (Grabowski 1994, p. 21).

are beginning to adopt narrow price bands which limit the range of acceptable prices, regardless of the country in which the product is to be sold.

In theory, it could be argued that, as long as companies have excess capacity, there is an incentive to sell in any market provided prices at least cover the marginal costs of production. The recent New Zealand experience, where most drugs still appear to be available despite company threats to withdraw from the market due to low prices, suggests that benchmark pricing is yet to have a significant impact on drug availability in other low price countries.

Prior to the Draft Report, the Commission received some evidence of benchmark pricing from Pfizer (see Table 8.5). However, because the examples relate largely to intra-European pricing comparisons, it is unclear whether Australia is used as one of the benchmarks.

Table 8.5: European inter-country price benchmarking, 1995

<i>Country</i>	<i>Price comparison countries</i>	<i>Comments</i>
Austria	Belgium, France, Germany, Italy, UK	Reimbursement prices usually below cross-border reference prices
Belgium	All EU countries	Price set at or below average price in these countries
France	All EU countries, Japan, Switzerland, US	Currently basis for negotiation only. Moves towards EU weighted average price
Ireland	UK wholesaler prices	Exchange rate fixed for 3 years
Netherlands	(Proposed) Belgium, France, Germany, UK	No current cross-border comparisons. Proposed law applies average price in comparison countries
Portugal	Spain, France, Italy	Lowest price in these countries applied
Spain	France, Italy, Belgium, UK, Germany	Price reduction sought on prices in these countries
Sweden	Austria, Belgium, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Switzerland, UK	Price set at or below median price in these countries. Price reduction if lower price in other countries after launch in Sweden.
Switzerland	Denmark, Germany, the Netherlands	Average price in these countries is applied

Source: Pfizer correspondence 6 November 1995

In its Draft Report the Commission requested information on the extent of the practice of benchmark pricing with Australia by overseas purchasers, but very limited additional evidence was received in response to this request. Some

information was provided by Glaxo Wellcome which stated:

Glaxo Wellcome has seen the reimbursement authority in New Zealand benchmark prices in that country against Australian prices. Benchmarking is also known to occur in Canada and Sweden (sub. 144, p. 9).

There is a perception amongst some companies that benchmarking will become more prevalent in the future, particularly as Governments seek further ways to restrain growing health budgets. For example Pfizer stated:

... now that [benchmark pricing] is in actual use, [it] is likely to be extended to include as many national markets as possible. ... as an advanced nation, with recognised low prices, Australia is likely to be included in benchmark pricing data sets (sub. 133, p. 5).

Similar comments were received from Astra (sub. 141, p. 6) and Glaxo Wellcome (sub. 144, pp. 9–10).

Some companies also said that despite its limited current use, the threat of benchmark pricing has the potential to influence company behaviour.

Pfizer argued that it could not accept a low Australian price for its product Zolofit, as it could jeopardise the price of the drug in the significantly larger US market:

Given the importance of the largest Northern Hemisphere markets to the corporation, Pfizer's international headquarters determined that it could not in the future accede to unreasonably low prices to obtain listing in Australasia (sub. 79, p. 14).

Similarly, Merck, Sharp & Dohme submitted that its policy of a single target price may mean innovative products from its product range will not be made available on the PBS in the future (or will be listed on the PBS a long time after the products are launched elsewhere) (sub. 27, p. 7). Merck, Sharp & Dohme argued:

... pricing is the most critical issue, the absolute level of price for new products particularly, and even if our prices were to go to 80 per cent of world average or OECD average or European average, this would still not be good enough because it wouldn't remove that threat to other countries, and Australia is quite a small market and companies like Merck would be prepared to give away the Australian market to protect the European market for example (transcript, p. 393).

One company also linked the trade-offs between indications and prices mentioned earlier to this threat. Glaxo Wellcome said that its refusal to negotiate on the price of Flixotide, due to the threat of benchmark pricing by other countries with Australia, had led to the imposition of market restrictions. As a result, Australia was the only country that had restricted the product to the

severe end of the asthmatic market (Glaxo Wellcome correspondence 16 February 1996).

As the industry increasingly takes on a global focus the withholding of drugs because of benchmarking is likely to become a more important issue.

FINDING

The Commission finds that there is limited evidence of international benchmark pricing with Australia. The Commission, however, accepts that the threat of benchmark pricing may affect decisions about the supply of drugs to Australia and that this threat is likely to increase.

8.6.2 Evidence on availability of drugs under the PBS

There are currently around 1600 products (or 537 pharmaceutical substances) listed on the PBS, representing the vast majority of drug treatments available overseas.

In its Draft Report, the Commission itemised drugs which companies said were not available in Australia or for which availability was significantly delayed because of the PBS. The Commission also requested further information on:

- drugs with significant therapeutic benefit for which there are no close substitutes and that are not available in Australia;
- similar drugs for which availability has been excessively delayed; and
- the market shares held by such drugs in other markets.

There may be other reasons besides the PBS for companies deciding not to market (or delay the marketing of) a product in Australia. For example, there may already be a large number of products competing in the market.

Information submitted by companies on drugs unavailable in Australia and drugs for which availability has been excessively delayed¹³—together with comments from the Pharmaceutical Benefits Branch (PBB)—have been presented as follows:

- drugs for which PBS listing was significantly delayed (see Box 8.2).
- drugs submitted for PBS listing but not listed (see Box 8.3); and
- drugs not submitted for PBS listing (see Box 8.4);

¹³ It is not clear whether excessive delays are caused by the company involved or the PBB.

Box 8.2: Drugs for which PBS listing was significantly delayed

Listing of Flixotide was delayed 20 months following its marketing approval date (Glaxo Wellcome, sub. 144, Appendix 1).

PBB: The product was approved for marketing in November 1993 and recommended for listing by the PBAC at its meeting in February 1994, but the company declined listing.

Listing of Serevent was delayed 2 years following its marketing approval date (Glaxo Wellcome, sub. 144, Appendix 1).

PBB: The product was considered by the Australian Drug Evaluation Committee in February 1993 and presented to PBAC in May 1993. This application was deferred pending advice from the Thoracic Society on the place of long acting beta agonists (there were reports that they may worsen asthma). Listing was recommended by the PBAC at its following meeting in August 1993. Any subsequent delay was due to the sponsor declining to list at that time.

Listing of Imigran has been delayed for more than 49 months following its marketing approval date (Glaxo Wellcome, sub. 144, Appendix 1).

PBB: Applications were rejected by the PBAC at its meetings in June and October 1992 due to concern about the safety of the product when used in the wider market and also about cost effectiveness (no cost effectiveness analysis was provided with the initial application. Listing of a 100 mg Sumatriptan tablet (Imigran) was recommended at the February 1993 PBAC meeting. This recommendation has since been rescinded in view of the availability of a 50 mg tablet (of similar efficacy but better side effects profile). The delay in listing after February 1993 was due to the sponsor declining to list.

Listing of Ceclor was delayed nine years following its marketing approval date (Eli Lilly Australia, sub. 142 p. 6) .

PBB: Marketed in Australia (mainly to hospitals) from 1981 and first PBS application was late 1986. Recommended for PBS listing at the PBAC's February 1987 meeting. The delay to actual listing in 1989 was due to the sponsor declining to list earlier.

Listing of Noroxin ophthalmic was delayed over 5 years following its marketing approval date (Merck, Sharp & Dohme, sub. 122, p. 3).

PBB: Initial application considered by the PBAC in June 1990 but deferred pending advice from the College of Ophthalmologists. Advice from the College was delayed and the matter was not reconsidered until October 1991. It was then again because of a general review of eye drops. Listing was recommended by the PBAC in February 1992. Any subsequent delay was due to the sponsor declining to list at that time.

Sources: Various submissions and PBB correspondence 19 April 1996

Box 8.3: Drugs not listed on the PBS due to unsatisfactory price offer or market restriction

Drug	Treatment	Company
PedvaxHIB	vaccine	CSL (sub. 118, p. 17)
<i>PBB: Vaccines for child immunisation programs funded by the Commonwealth through schemes other than the PBS. Alternative drug is listed on the PBS.</i>		
Daivonex	psoriasis	CSL (sub. 118, p. 18)
<i>PBB: Relatively expensive for small additional benefit over current therapy. The data presented so far have suggested that the cost effectiveness is unacceptable. Alternative drug is listed on the PBS.</i>		
Lispro	insulin	Eli Lilly (sub. 142, p. 7)
<i>PBB: Product only recently approved for registration and PBS application received in March 1996 for consideration by the PBAC at its next meeting. Alternative drug is listed on the PBS.</i>		
Hytrin	benign prostatic hyperplasia	Abbott (sub. 48, p. 6)
<i>PBB: Improvements in symptoms due to the drug are relatively small and acceptable cost effectiveness has been unable to be substantiated. Alternative drug is listed on the PBS.</i>		
Zinnat	oral antibiotic	Glaxo Wellcome (sub. 144, p. 10)
<i>PBB: Recommended for listing in May 1993. Sponsor subsequently withdrew application. Alternative drug is listed on the PBS.</i>		
Dicodin	moderate to severe pain	SmithKline Beecham (sub. 13, p. 27)
<i>PBB: Listing recommended by the PBAC in March 1995. Cost effectiveness compared to codeine not supported by data. The community is not being denied an important drug.</i>		
Noroxin	ophthalmic solution	Merck Sharp & Dohme (sub. 27, p. 8)
<i>PBB: June 1990 application deferred pending expert advice and general review of eye drops. Listing recommended February 1992, amended recently on the basis of bio-equivalence with other drops. Merck, Sharp & Dohme wanted a higher price for a broad patient group. Only cost effective at that price for a smaller group. There is an equivalent drug on the PBS.</i>		
Carduran	antihypertensive	Pfizer (sub. 79, p. 19)
<i>PBB: Argument over comparator. An old drug around since 1982, did not apply for listing till 1992. The PBAC recommended listing February 1992, as a marginal benefit over alternative alpha blocker. Company wanted comparator to be ACE inhibitors. Alternative alpha blocker is listed.</i>		
Oxybutinin	urinary incontinence	Fisons (sub. 35, p. 10)
<i>PBB: Alternative drug is listed. Application considered November 1994. Claimed superiority to existing drug not supported by clinical trials. Compromise price offer rejected by company.</i>		
Clarithromycin	antibiotic	Abbott (sub. 48, p. 5)
<i>PBB: Alternative drugs are listed. The PBAC recommended listing in December 1995.</i>		
<i>Sources: Various submissions, PBB correspondence 7 November 1995 & 1 April 1995</i>		

Box 8.4: Drugs not submitted for PBS listing due to expectation of unsatisfactory price or market restriction

<i>Drug</i>	<i>Treatment</i>	<i>Company</i>
Relifex/nabumetone	osteo & rheumatoid arthritis	SmithKline Beecham (sub. 13, p. 27)
<i>PBB: There are over 30 similar treatments available on the PBS. The sponsor requested listing outside marketing approval—the PBAC advised it would consider listing only in accordance with registration. Additional clinical studies currently under way may justify a higher price if relative effectiveness proved.</i>		
Dermovate and Cutivate	topical corticosteroids	Glaxo Wellcome (sub. 144, p. 10)
<i>PBB: No application made.</i>		
Lorabid	antibiotic	Eli Lilly (sub. 142, p. 7)
<i>PBB: No application made.</i>		
Tramal	analgesic	CSL (sub. 118, p. 19)
<i>PBB: No application made.</i>		
Zinacef	injectable antibiotic	Glaxo Wellcome (sub. 144, p. 10)
<i>PBB: No application made. Alternative drug is listed on the PBS.</i>		
Flixonase	perennial rhinitis	Glaxo Wellcome (sub. 144, p. 10)
<i>PBB: No application made. Alternative drug is listed on the PBS.</i>		
<i>Sources:</i> Various submissions, PBB correspondence 7 November 1995 and 1 April 1996		

Only two participants submitted quantitative information on international market shares of drugs not available (or severely restricted) in Australia (see Table 8.6).

Impact on consumers

The impact on consumers of the non-availability of specific drugs is unclear. Such drugs may be either close substitutes for existing drugs, or important breakthrough products. In response to Draft Report examples of drugs not available in Australia the then Department of Human Services and Health (now the Department of Health and Family Services) stated:

The examples ... have alternatives available and the non listing or listing delays could not be considered as disadvantaging the Australian community (sub. 153, p. 8).

Companies would most likely dispute such a claim.

Table 8.6: Sales of Daivonex (marketed by CSL) and market shares of Zithromax (marketed by Pfizer) 1995

<i>Daivonex</i>		<i>Zithromax</i>	
<i>Country</i>	<i>Sales of 30g units^a</i>	<i>Country</i>	<i>Share of market (%)^b</i>
Norway	42 800	Italy	14.9
UK	32 800	Finland	6.2
Sweden	30 000	Austria	5.4
France	17 100	Switzerland	4.7
Denmark	16 400	US	4.3
Holland	16 400	Norway	4.1
Switzerland	16 400	Turkey	4.0
Canada	12 900	Spain	3.4
Ireland	12 500	Belgium	3.3
Finland	12 100	Netherlands	3.2
New Zealand	12 100	France	2.6
Germany	10 000	Germany	1.4
Austria	8 600	Canada	1.4
Greece	7 500	Sweden	1.1
US	5 700	UK	0.9
Belgium	3 600	Australia	na
Australia	2 900		

a Per million inhabitants.

b Market defined as sales of oral systemic antiinfectives except trimethprims and older quinolones.

na not available

Sources: CSL sub. 118, p. 18; Pfizer sub. 97, p. 4

An independent indication of the relative importance of non-available drugs (or indications of drugs) could be their market share overseas. If they capture significant market shares, this may indicate that they have attributes which are superior to competing drugs. One limitation of this approach is that market share can reflect other factors such as marketing effort and the availability of substitutes or competing products in that market.

CSL provided international sales data for Daivonex which is not currently listed on the PBS but is available in most other developed countries as a treatment for psoriasis. These data (although not a measure of market shares) show that consumption of Daivonex per person is relatively high overseas (see Table 8.6).

Similarly, Pfizer provided market share data for Zithromax which is only listed on the PBS under authority, but available overseas to treat a wide range of infections. These data show that Zithromax has substantial shares of oral systemic antiinfectives markets overseas.

Overall, it would appear that, to date, Australia has been able to suppress drug prices and impose narrow market restrictions for some drugs with only marginal impact on their availability to consumers. However, there are signs that consumers are being denied access to drugs for the range of indications enjoyed by consumers in other countries. If this is the case, it is likely that the PBS will come under greater political pressure to which the Government will be forced to respond.

FINDING

The Commission finds there is evidence that the community's access to some drugs or important applications is adversely affected by the Pharmaceutical Benefits Scheme, but to date these effects have not been severe. There is risk of the situation worsening in the future.

8.6.3 Alternative ways of increasing availability

There are two possible ways in which drugs or certain indications for drugs can be made available in Australia without full subsidisation under the PBS:

- supply through the private prescription market; and
- extending the special patient contribution arrangements to allow for broader indications.

The private prescription market

The private prescription market provides an alternative for companies unable to negotiate a satisfactory PBS price. However, for a number of reasons, it is not considered commercially viable for most products. The private prescription market in Australia represented just 9.3 per cent of prescription drug sales in 1992–93 (AIHW 1994, pp. 141–143).

Participants raised several reasons why the private prescription market is not attractive to companies:

- excessive retail pharmacy mark-ups—the APMA argued that the lack of retail pharmacy competition has led to pharmacists charging much higher mark-ups and dispensing fees on ‘private’ or non-PBS prescriptions (sub. 31, p. 37);

- a tendency for doctors to prescribe PBS listed drugs—doctors may face pressure from patients to prescribe, wherever possible, drugs that are subsidised under the PBS (for example, doctors switched to prescribing PBS subsidised codeine when paracetamol was (briefly) delisted from the PBS); and
- the small private insurance market for drugs which offers only limited coverage to consumers (see Table 8.5).

Table 8.5: Private prescription insurance cover

<i>Insurer</i>	<i>Type of cover^a</i>	<i>Copayment required</i>	<i>Insurer payout</i>	<i>Annual limit</i>
Medibank Private	‘Super extras’	\$16.80	\$20.00	\$350.00
Medibank Private	‘Special extras’	\$16.80	\$15.00	\$200.00
Australian Unity		\$16.80	\$20.00	\$250.00
HBA	‘Premier extras’	\$16.00	100 per cent of drug cost	\$400.00
HBA	‘Your choice extras with hospital maximum’	\$16.00	100 per cent of drug cost	\$350.00
HBA	‘Your choice extras maximum’	\$16.00	100 per cent of drug cost	\$250.00
MBF	‘Health & wellbeing services’	No	60 or 80 per cent of normal charge	\$250 first year (\$500 in each subsequent 2 year period)

^a This cover is available only as an addition to private medical and hospital insurance.

As the BIE (1991) noted, supplying a product through the private prescription market is a commercial option only for breakthrough or ‘unique’ products with no close substitutes on the PBS, or for products that are relatively cheap and not aimed at pensioners and other concessional beneficiaries. The BIE concluded:

In most cases, companies can be thought of as being faced with the option of supplying Australia through the PBS ... or not supplying Australia at all (BIE 1991, p. 35).

Broadening indications

A feature of the PBS is that listing and hence the consumer subsidy, is confined to indications for which the product is deemed to be cost effective (at a certain

price) relative to other listed products. But because individual consumers place different values on the benefits of different drugs, which are not necessarily reflected in the cost effectiveness calculation, they may be willing to pay more for a drug (or particular indication) than the PBS cost effective price. As a consequence, some consumers will be denied access to drugs (or particular indications) for which they may be prepared to fund the difference between the PBS cost effective price and the price acceptable to the company. This inaccessibility can result in a loss in public welfare.

An alternative approach would be for the PBS to subsidise all indications of a drug up to their cost effective price and allow consumers to pay the difference between this price and the price acceptable to the company if they still perceive the drug to be valuable at the higher price.

Although extension of the PBS subsidy in this way would increase consumption of particular drugs, this could be offset by a decrease in consumption of other PBS listed products for which the PBS subsidy would have been paid. The overall impact on PBS cost is therefore likely to be minimal.

Consideration should be given to allowing consumers the option of obtaining products under the PBS for a wider range of indications provided they meet the shortfall between the market price and the cost effective price. In this way access to drugs could be improved without increasing the cost of the PBS subsidy.

Extending the special patient contribution arrangements to allow for broader indications is probably a more viable option for most drugs than the private prescription market, but alone, probably not sufficient to address non-availability, should it become more widespread.

8.7 Pressures on the PBS

Despite its longevity and apparent bipartisan political support, the PBS is a system under considerable pressure. This pressure is an inevitable result of the tension between budgetary and health policy objectives and in turn, between these and industry policy objectives.

Existing pressures on the PBS come from three major sources: Government, companies and consumers.

Government attempts to contain the rapidly escalating cost of the PBS is a major source of pressure. Over the decade to 1994–95, real outlays on pharmaceutical services and benefits grew by an average of 8 per cent real per annum. The key factors driving this growth have been the listing of new, more expensive drugs,

the shift in prescribing patterns towards these drugs, growth in demand reflecting both growth in use and changes in the size and composition of the population (particularly ageing). Moreover, the Government expects this strong growth to continue (Willis & Beazley 1995, pp. 3-99). In an attempt to contain these growing costs, Governments have attempted to negotiate lower prices for pharmaceuticals or imposed market restrictions on their availability.

The PBS is also under pressure from companies seeking a better deal on prices and less restrictions on indications. The available evidence suggests that Australian prices are between 50 and 70 per cent of overseas prices for top selling drugs, and between 70 and 83 per cent for newer drugs. The evidence also suggests that the PBS is a major cause of this difference. In response to the rising threat of country of origin and benchmark pricing, companies are threatening to withhold supply, particularly for newer drugs.

Consumers are a third source of pressure on the PBS. Their concern is ensuring access to the same range of drugs as that available overseas. On balance, the evidence suggests that low prices negotiated for some drugs and market restrictions imposed by Governments have reduced the availability of certain products.

The current indications are that the underlying tensions are likely to grow, rather than abate, in the future.

The pressure from companies for higher drug prices in Australia is likely to continue, further aggravating budgetary pressures. The Government could be expected to respond to continuing PBS budgetary pressures with further measures to control pharmaceutical expenditure, while still attempting to provide equitable, timely access to pharmaceutical products. For example, the Government could simply extend the use of current strategies through further copayment and safety net changes, encouraging further generic substitution or providing more government education on appropriate drug use.

It is possible that this pressure will be offset, to some extent, by other countries implementing stricter cost containment policies that will narrow the gap between Australian and overseas prices. But there is no certainty of this occurring or of overseas prices falling far enough to eliminate the current gap.

Overall, future Government changes to the PBS and developments overseas may simply provide a temporary respite for the community while exacerbating company uncertainty. In the future, more significant changes may be required if pressures on the PBS system further intensify.

This Chapter has discussed the impact of the PBS on the availability of drugs in Australia. Issues relating to the PBS listing process are discussed in Chapters 9 and 10.

9 PHARMACEUTICAL BENEFITS SCHEME— PROCESS ISSUES

A wide range of issues relating to the processes involved in obtaining PBS listing was brought to the Commission's attention during this Inquiry. The lack of clarity in the listing process makes it difficult to assess fully the merits of many industry criticisms. However, the number of companies expressing concern and the number of issues raised indicate a high level of dissatisfaction with the current process. These add to the negative impact that PBS prices and volume constraints have on industry's perceptions. They can also affect health outcomes by delaying access to new drugs.

9.1 Introduction

The previous Chapter dealt with the price and availability outcomes of Pharmaceutical Benefits Scheme (PBS) listing decisions. One of the things highlighted was the fundamental tension that exists between government budgetary, industry and public health objectives. Given these tensions, it is inevitable that PBS decision making processes will be subject to criticism from companies dissatisfied with the outcomes of those processes.

Participants raised several concerns about the PBS listing process. Potential problems included a lack of coordination between the key administrative bodies, delays in listing drugs and the lack of transparency and accountability in decision making. The focus in this Chapter is on the extent to which these potential problems impose unnecessary costs or result in unnecessary delays in the availability of drugs to the community.

The Commission faced several problems in assessing these concerns. Most importantly, other than anecdotal evidence from some companies, the Commission had little independent information on which to base its assessment of the severity of the problems. An overall lack of transparency in aspects of the process contributed to difficulties in assessing company concerns.

Therefore, rather than attempt to evaluate fully the major concerns of industry with the PBS listing process, this Chapter simply seeks to comment on some problems raised by participants (see Section 9.2). Suggestions for addressing these concerns are outlined in Section 9.3.

9.2 Process issues

Participants raised concerns about several aspects of the PBS listing process:

- coordination of the PBS listing process and the Therapeutic Goods Administration (TGA) drug approval process;
- delays;
- decision making by the Pharmaceutical Benefits Pricing Authority (PBPA);
- use of authorities and other listing restrictions; and
- consultation, transparency and appeals processes.

Another important issue raised by participants relates to the application of cost effectiveness analysis. This issue is discussed separately in Chapter 10.

9.2.1 Coordinating the PBS listing process

Participants claimed that a lack of coordination and integration of the drug approval and listing processes caused delays in listing and imposed avoidable costs on industry and the community. Companies were particularly concerned about the lack of coordination between the bodies responsible for drug approval and the PBS listing process as well as between the bodies responsible for listing approval and price negotiation.

Drug approval and PBS listing processes

The TGA assesses the safety, efficacy and quality of drugs and approves them for sale in Australia (see Chapter 3). The Pharmaceutical Benefits Advisory Committee (PBAC) then uses the TGA assessment as an input to its assessment of the relative suitability of drugs for subsidisation (see Chapter 4). Some participants argued that the two bodies are not sufficiently coordinated and that, as a result, opportunities exist for streamlining their activities.

One concern was that TGA and PBAC processes tend to run consecutively rather than in parallel. The PBAC can recommend listing a drug on the PBS only for an indication for which it has been approved by the TGA. The PBAC can commence its consideration of a drug listing ahead of TGA approval, if approved indications can be anticipated (sub. 22, p. 3). However, in discussions with the Commission, the Pharmaceutical Benefits Branch (PBB) said that this was ‘uncommon’.

Several participants pointed to the scope for achieving greater coordination of TGA and PBS processes, including scope to consider PBS listing in parallel with consideration of marketing approval. For example, Faulding stated that:

Closer coordination between listing on the PBS and other aspects of pharmaceutical evaluation is essential (sub. 85, p. 17).

Some companies claimed that inadequate coordination had led to instances of duplication. For example, Glaxo Wellcome argued that the PBAC revisited TGA decisions about its asthma drug Serevent:

There was ... the beta-agonist debate. ... The PBAC ... revisited the same issue ... although the TGA had stopped the review process for 12 months to consider [it]. So there was unnecessary duplication (transcript, p. 1286).

Responding to these issues, the PBAC agreed that there could be closer coordination between the TGA approval process and the PBAC listing process, and stated that ‘steps to achieve this are currently being taken’ (sub. 123, p. 3). Although they did not elaborate on what these steps involved, the PBAC stated:

We are moving to coordinate better with the TGA ... there are some pluses and minuses .. but hopefully that will provide some further benefits (transcript, p. 644).

Although streamlining of approval and listing should be pursued where possible, scope for such streamlining may be limited because of differences in the nature of the two decisions. Registration is concerned with the safety, efficacy and quality of a drug. PBS listing accepts TGA registration as an assurance of these qualities and is concerned with a drug’s relative suitability for subsidisation by Government, based on community need and value for money. Rather than eliminating the possibility of duplication, attempts to run TGA and PBS processes too closely in parallel may merely ensure that greater duplication occurs.

Listing approval and price negotiation

As noted in Chapter 4, the current listing process involves at least three, and sometimes four, stages. The PBAC recommends whether a product should be listed and advises the PBPA of the price at which a drug is found to be cost effective. Following this, the PBPA recommends a price based on nine factors to the Department of Health and Family Services (DHFS). The DHFS then negotiates a price with the company. Drugs expected to cost the PBS more than \$10 million a year must also receive Cabinet approval.

Some participants argued that the listing process is overly complicated and could unnecessarily deny the community timely access to drugs and reduce company revenues.

For example, Bristol Myers Squibb stated that:

... the PBS listing process is a nightmare ... Currently a drug which is estimated to cost the PBS \$10 million per annum must negotiate five committees. This is ridiculous (sub. 151, p. 2).

Participants identified three specific areas where the PBS listing process could be streamlined. One suggestion was that the current allocation of responsibility for clinical analysis, economic evaluation and pricing decisions should be altered. Pfizer argued that pricing and economic aspects should be combined in the pricing authority and that the Economics Sub-Committee (ESC) should be a sub-committee of the PBPA, not of the PBAC (transcript, p. 534).

Second, participants argued for greater coordination of the PBAC and the PBPA. For example, the Australian Pharmaceutical Manufacturers' Association (APMA) stated that there was scope for greater coordination between these two bodies, as well as coordination with other bodies advising the Health Minister on the PBS and the use of pharmaceuticals:

At present there is little coordination, and no integrated terms of reference or operating procedures, between the PBAC, PBPA, the Australian Pharmaceutical Advisory Council (APAC) and the [Pharmaceutical Health and Rational Use of Medicines] PHARM Committee (sub. 31, p. 41).

The APMA proposed that a single body be established with responsibility for both listing and price decisions. However, the PBPA rejected the need for such action by arguing that the PBAC and PBPA have already established close links:

... the links between the PBAC and PBPA are very close, with cross membership and attendance at PBPA meetings of the secretaries of the PBAC and ESC. Meetings of the PBPA are coordinated with PBAC meetings ... to permit the company to provide pricing information in response to the PBAC recommendation (sub. 145, p. 4).

Furthermore, in discussions with the Commission, the Department of Human Services and Health (DHS) (now the DHFS) stated that the PBPA is the only body responsible for balancing health and industry considerations and that current arrangements reduce the risk of bias or corruption in the system. It also stated that different skills are required for therapeutic evaluation and price negotiation.

Finally, participants argued that further streamlining of the listing process could be achieved by formally combining the activities of the Factor f Secretariat with the other activities of the PBPA. The PBPA stated that the split between the Authority's pricing and Factor f responsibilities was developed to avoid any

perceived conflict. However, the Chairman noted ‘subject to dealing with this aspect, ... one Secretariat would be more efficient’ (sub. 201, p. 6).

The Commission’s view

The Commission notes that despite significant efforts by the DHFS to ensure that PBAC and PBPA processes are closely linked, companies are still concerned about the extent of coordination and duplication. However, while there may be some scope for rationalising the PBS listing process across the PBAC and PBPA, the extent of these opportunities is unclear.

However, there does appear to be some merit in considering a number of options raised by participants.

First, clearly aligning roles with expertise may be one way to eliminate confusion about organisational roles. At present, the PBAC makes decisions based on both clinical and economic evidence. The current composition of the PBAC makes it well qualified for making clinical decisions. Although the PBAC is advised by the ESC, which includes economists, the ESC also appears to be strongly influenced by clinical concerns. It may be more appropriate to place responsibility for the evaluation of cost effectiveness analyses with the pricing authority to allow the PBAC to focus on clinical decisions and the pricing authority to focus on all ‘economic’ decisions.

Second, the Commission can see little reason for maintaining a separate Secretariat for Factor f. This appears to be neither administratively efficient nor an appropriate way of addressing combined industry and health policy objectives.

Approaches to resolving organisational issues are examined further in Section 9.3.1.

9.2.2 Delays

As discussed in Chapter 8, any delays in the PBS listing process are of concern because of their potential adverse impact on companies’ revenues and consumer access to new drugs. There is concern that, as predicted in the Baume Review, the bottleneck in the market availability of drugs has shifted from TGA registration to PBS listing processes.

Given the complex nature of the PBS listing decision and the need to negotiate prices, some delay is inevitable. However, unnecessary or excessive delays can restrict community access to beneficial treatments.

Delays in the PBS listing process reduce the time a company has to generate a return while patent protection is available.

Glaxo Wellcome commented that:

... the PBS listing process leads to unacceptably long time lags between marketing approval and reimbursement of new pharmaceuticals, thereby dramatically reducing effective patent life (sub. 143, Attachment 1, p. 1).

Faulding stated that:

Delays in the PBS system are a problem. ... This results in financial costs and loss of revenue and administrative inefficiencies for all parties. There is also a human and broader cost (sub. 85, p. 17).

CSL considered that delays in PBS listing particularly disadvantaged Australian companies. It argued that it caused delays to commercialisation overseas, because PBS listing is essential to demonstrate to other countries widespread acceptance and use of the product in the country of origin (sub. 39, p. 8).

Ideally, information on both the prevalence (how many applications are delayed) and duration of delays is required to properly assess the impact of delays on companies' revenues and drug availability. However, only data on prevalence were available to the Commission.

Current delays

The PBAC attempts to process applications according to a self-imposed set of time limits. Meetings of the PBAC and the PBPA and the timing of the printing of the PBS schedule have been coordinated so that the time between PBAC application and implementation of PBS subsidy should be a maximum of eight months. This is composed of a period of three months prior and five months post PBAC consideration.

In this eight month period, submissions are evaluated by the Pharmaceutical Evaluation Section (PES), considered by the ESC, considered and recommended by the PBAC, considered by the PBPA, approved by the Minister, pricing negotiations finalised, assay of samples undertaken and the sponsor contacted to ensure that stock will be available for distribution (sub. 183, p. 1).

The DSHS advised that a large proportion of listing applications fail to meet the PBAC's own deadlines. Following PBAC meetings for 1994 and 1995, only 68 out of 116 products, or 59 per cent, 'proceeded to implementation in the given time'. It noted that if products not listed because the sponsor was not ready (that is, internal PBS listing processes did not cause the delay) were taken into account the figure reaches 74 per cent (sub. 183, p. 2).

Causes of delays

As well as delays inherent in the listing process itself (such as time taken in preparing submissions and approval of applications), further delays in PBS listing can be caused where an inadequate application is submitted, pricing agreement is not reached quickly or Cabinet approval for listing is required.

Companies such as SmithKline Beecham noted that rejection of an application caused a minimum six month delay because of PBAC meeting and agenda cut-off dates (sub. 13, p. 31). The PBAC acknowledged that if an application is sent back to the company, it will be delayed by six months, as it will inevitably miss the next quarter's meeting.

The APMA argued that extensive delays can be caused by disagreements with the PBPA over product prices (sub. 31, p. 39). It argued that such pricing disagreements are likely to become more common as companies adopt narrow acceptable 'price bands' in response to international benchmark pricing.¹ Similar delays can be caused by disagreements over the indications for which a drug will be subsidised.

The APMA also stated that Cabinet approval (required for products estimated to cost the PBS more than \$10 million per year) imposes further substantial delays (sub. 31, p. 39). Indeed, Schering-Plough argued that in one case, the PBB was overly conservative in estimating potential costs, thereby putting products through an unnecessary Cabinet review. It stated that the:

... [PBB] ignored [a] company submitted estimate (\$5.04 million) and somehow came up with figures which went over the \$10 million threshold. ... The product has since been listed for one year, with an actual cost to the PBB of approximately \$1.5 million (sub. 94, p. 1–2).

In responding to industry criticisms, the DSHS stated that it has taken steps to reduce delays.

To reduce the potential for delays caused by rejection of inadequate submissions, the DSHS has published guidelines that, amongst other things, provide a checklist of material to be provided and a list of key questions to help determine the acceptability of a major submission.² A large part of the guidelines is concerned with conducting economic analyses (see Chapter 10). In addition, the PBAC provides sponsors with an opportunity for a pre-PBAC

¹ Benchmark pricing is discussed further in Chapter 8.

² These are *Guidelines for the Pharmaceutical Industry on Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee* (DSHS 1995e). Guidelines were first published in draft form in 1990.

consultation in relation to the submission, gives sponsors copies of relevant documents and evaluations considered by the Committee and forwards advice of PBAC decisions in writing within 15 working days of a meeting.

In addition, PBS applications may now be lodged from the time that the TGA issues a draft decision on that product. This has reduced the average period between the marketing application to PBS listing by up to two months (sub. 153, p. 11).

The DSHS argued that further reductions in delays were unlikely. A recent internal audit of the PBS listing process found that:

... within the existing policy and resource framework, the processes administered by the PBB are working well. Opportunities to achieve significant time efficiencies from improved processes were not probable (DSHS 1995f, p. 28).

The DSHS also responded to criticisms over delays in price negotiations by stating that it was unwilling to place a time constraint on negotiations because of the risk that companies would hold out for higher prices when a deadline approached. The DSHS acknowledged that the PBS process takes time, but refuted that this is necessarily 'inappropriate' (sub. 153, p. 11).

The Commission's view

The Commission is not in a position to determine what is an appropriate time period for processing a PBS listing application. The PBAC has set itself a target of eight months but around one quarter of the applications were not processed within this time frame. This, combined with the significant amount of criticism from industry, suggests that there is still scope for a reduction in delays.

The Commission notes the DSHS's claim that there is little scope for improvements in processes that would lessen delays. However, these claims are based on an internal departmental audit.

Delays from failure to negotiate a satisfactory price are to a degree outside the control of the PBPA. However, officials responsible for listing do not appear to take adequate account of the cost that such delays impose on consumers and industry.

Unlike the TGA, the PBB does not operate under an explicit 'timely availability' objective. For example, some PBB proposals do not appear to place great emphasis on the objective of 'timely access'. The ESC recently proposed that some products become PBS listed only for patients enrolled in a long term clinical trial to determine elements of cost effectiveness. Glaxo Wellcome argued that 'no consideration is given to the cost of the trial or the

‘timely availability’ of the medicine which is restricted to this clinical trial avenue’ (sub. 143, Attachment 1, p. 4).

The absence of a ‘timely availability’ objective for the PBB appears to have had a similar delaying effect to that experienced in drug evaluation prior to the implementation of the Baume Review recommendations.

In relation to the requirement for Cabinet approval, the Commission considers that the decision to subsidise a particular product, especially one involving significant expenditure, is an appropriate matter for Government consideration and Cabinet approval may be an appropriate way of ensuring political responsibility.

The extent, impact and causes of delays, along with any remedies, should be examined as part of the independent process review proposed by the Commission in Section 9.3.2.

FINDINGS

The Commission finds that a significant proportion of Pharmaceutical Benefits Scheme listing applications fail to meet the time limits adopted by the Pharmaceutical Benefits Branch.

The Commission finds that the Pharmaceutical Benefits Branch should take greater account of the costs unnecessary delays impose on consumers and industry.

9.2.3 Application of factors in PBPA decisions

As discussed in Chapter 4, the PBPA pricing guidelines set out nine factors which the PBPA is required to take into account when recommending a price to be negotiated by the DHFS. Companies raised two specific problems. First, they believed that the PBPA merely used the nine factors as a set of ‘screens’ to obtain the lowest possible price. Second, companies were unclear about the weight given to various factors. The companies argued that the lack of clarity in the reasons for PBPA decisions has added to uncertainty in the industry. Companies’ revenues have also been adversely affected.

The APMA argued that the PBPA applies the pricing criteria to determine the lowest possible price, rather than the most appropriate price:

It’s a layered approach. You have to satisfy all of the screens to get the price that you have requested which happens in about one per cent of cases (roundtable, p. 238).

This argument appears to be borne out by the approach of the PBPA:

The Authority will ... recommend that the Department negotiate for the best price at all times (sub. 201, p. 1).

Participants also highlighted problems in the way specific criteria were applied.

Factor a—PBAC advice: many participants argued that the PBPA uses the cost effective price recommended by the PBAC as an upper limit in negotiations, meaning that a product will rarely attain the price at which it is deemed cost effective.

Factors b and c—reference pricing: participants argued that the PBPA has chosen inappropriate reference drugs with which to link prices. Fisons provided a case study of what it considered to be an incorrect pricing decision, based on the choice of an inappropriate reference drug (see Box 9.1);

Factor d—cost margins: participants such as Fisons argued that the maximum 30 per cent margin that is applied to some products unacceptably limits industry profitability (sub. 35, p. 11).³ The PBPA stated that where a product is priced on the basis of costs, no set margin is applied (sub. 201, p. 5). The ATO noted that actual gross margins are well above the 30 per cent rule of thumb said to be applied by the PBPA (sub. 92, p. 7).

Factor f—local activity: participants specifically noted the lack of weight given to Factor f in PBAC recommendations. Participants argued that Factor f only applied to those companies involved in the formal scheme and that the extent of local activity was ignored for other companies.⁴ In addition, Merck, Sharp & Dohme criticised the criteria for not addressing the ‘viable industry’ objective of the National Medicinal Drug Policy (sub. 27, p. 14).

Factor g—prices overseas: as discussed in Chapter 8, although the PBPA is required to take overseas prices into account when recommending Australian drug prices, the PBPA does not maintain a database to enable them to do this. The PBPA typically only looks at New Zealand and UK prices.

PBPA response

The PBPA acknowledged that it had no formal weighting system for the nine factors it is required to take into account and stated that:

³ When mechanisms such as reference pricing cannot be applied, drugs may be priced by applying a margin to the cost of production.

⁴ The operation of Factor f is discussed in detail in Chapter 5.

... it may vary from drug to drug—on the advice that we get from the PBAC, the perceived need for that particular drug and the expected usage. The extent to which these factors are taken into account and the weight applied varies from product to product due to issues such as availability of alternatives, the cost of manufacture, expected volume, and expected cost to Government (transcript, p. 738).

Box 9.1: Price decision making—Fisons case study

Fisons applied for PBS listing of a new drug, oxybutinin, for a particular form of urinary incontinence. The PBAC recommended listing.

Another drug, extremely old and very cheap, is listed on the PBS as first line therapy for the same indication.

This drug was used as the reference by the pricing authorities and Fisons was offered a price for oxybutinin 50 per cent above the price of the reference drug.

Fisons argued that, by definition, second line therapies are used when first line therapies have failed, and that oxybutinin should not be compared in cost effectiveness terms with the failed therapy. Fisons has refused the offered PBS price.

The DSHS argued that an alternative drug is listed on the PBS, and that the claimed superiority of oxybutinin has not yet been supported by clinical trial evidence.

Sources: Fisons sub. 35, p. 11; DSHS correspondence 7 November 1995

The PBPA did indicate that in practice it distinguishes between major and minor factors:

... the major factors it takes into account are the advice from the PBAC and the costs involved in the manufacture. They're the major two factors (transcript, p. 738).

In particular, the cost effective price recommended by the PBAC, in combination with reference pricing, has become an extremely important factor:

...the Pricing Authority relies heavily on the PBAC recommendation ... and also much of the pricing is based on reference pricing ... and that makes the pricing decision very easy. The other considerations, such as industry development, really don't occur (transcript, p. 735–736).

In relation to Factor f, the PBB stated that:

The authority has made a conscious decision that it would treat Factor f in isolation to the other factors, so for normal pricing reviews or for the price that it recommends that should be negotiated for listing, there is specific exclusion of the Factor f element (transcript, p. 735).

The PBB argued that it would be difficult to take Factor f into account for non-Factor f scheme companies without moving away from consistency of decision making or transparency of the process (transcript, p. 736).

The Commission's view

The Commission considers that the lack of any clear weighting given to the various factors contributes to industry concerns about the transparency and accountability of the listing and pricing process (see Section 9.2.6).

FINDING

The Commission finds that there is an undesirable lack of clarity in the weighting given to the various factors in Pharmaceutical Benefits Pricing Authority pricing decisions.

Although some bureaucratic discretion is desirable in pricing negotiations, the exercise of such discretion should be standardised as far as possible, so as to reduce uncertainty and potential inconsistencies in decision making. The process review proposed by the Commission in Section 9.3.2 should therefore consider the development of clear procedural guidelines for the PBPA, which set out clear objectives and appropriate weighting of factors. The development of such guidelines would help ensure that the PBPA's discretion is exercised within suitable constraints, provide clearer policy direction to the PBPA and give greater certainty to companies.

As for the specific factors, the Commission recognises that there are significant practical difficulties associated with pricing on a gross margin basis (Factor d). As well as problems in auditing the information provided by the companies, there are also issues of transfer pricing and joint costs (where products share some overheads) to be resolved.

The Commission considers that local activity (Factor f) is not adequately addressed by current arrangements. It is not taken into account at all for non-Factor f scheme companies and even for scheme participants it is dealt with in a mechanical fashion. This reflects a major failure of policy coordination.

However, the Commission considers that it is unlikely that health and industry objectives can be reconciled satisfactorily without reform of the current fragmented organisational structures and complex processes. The potential for such reform is discussed further in Section 9.3.1.

FINDING

The Commission finds that under current Pharmaceutical Benefits Pricing Authority pricing processes there is no mechanism for considering the level of local activity for companies that are not participants in the Factor f scheme. However, the Commission

considers that it would be unreasonable to expect the decision making process, as currently constituted, to integrate the conflicting objectives of health and industry policy.

9.2.4 Pricing reviews

The PBPA undertakes both annual reviews and *ad hoc* price revisions.⁵ The PBPA meets quarterly and at each meeting reviews approximately one quarter of the listed products. Suppliers are advised when these reviews are to be held and invited to submit relevant data. Companies were concerned that insufficient notice is given of *ad hoc* reviews and that the review process lacks clarity.

The PBPA noted that negotiated prices are not set for a fixed period (sub. 201, p. 4). In addition to annual reviews, companies may face *ad hoc* price revisions at relatively short notice. Several factors, such as price/volume agreements, the availability and price of alternatives, the addition of new indications, the removal or addition of restrictions and increased costs incurred by the supplier, can trigger reviews.

The DSHS stated that, in its view, companies are given adequate opportunity to respond to such reviews, ‘certainly much more than what would apply in a free market’ (sub. 153, p. 12).

As part of the price review process, the PBAC may provide additional advice to the PBPA. Some companies claimed that, without consulting the industry, the PBAC recently changed the relative weighting it places on efficacy and safety, and began placing greater emphasis on intermediate indicators rather than final health outcomes. Companies also stated that the PBAC has used different indicators to those included in the cost effectiveness analysis guidelines and is selectively choosing only studies that support its preferred position.

However, according to the PBAC, ‘the comment that the [PBAC] has recently adopted a new approach to reviewing PBS prices is not correct’ (sub. 123, p. 2).

The PBPA outlined the criteria for reviewing prices as:

- gross margin on the cost of manufacture, or landed cost; and
- comparative prices of products that are considered by the PBAC to have similar therapeutic effect or benefit (PBPA 1995, p. 5).

The Commission acknowledges that regular price reviews are inevitable given the continual introduction of new drugs and the collection of more information about existing drug treatments. However, the Commission considers that the

⁵ Prior to 1995–96, the PBPA undertook price reviews of each listed item twice yearly.

price review process, like the listing and pricing decisions, lacks sufficient clarity.

The criteria for reviewing prices outlined by the PBPA do not provide sufficient guidance for companies facing reviews, and may, in practice, be inconsistent with the criteria applied in the initial pricing decision. This is particularly important in relation to *ad hoc* price reviews, where a company may have only a limited opportunity to respond to proposed price changes.

FINDING

The Commission finds that the criteria applied in pricing reviews lack specificity and may be inconsistent with those applied in the initial pricing decision.

9.2.5 Authorities and other listing restrictions

As discussed in Chapter 4, the aims of utilisation controls are to encourage appropriate prescribing habits in doctors and appropriate use of pharmaceuticals by patients. However, participants expressed concern that such controls should be applied appropriately, because of their impact on companies' revenues and consumer access to drugs (see Chapter 8). These controls include prescribing restrictions on clinical uses, the quantities per prescription, the number of repeat prescriptions and requiring special authority approval for prescription of certain drugs under the PBS.

Companies such as Glaxo Wellcome were concerned that the imposition of prescribing restrictions in addition to cost effectiveness controls was arbitrary:

Glaxo Wellcome's position is that if a product shows definitive cost effectiveness as a first line agent at a particular price, then that use should be allowed without restriction (sub. 143, Attachment 1, p. 5).

Glaxo Wellcome noted that several of its products (Serevent, Flixotide, Lamictal and Imigran) were listed or proposed for listing on the PBS subject to restrictions imposed for non-medical reasons.

The Commission is concerned that the authority system appears to require public servants without medical backgrounds to make what are, in effect, clinical decisions, without detailed knowledge of the prescribing circumstances. If they are not making clinical decisions, they are simply adding an administrative hurdle by requiring a 'rubber stamping' of prescribing decisions, which may also act to deter appropriate prescribing. In addition, the process adds to the costs of health professionals and increases administrative costs.

FINDING

The Commission finds that, while restricted prescribing or authorisations may be justified on medical grounds, there is no evidence to suggest that cost based ‘economic style’ authorities are an effective approach to ensuring appropriate prescribing for certain indications.

Price/volume agreements

In a further attempt to contain costs, the PBPA has moved to negotiate price/volume agreements for some new products. This approach is likely to be used where:

- there is uncertainty on future volumes;
- new indications are expected to add volume; and
- bottom line profits are expected to increase significantly with volume.

Although no agreements have yet been made relating to total expenditure capping arrangements (‘capitation’), the PBPA considers that there will be greater scope for such agreements in the future. The PBPA stated that it is also willing to consider other options, provided these are consistent with cost effectiveness and their application is transparent (sub. 201, p. 3).

Some companies argued that price/volume agreements are based on cost containment, not value for money, and run contrary to the spirit of cost effectiveness. For example, Glaxo Wellcome argued that if a drug is found to be cost effective for a particular indication, its price should not be further discounted if volumes increase. Glaxo Wellcome characterised the PBPA response to this argument as being that increases in sales volumes may reflect the drug being prescribed for indications outside those found to be cost effective at the current price (sub. 143, Attachment 1, p. 9).

The Commission notes that price/volume agreements are not consistent with the strict application of cost effectiveness criteria as adopted by the PBPA in most negotiations. However, the results of cost effectiveness analysis may be imprecise (see Chapter 10). The PBPA has acknowledged that, where cost effective prices are uncertain, risk sharing arrangements may be appropriate.

Price/volume agreements, perhaps extending to capitation, can form a useful means of ‘risk sharing’ between the Government and companies when there is uncertainty about the level of future demand or other issues.

FINDING

The Commission finds that there is potential for greater use of risk sharing arrangements such as price/volume agreements and capitation between the Pharmaceutical Benefits Scheme and pharmaceutical companies.

9.2.6 Consultation, transparency and appeal processes

Some companies claimed that the accountability of the PBAC and PBPA for the PBS listing process was impaired by several interrelated problems. These include inadequate consultation with the industry on policies and procedures, non-transparency in decision making and absence of an appeals process.⁶

To highlight these problems, SmithKline Beecham contrasted the PBAC process with that of the TGA. It said that:

The PBAC reimbursement process is considered to lack efficiency and decision making transparency and added to this, there is no legal challenge mechanism available for companies (in contrast to the TGA regulatory process) (sub. 13, p. 29).

Although some participants acknowledged recent improvements had occurred, the PBAC and PBPA were criticised for failing to consult adequately with industry. For example, the APMA stated that:

... although communication between APMA and PBAC has improved in recent years and some improvements in the transparency of PBAC operations has occurred, the fundamental situation remains unchanged (sub. 31, p. 40).

Industry argued that a fundamental problem is the lack of transparency in the PBAC and PBPA decision making processes. For example, the APMA argued that:

The unilateral nature of PBAC decisions in regard to both new and currently listed PBS products contrasts with the communication and consultation by other sections of the DSHS and Government. The inefficiencies and inconsistencies of the PBS decision making processes remain hidden behind operating

Bayer argued that while the PBAC is prepared to consider, over a protracted period, matters which gravely affect company viability, it has denied companies the opportunity for comment (sub. 43, p. 9). Bayer provided a critical case study of non-transparent PBS processes (see Box 9.2).

⁶ As discussed in Section 9.2.3, companies were also concerned about the lack of transparency in PBPA pricing decisions, particularly the weighting given to the various pricing factors.

Box 9.2: Transparency of PBS processes—Bayer case study

1 December 1994—prior approval is introduced for Authority Required items. It becomes mandatory for prior approval to be obtained before prescribing.

8 December 1994—Bayer first learns of PBAC's concerns regarding the use of ciprofloxacin (an oral antimicrobial). PBAC recommends severe tightening of the Authority Required listing and proposes this occur effective from 1 April 1995. The proposed listing states that ciprofloxacin may only be prescribed for serious infections for which no other oral antimicrobial is appropriate. Bayer said that it had no prior notice of PBAC concerns.

6 January 1995—PBAC responds to Bayer's requests for details of PBAC concerns and documentation considered by the PBAC in reaching its decision. This shows that the PBAC's concern was first expressed in May 1994; the PBAC had sought advice from the Expert Panel of Antibiotics on two occasions; and that at its November 1994 meeting, had recommended restriction of ciprofloxacin based on this advice. At no stage was Bayer informed of these developments or asked to comment. Indeed, in response to Secretariat suggestions that Bayer be informed of the potential restriction, the PBAC stated that 'such a delay was unacceptable and immediate action was required'.

1 April 1995—new listing becomes effective.

21 April 1995—letter from PBAC advises Bayer that listing of ciprofloxacin will again be discussed at its June 1995 meeting. Three weeks after the new listing becomes effective, PBAC is proposing further discussion and possible amendment.

May 1995—PBAC advises Bayer that PBS listing for ciprofloxacin has been further modified due to representations by prescribers and specialist colleges.

24 May 1995—new listing is Gazetted. This is unusual—the modification has been agreed to by PBAC under informal conditions outside its normal meeting schedule.

1 August 1995—the new PBS listing for ciprofloxacin becomes widely effective with the publication of the PBS schedule.

Source: Bayer sub. 43, pp. 7–9

In addition to concerns about inadequate consultation and non-transparent decision making, participants were critical of the lack of a formal appeals process.

The APMA argued that a major problem with the listing process is the limited responsibility and accountability of the PBAC and its sub-committees. The APMA expressed concern that the PBAC is not legally accountable for the advice it gives the Minister about PBS listing, and that there is no process of

appeal against a recommendation by the PBAC. A company can only resubmit its application with revised arguments (sub. 31, p. 40).

SmithKline Beecham argued that because a PBAC rejection causes a minimum six month delay, a formal legal appeals process is needed (sub. 13, p. 31).

The Administrative Review Council addressed the issue of appeals of decisions under the PBS in advice to the Minister for Justice (Kenny 1995). The Council concluded that elements of the listing process are not appropriate for merit review because:

- the Minister's declarations are legislative in character, and declarations are subject to Parliamentary tabling and disallowance proceedings;
- PBAC recommendations to the Minister are not considered to be final determinations and have no operative effect; and
- PBPA pricing decisions are not made under an enactment and therefore like the PBAC are not subject to merit review. However, even if PBPA decisions were made under an enactment, they would be unsuitable for merit review as they are the result of negotiation with the manufacturer.

Department responses

The PBAC argued that, over the past three years, annual meetings with the APMA have facilitated discussion on the transparency, policies and practices of the PBS listing process. Initiatives adopted from these meetings are outlined in Chapter 4.

Apart from these initiatives, the DSHS noted that there is also industry representation on the:

- Drug Utilisation Sub-Committee (of the PBAC);
- ESC (of the PBAC);
- APAC;
- PHARM; and
- PBPA (sub. 153, p. 12).

The DSHS also argued that the PBAC, the PBPA and the PBB attempt to provide as much information as possible to suppliers and that companies are welcome at any time to discuss issues:

Initiatives introduced include providing companies with the PBAC Secretariat overview and the economic commentary and the ability for companies to provide comment prior to the meeting to the PBAC.

Following the PBAC meeting, resolutions are supplied to the company within 15 working days (verbal advice is often given immediately following the meeting) along with Economics Sub-Committee advice. PBAC minutes are provided when ratified (sub. 153, p. 12).

The PBAC argued that it ‘has shown its willingness to respond to industry concerns but in this area has been quite unable to discern what are the remaining concerns’ (sub. 123, p. 2).

However, in relation to claims that PBS processes are not sufficiently transparent and are non-consultative, the PBB acknowledged that some mistakes had been made:

There have been a couple of examples where there have been changes which, in hindsight, would have been better ... to go back to the company first and give them an opportunity to put in a contrary view if they wanted to, rather than to proceed with the change ... It’s difficult, but I think there is a legitimate circumstance where there should be an opportunity on those occasions for the industry—or the company—to respond before the change is made (transcript, p. 726).

The Commission’s view

The Commission considers that, although consultation at an industry association level appears to be greatly improved, it is of concern that companies have to resort to mechanisms such as the *Freedom of Information Act* to ascertain the reasons for individual PBAC decisions.

The Commission acknowledges that PBPA price negotiations, by their very nature, are not amenable to formal review. However, the lack of administrative appeal processes for recommendations of the PBAC reduces transparency and accountability.

The Administrative Review Council argued that PBAC decisions are not suitable for review because they merely form recommendations to the Minister, rather than operative decisions (Kenny 1995). This argument plays down the practical impact of PBAC listing and cost effectiveness recommendations on PBPA pricing negotiations and company returns. Although Administrative Council review of PBAC recommendations may be inappropriate, some form of structured review may be justified, particularly given the importance of these recommendations for company returns and the availability of drugs to the community.

The *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standards Setting Bodies* were adopted by COAG in 1995 (COAG 1995a). These principles represent nationally accepted standards of regulatory action and administrative decision making. Application

of these principles to the PBS listing process would ensure that the process was made more transparent.

FINDINGS

The Commission finds that it is appropriate that the basis for decisions made in the Pharmaceutical Benefits Scheme listing process be made clear to companies.

The Commission finds that current processes, particularly review processes, may not provide companies with adequate opportunities for consultation.

9.3 Responding to the process issues

The Commission considers that there are two components to addressing the problems identified in the previous Sections. These are:

- organisational change to rationalise the operations of the PBAC and PBPA; and
- a process review to identify ways of improving those operations.

9.3.1 Organisational changes

As discussed in Section 9.2.1, the Commission considers that there is merit in reviewing in more detail the approaches to resolving coordination and integration problems identified by companies. Participants identified three possible approaches to resolving these issues:

- altering the current division of responsibilities between the PBAC and the PBPA;
- increased coordination of PBAC and PBPA operations; and
- combining the two PBPA Secretariats.

The remainder of this Section examines the most appropriate organisational structure for undertaking the PBS listing process.

Role of the PBAC

As discussed in Chapter 4, the PBAC is required to make recommendations on the suitability of drug products for subsidy by the Commonwealth Government. Prior to the mandatory application of economic analysis in 1993, the PBAC based its deliberations on the role of a drug in meeting the health needs of the Australian community. Although this is still the primary consideration, drugs

considered appropriate for PBS listing on medical grounds are now also subject to economic criteria, based on cost effectiveness analysis.

The PBAC only considers drugs for PBS listing after they have received TGA approval. TGA approval is accepted as sufficient evidence of safety and efficacy. Currently, the real role of the PBAC is to determine which drugs should be subsidised by Government—that is, it defines the scope of the Australian formulary of subsidised drugs.

The Commission considers that the initial PBAC advice should be based solely on the relative efficacy and safety of a drug. The PBAC should determine the appropriate therapeutic class or treatment with which a drug should be compared and provide clinical advice about how it compares with that comparator.

It is possible to separate out the application of economic criteria from this stage of the listing process. Although relative efficacy is an important input into cost effectiveness analysis, it should be considered separately from the economic assessment.

The PBAC should restrict its consideration to the clinical issues of relative efficacy and ‘community need’. The PBPA should take responsibility for evaluating cost effectiveness analyses provided in company submissions and using this information as part of its pricing decisions. The skills necessary to assess the clinical data and make a clinical decision about relative efficacy and appropriateness of a drug for subsidisation are different to those required to assess the economic data and answer the economic question of at what price a drug is cost effective.

FINDING

The Commission finds that, because of the different skills required, it is undesirable for the Pharmaceutical Benefits Advisory Committee to make both clinical and economic decisions about Pharmaceutical Benefits Scheme listing.

Role of the PBPA

As discussed in Chapter 4, the PBPA currently determines prices for items listed, or recommended for listing on the PBS, where annual expenditure on those items falls within limits advised by the Health Minister. In other cases, it recommends prices to the Health Minister.

The PBPA’s objective is to secure a reliable supply of subsidised drugs at the most reasonable cost to Australian taxpayers and consumers (PBPA 1995, p. 4).

In its pricing decisions, the PBPA is required to take account of nine factors. It takes into account eight of these factors in initial pricing decisions. The sixth factor (Factor f) is considered separately in the context of the Factor f scheme. This scheme is supported by a separate Secretariat based in the Department of Industry, Science and Tourism (DIST). Technical advice to assist the PBPA in its deliberations is provided by the PBAC, particularly in relation to clinical aspects (drug relativities) and cost effectiveness.

There are certain lessons that can be learnt from history in this area. In 1987, the Ministers for Health and Industry announced the intention to replace the Pharmaceutical Benefits Pricing Bureau with an independent Authority. This Authority was to develop the guidelines by which Factor f (the level of local activity) would be taken into account in pricing decisions. These guidelines became the genesis of the Factor f scheme.

Recognising the difficulty of requiring a health body to administer an industry compensation/development scheme, in 1991 the PBPA set up two Secretariats, one in Health and one in Industry. This awkward organisational structure made it more difficult to integrate health and industry policies.

The APMA noted that the PBPA was initially established as an ‘independent’ authority but that PBAC advice on cost effectiveness has eroded that independence:

When the pricing authority was first set up I think it had an opportunity to exert far more influence than it does now.

... Unfortunately, the influence now of the PBAC and the recommendations arising because of the cost effectiveness studies that are carried out really curtails the opportunity for the pricing authority ... to exercise that original intention (transcript, p. 602).

As discussed above, the Commission considers that it is desirable that there be a clear distinction between the clinical aspects of PBS listing, and the economic aspects. Therefore, the PBPA should be responsible for all economic aspects of PBS listing, including the evaluation of cost effectiveness analyses.

As discussed in Section 9.2.3, the Commission considers that it is unlikely that health and industry objectives can be reconciled satisfactorily within the current organisational structure.

Many of the criticisms of the current PBS process stem from participants’ beliefs that pricing decisions are being driven by short run PBS budget priorities rather than broader health and industry objectives.

If the pricing authority were to remain within the health portfolio, short term budgetary imperatives mean that it would be unlikely to make the appropriate

trade-offs between industry and health objectives. Similarly, a pricing authority within DIST would be likely to favour industry objectives over health objectives.

Separation of the pricing authority from DHFS and DIST would allow the objectives of the organisation to be set by Government independently of those charged with pursuing those objectives. This would also allow for greater accountability on the part of Government (which would be charged with explicitly setting objectives and resourcing the pricing authority) and the authority (charged with pursuing those objectives).

Establishing an independent pricing authority would also facilitate improvements in listing processes. An independent authority could be given clear guidelines setting out its objectives, specified performance targets and reporting standards. Such guidelines would address problems such as the lack of transparency and accountability of PBPA decisions.

If it is considered desirable to attempt to reconcile industry and health objectives through the PBS pricing system, the Commission considers that there is a strong case for establishing an independent pricing authority.

Such an independent pricing authority could take on wider responsibilities than the previous PBPA. It could:

- maintain a data base of prices, market shares and indications for which drugs are available in Europe;
- evaluate cost effectiveness analyses;
- negotiate prices; and
- recommend which drugs should be listed at these prices (for final approval by the Health Minister).

The PBAC would provide clinical advice to the independent pricing authority on the appropriateness of products for subsidisation and their relative efficacy.

9.3.2 A review of the PBS listing process

In taking account of the impact of the PBS on the pharmaceutical industry, the Commission considered the concerns with the PBS listing process raised by participants.

The lack of clarity and accountability in the listing process makes it difficult to assess fully the merits of many industry criticisms. However, the number of companies expressing concern, and the number of issues raised indicate to the

Commission a high level of dissatisfaction with the current process. As a result, the Commission considers that there is scope for improvement in the efficiency, transparency and accountability of PBS listing processes.

Although this Inquiry is not in a position to review these matters in detail, the Draft Report recommended that a review of PBS processes be undertaken as a matter of urgency. The Commission proposed an independent ‘Baume type’ inquiry. Such an inquiry, which has been used with success in the review of the TGA, would involve an intensive examination over a short period of PBS listing arrangements in close consultation with the relevant agencies.

Participants’ views

This proposal received strong support from all sectors of the industry, consumer groups and health professionals.

APAC believed that the PBS has served the Australian population well over many years, but did not object to a review of the procedures for PBS listing. It stated that ‘APAC would be happy to take a leading role in any such review’ and that ‘any such review should take all the aims of the NMDP into consideration and it should not be confined to the industry policy’ (sub. 137, p. 5).

The Victorian Government supported the recommendation for an urgent review and stated that the ‘current difficulties and delays with the PBS listing process are a cause of concern from the viewpoint of the consumer as well as the industry’ (sub. 182, p. 3).

Among health professionals and consumer representatives, the Royal Australasian College of Physicians supported ‘any moves to increase the transparency and predictability with which applications to bodies such as the PBAC are handled (sub. 140, p. 1).

The Australian Nursing Federation supported the review and noted that it had

... received comment from members relating to delays in the PBS listing ... A review of the PBS listing process should give a single body overriding responsibility for the outcome so that accountability rests somewhere (sub. 111, p. 1).

The Consumers’ Health Forum (sub. 139, p. 8) and the AIDS Council of NSW (sub. 196, p. 1) also agreed with the Commission’s recommendation that there should be a review of the PBS listing arrangements.

Companies and their associations were also in favour of the review. For example, the APMA ‘strongly supported’ the recommended review (sub. 119, p. 9) and Sandoz stated that it ‘heartily supports the Commission’s

recommendation that the listing process be reviewed’ and stressed that it was a ‘matter of urgency’ (sub. 132, p. 1).

However, the DSHS opposed the recommended review, noting that an internal audit report involving the administrative processes involved in the listing of drugs on the PBS was released on 1 December 1995, and that an Australian National Audit Office efficiency audit into aspects of the PBS is scheduled to commence in 1996. It argued that an additional review of the PBS listing process was unnecessary (sub. 153, p. 13).

The Commission’s view

The Commission considers that evidence presented to it since the Draft Report and discussed in this Chapter has reinforced the need for an independent review of the PBS listing process. The internal review conducted by the Department has not allayed industry concerns about the process issues canvassed in this Chapter. Furthermore, evidence provided by the PBAC shows that it is failing to meet its self-imposed targets for processing applications.

Recommendation 9.1

The Commission recommends that, as a matter of urgency, the Pharmaceutical Benefits Scheme listing process be subject to a review.

9.3.3 Scope of the proposed PBS listing process review

Participants’ views

In addition to supporting the Commission’s proposal for a review of the PBS listing process, a number of participants proposed a wide range of issues to be included in such a review.

The APMA suggested detailed factors to be considered in a review of the PBS process (see Box 9.3).

Box 9.3: APMA factors to be considered in a review of the PBS listing process

The APMA considered that the proposed review of the PBS listing process should:

- cover all components of the process including evaluation and consideration of applications by PES, ESC, PBAC, PBPA, the Highly Specialised Drugs Working Party, the Minister for Health and Cabinet;

- consider changes to the administrative structure of the PBS listing process, including the PBAC and the PBPA, their links to each other, their sub-committees and advisory groups, the DHFS and the Minister for Health;
- consider the need for transparency and accountability, including the administrative processes, the evaluation and decision making process, and clarification of the role of outside advisers, taking into account the need to avoid undue influence by individuals, and the introduction of appeal procedures applicable throughout the process;
- determine the appropriate focus, emphasis, timing and application of comparative cost effectiveness criteria for PBS listing;
- consider specific details of the guidelines for submissions to the PBAC (for example, comparators, flexibility of approach, quality of life considerations);
- consider how PBAC recommendations and the full range of PBPA factors are translated into price;
- investigate causes of delay in the inclusion of new and revised items in the PBS Book;
- investigate the factors that affect the revision of entries in the PBS Book, including the process of therapeutic area reviews; and
- transitional arrangements for any reform proposals.

Source: APMA sub. 199, Attachment B.

The Commission's view

The Commission considers that the review should cover all aspects of the PBS listing process. However, priority areas in need of review include:

- the organisational arrangements for the PBS listing process, particularly the roles and responsibilities of the PBAC and the PBPA;
- scope for greater independence of the pricing authority;
- measures to increase transparency and accountability, including consumer representation on committees;
- an examination of the extent, impact and causes of delay in listing, and the development of measures to reduce such delays;
- the application of cost effectiveness analysis, including the prescriptiveness of the guidelines, methodological questions and the Commission's proposal for a two year delay (see Chapter 10);

- the need for guidelines covering the role of the various pricing factors in pricing decisions;
- the criteria and processes involved in pricing reviews;
- the appropriateness of an appeals mechanism for recommendations by the PBAC and the PBPA;
- the need for Economic Authorities and ‘cost effectiveness’ style authorisations; and
- appropriate risk sharing arrangements between companies and the PBS.

9.3.4 A policy review

As discussed in Chapter 8, the Commission considers that many of the process issues reflect more fundamental pressures on the PBS. In these circumstances it may not be possible, nor desirable, to address these process issues in isolation from a broader examination of the scheme’s policy underpinnings.

The need for a review of the policies underpinning the PBS was supported by a number of participants. For example, the PBAC suggested that the review should address certain policy issues that are outside its scope:

... if there is to be a review we would like to see it look at broader issues and to properly involve the committee and other interested people.

... Some more difficult situations that we would like to see advice and thought about are, for example, the subsidy of drugs for relatively minor medical conditions, how to make value for money judgments, and the issue of how many ‘me too’ drugs in particular classes, for example, might be subsidised under the scheme (transcript, p. 636).

Similarly, Schering-Plough recommended that the operations of the Highly Specialised Drugs Working Party and the role of section 100 listings be included in the review. It cited a ‘number of difficulties’ including ‘apparently no direct reporting relationship between the PBAC and the [Working Party] and divergent interests of the States and Commonwealth’. In addition, it identified ‘illogical arrangements as a result of differences between section 85 and section 100 listings’ (sub. 128, p. 8).

Princess Margaret Hospital also recommended changes to PBS section 100 arrangements to allow the use of section 100 drugs when approved patients are admitted to hospital. It observed that ‘the current situation is purely the result of the Commonwealth—State funding arrangements and has no therapeutic rationality’ (sub. 131, pp. 1–2).

The process review could be extended to address the role of the PBS in a wider health policy context or, preferably, a separate policy review should be undertaken. The need for a policy review to better balance the interests of taxpayers, consumers and the industry is discussed further in Chapter 13. Such a review should examine a number of key policy questions.

- What is the most appropriate way to manage growing demand and supply pressures?
- Who should be eligible for subsidised drugs?
- Which drugs should be subsidised?
- What should be the extent of the subsidy?
- Should the subsidy vary between sections of the community?
- Should the subsidy vary between different drugs?
- Could limited consumer copayments play a broader role in increasing consumer choice?
- Should drugs for minor medical conditions be subsidised?
- How many ‘me too’ drugs should be subsidised?
- What are the most appropriate arrangements for the subsidisation of section 100 drugs?

The Commission notes that COAG has established an agenda for coordinated reform of health and community services (COAG 1995b). Several problems were identified as contributing to fragmentation and discontinuity between Commonwealth and State programs and a lack of a clear consumer focus in the delivery of services. COAG endorsed the need for systematic reform to the way health and community services are planned, organised and funded.

The Commission considers that either the proposed review of PBS processes be given sufficient scope to address the role of the PBS in the context of wider health policy, or preferably, a separate review of PBS related policy issues be undertaken. Such a review could make a valuable contribution to the broader health and community services reform process.

10 COST EFFECTIVENESS ANALYSIS

In addition to those issues discussed in Chapter 9, one of the most criticised aspects of the listing process was the application of economic analysis, particularly cost effectiveness analysis. Participants were concerned that cost effectiveness analysis requirements are being used to contain PBS costs.

10.1 Introduction

Chapter 9 examined industry concerns about aspects of the Pharmaceutical Benefits Scheme (PBS) listing process. Cost effectiveness analysis is an important part of this process. The Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Minister for Health about which drugs should be listed on the PBS. These recommendations are based on the effectiveness, cost effectiveness and clinical place of a product compared with other products already listed on the PBS for the same, or similar indications.

Many participants accepted that economic analysis has a role to play and supported the use of cost effectiveness analysis in the listing process. For example, the Australian Pharmaceutical Advisory Council (APAC) stated that:

The introduction of a cost effectiveness requirement is a valid attempt to ensure that on the one hand, the industry has the possibility to justify its requested price, and on the other, to ensure the long term viability of a comprehensive Pharmaceutical Benefits Scheme (sub. 137, p. 2).

However, many participants were concerned that cost effectiveness requirements were being used inappropriately to restrict or delay drugs from obtaining PBS listing in order to contain the cost of the scheme.

The most significant industry concerns related to:

- methodology and data requirements;
- delays;
- valuation of indirect and intangible benefits;
- scope for retrospective versus prospective analyses; and
- reliance on cost effectiveness analysis.

This Chapter examines these concerns. The focus is on highlighting potential problems and proposing some solutions. Before examining these issues, Section 10.2 discusses the role of economic analysis in more detail.

10.2 Economic analysis

As discussed in Appendix I, the PBAC was established under the *National Health Act* 1953 (the Act) to make recommendations to the Minister for Health about which drugs should be listed on the PBS.

The PBAC bases its deliberations on the requirements of the Act. The role of a drug in meeting the health needs of the community is of primary consideration. For drugs considered appropriate for PBS listing on medical grounds, economic factors including cost effectiveness are then taken into account in the final decision (DHS 1995e, p. 3).

When recommending listings, the PBAC also provides advice to the PBPA regarding comparison with alternatives or their cost effectiveness.

The use of formal economic analysis in the PBAC's deliberations is of relatively recent origin. A 1987 amendment to the Act required the PBAC to consider effectiveness and cost when recommending drugs for PBS listing. When introducing the amendment, the then Minister said that the purpose was:

... primarily to reduce the burgeoning cost of the so called free health system (Australia, House of Representatives 1987, *Debates*, vol. HR157 pp. 1642–1647).

Mandatory economic analysis for new products was introduced in January 1993. The PBAC established the Economics Sub-Committee (ESC) to advise on cost effectiveness policies and evaluate cost effectiveness aspects of major submissions.

The introduction of formal economic analysis constituted a departure from accepted practice overseas. For example, the then Department of Industry, Science and Technology (now the Department of Industry, Science and Tourism) (DIST) stated that:

Mandatory economic analysis (cost effectiveness, cost utility or cost minimisation analysis) ... introduced more stringent requirements than those required in any other developed country (sub. 56, p. 35).

Various types of economic analysis and the role of cost effectiveness analysis are briefly summarised in Box 10.1.

Box 10.1: Types of economic analysis

The PBAC has set out its requirements for the type of economic analysis to be included in applications for PBS listing in a series of guidelines. An overview of the development of the guidelines, the types of economic analysis required and the methodology to be adopted is provided in Appendix I.

The main type of economic evaluation specified is cost effectiveness analysis. This takes the form of comparing the costs and benefits of the drug for which listing is sought with the costs and benefits of the alternative drug or therapy. The overall measure of cost effectiveness is the incremental cost per additional unit of outcome achieved.

For drugs which provide significant clinical advantages, applicants are requested to quantify the increase in benefits and compare these with the increase in costs. The guidelines specify cost effectiveness analysis or cost utility analysis be applied for these drugs.

For drugs regarded as therapeutically equivalent to existing drugs, cost minimisation analysis is required.

For drugs where the therapeutic advantage is less clear, there are clinical trade-offs as well as cost trade-offs to be considered. Therefore, an evaluation of possible adverse health outcomes of listing the drug is required.

Because of the difficulty of expressing all medical outcomes in monetary units (for example, putting a value on human life or improvement in quality of life) the use of cost benefit analysis is not encouraged.

Source: DSHS 1995e, p. 49

While Australia may be regarded as being at the 'leading edge' in requiring economic analysis, drug purchasers or price setters in several other countries either currently make use of economic analysis or are proposing its introduction. For example, economic analysis is required to assess the cost effectiveness of drugs requested for reimbursement under the Ontario Drug Benefit Program (DQTC 1993). At a national level, Canada has developed pharmacoeconomic guidelines to encourage a consistent approach to economic analysis by Provincial purchasers (CCOHTA 1994). In France, the Transparency Commission released cost effectiveness guidelines in September 1995 (Direction des Etudes et de l'Information Pharmaco-Economiques 1995).

Standards for cost effectiveness analysis have also been developed by other organisations, although they are not directly linked to pricing decisions. For example, the UK Government and pharmaceutical industry association released a set of guidelines (Joint Government/Pharmaceutical Industry Working Party

1994). In addition, German academics have released a set of guidelines (Graf von der Schulenburg J M *et al* 1995).

Cost effectiveness analysis appears to be used as a marketing tool in the US, where many health maintenance organisations pay close attention to the value for money of the drugs they include in their formularies. Guidelines for cost effectiveness analysis have been released by the US pharmaceutical industry association (PhRMA 1995). In addition, the Food and Drug Administration (FDA) has released a position paper on principles for the review of pharmacoeconomic promotion (FDA 1995).

Although industry generally accepts that economic analysis has a role to play in informing PBS listing decisions, participants were concerned about a number of methodological and practical aspects of the application of cost effectiveness analysis. Many of these concerns centred around the role and nature of the *Guidelines for the pharmaceutical industry on preparation of submissions to the Pharmaceutical Benefits Advisory Committee* (DHS 1995e).

Although guidelines can play an important role in reducing uncertainty and standardising the exercise of bureaucratic discretion, participants criticised the methodology underlying the current cost effectiveness guidelines and the data which they require. Major industry concerns about the guidelines are discussed below. Further detail about the development of the guidelines and other areas of industry concern are contained in Appendix I.

10.3 Methodology and data requirements

There is an ongoing debate between the industry and the PBAC on the methodology and data requirements specified in the cost effectiveness analysis guidelines. For example, ICI stated that ‘as the guidelines evolve, they are becoming more cumbersome, directive and patronising’ (sub. 50, p. 2).

The guidelines have undergone several revisions since they were originally drafted in 1990. They were most recently revised in November 1995 after consultation with industry.

The Health Economics Sub-committee of the Australian Pharmaceutical Manufacturers’ Association (APMA) provided detailed comments on draft guidelines circulated in July 1995 (APMA 1995c) and the then Department of Human Services and Health (DHS) (now the Department of Health and Family Services) (DHFS) responded to their comments (DHS correspondence 31 October 1995). Although a revised version of the guidelines was published in November 1995, it did not differ significantly from the draft and many of

industry's concerns were not addressed. Several methodological and data issues are still of concern to the APMA and other participants:

- the prescriptiveness of the guidelines;
- the use of comparators;
- the role of expert opinion; and
- the reliance on data from clinical trials.

Prescriptiveness of the guidelines

SmithKline Beecham stated that:

... [the] guidelines are generally seen as unique in the world, highly restrictive, company resource intensive and requirement-driven (as opposed to suggestive guidelines) (sub. 13, p. 29).

The APMA argued that the new guidelines are more onerous and less flexible than the guidelines that they replace and that there has been a change in emphasis on the type of submissions required and the type of evaluations expected. It noted that the earlier guidelines specified the use of the best available evidence, whereas the revised guidelines specify the type of evidence which is acceptable (APMA 1995c).

Langley (1996) analysed the revised guidelines. He concluded that:

The new document sets substantially more demanding and more rigorous evidentiary standards in the reporting of randomised clinical trials and in the justification of the selected evaluation methodology ...The guidelines, in a US environment, would be seen as ... unreasonable in their evidentiary demands (Langley 1996, p. 1).

Langley noted that, in the three years since the implementation of the original Australian guidelines, a number of other countries had followed suit, but that 'none have followed Australia in the degree of prescription imposed on pharmaceutical manufacturers' (Langley 1996, p. 1).

For example, Ontario's guidelines stress the need to apply economic analysis flexibly, particularly while it is still in its formative stages:

... Economic analyses will be reviewed with considerable flexibility ... while the [Drug Quality and Therapeutics Committee] DQTC continues to revise these guidelines as it gains experience, and as the science of measurement and analysis advances. Those preparing submissions should be encouraged to experiment with various approaches as a part of the general development of this field, and to engage the DQTC in ongoing discussions about these efforts (DQTC 1993, p. 11)

DHSH response

In defence of the guidelines, the DHSH argued that their prescriptive nature has arisen partly as a result of applicants' requests for clarification of the evidence and the analysis required and partly as a result of applicants providing less than satisfactory submissions.

Dr David Henry, (Chairperson of the ESC), also argued that, despite the apparent prescriptiveness of the guidelines:

... under the current provisions companies are not forced to submit data in the format advised in the guidelines. However, the great majority recognise that ... it is definitely in their best interests to follow this course (sub. 170, p. 2).

The guidelines themselves state that:

These developments are not intended to create minimum standards of evidence. The PBAC has and will continue to consider all evidence, but is most likely to be persuaded by the data from the trials of the highest scientific rigour (DHSH 1995e, p. 75).

Comparators

Companies expressed particular concerns with the selection and use of comparators in cost effectiveness analysis. Because of costs involved in conducting clinical trials and preparing applications for PBS listing, participants argued it was important to select and get agreement on the most appropriate comparator to be used early in the process.

However, this was not always possible. Some participants stated that although the PBAC, the ESC and the Pharmaceutical Evaluation Section (PES) are available for consultation on matters such as the selection of a comparator, PBAC could provide no guarantee that any one comparator would be accepted in its considerations. For example, Merck, Sharp & Dohme stated that:

[It] sought the PBAC and ESC Secretariat's advice as to the appropriate drug with which to compare its new product. It will spend more than \$1 million to design, run and analyse a clinical trial using the agreed comparator in order to meet the unique requirements of Australian authorities.

However, [Merck, Sharp & Dohme] MSD cannot feel secure that the results of the clinical trial which it has put in place will be acceptable. The same guidelines state that 'no guarantee can be given that the PBAC will be constrained by this advice' (sub. 27, pp. 10–11).

Glaxo Wellcome made a similar point, and argued that uncertainty over the choice of comparator would have the effect of deterring investment in clinical research (sub. 143, Attachment 1, p. 1).

Participants also raised concerns about the comparator chosen or accepted by the PBAC. The guidelines indicate that the main comparator to be used in the analysis is the therapy which most prescribers will replace with the new drug proposed in the application for PBS listing.

Participants stated that the comparator specified as acceptable to the PES and the PBAC was often an inappropriate drug, chosen because it was off patent, now produced as a generic product and relatively cheap.

For example, Fisons argued that it was not appropriate to compare first line therapies with a new product which was more effective. Fisons provided an example where the first line therapy was extremely old and cheap. Where this therapy failed to control the indications, Fison's alternative therapy was effective. However, Fisons failed to receive an 'adequate' price and the application for listing was withdrawn (sub. 35, p. 11).

Abbott provided a case study of the use of what it regarded as an inappropriate comparator (see Box 10.2).

Box 10.2: Choice of comparator—Abbott case study

Clarithromycin is one of three new macrolide antibiotics that have been available for more than four years to patients around the world. Australia is one of the few countries where Clarithromycin has not been made available to the general patient population.

Because it resides in the same therapeutic group (macrolide antibiotics) as the forms of Erythromycin, the PBAC originally recommended that the pricing comparator would be Erythromycin Ethyl Succinate which is a generic product, priced at one third of the world average selling price of Clarithromycin.

If Abbott were able to prove that Roxithromycin was the comparator for Clarithromycin the price to be expected would be \$6.57. This is less than half of the lowest price elsewhere in the world for this compound and as such is unacceptable to the company.

The cost effectiveness data that would be required to show significant benefit over the comparator would not be economically viable to produce as it has not been requested for any other country and would be a poor investment to produce just for Australia.

Source: Abbott sub. 48, p. 5

Langley noted that care must be taken in making the choice of comparator for cost effectiveness analysis as distinct from determination of clinical efficacy. He concluded that:

Where a number of options are open, the choice of comparator, in drug switching terms, should not be made in terms of the most commonly used drug, but in terms

of the drug which in cost-outcomes terms and for the characteristics of the treating population yields the most efficient outcome for the prospective treating population. To focus on clinical analogues defeats the purpose of the economic evaluation (Langley 1996, p. 5).

PBAC response

In discussions with the Commission, representatives of the PES, ESC and the PBAC stated that they provide the best advice possible on the choice of comparators, given the information supplied by companies seeking PBS listing. However, they said that, for two significant reasons, the advice on the comparator to be used cannot be guaranteed. First, the information supplied by companies may be incomplete, partial, biased or inaccurate. Second, it is possible that during the period between providing advice and the time of evaluating a drug, another drug could be introduced into the market which could become the relevant comparator.

The PBAC noted that the incidence of disagreement on comparators has declined as the use of cost effectiveness analysis has become established. Between 1991 and 1992, when the initial draft guidelines were used, companies and the PBAC disagreed in 20 per cent of cases. If only economic submissions are taken into account, the level of disagreement increases to 37 per cent of cases. After the 1992 guidelines were introduced, this declined to 8 per cent of cases. The PBAC argued that this reflected clearer advice in the revised guidelines, greater consultation between the PBAC and companies and greater company familiarity with the system (PBAC correspondence 15 April 1996).

Expert opinion

Participants argued that an inconsistent standard applied to the use of expert opinion, and that industry was expected to meet a higher standard than that required of the PBAC. The APMA stated that the issue of inconsistency of standards has not been addressed in the new guidelines. For example, Schering-Plough stated that:

... there is a difference in the standard expected of the pharmaceutical industry in obtaining expert opinion compared to the PBAC. Industry is required to disclose a lot of information to the PBAC on how the expert opinion is obtained (even fees to the expert) whereas the PBAC simply telephones the 'expert' to seek his/her opinion (sub. 128, p. 8).

Schering-Plough further noted that the PBAC does not regard anyone involved with a trial as 'independent', and pointed out the difficulties this caused:

As research with patented drugs is invariably undertaken or sponsored by drug companies, it would appear, by extension of the reasoning of the PBAC, that

only clinicians not having any first-hand experience with the drug could be sought out for expert opinion (sub. 128, p. 9).

DHSH response

The DHSH stated that the guidelines specify when expert opinion is required. Expert opinion will only be considered if there are no data from randomised trials or non-randomised studies. The guidelines also outline how expert opinion should be collected, collated and presented.

The PBAC stated that there are 'areas where we would like to base our judgments on some evidence rather than opinion'. Estimating cost offsets was one such area:

Our impression is that the opinion of medical specialists ... not in a wilful way, can be influenced and can be quite inaccurate as a means of estimating cost offsets, and therefore some better means of supporting these claims really has to be made (transcript, p. 662).

Clinical trials

The guidelines place a great deal of emphasis on data collected in clinical trials. In some cases, sponsors have been required to run special clinical trials to collect the required information, involving expenditure of several million dollars. This can have a direct effect on a company's profitability. Abbott provided the following example:

It was indicated by the PBAC in their concluding statement that they would not recommend listing until 'large scale, long-term clinical studies are available which demonstrate defined clinical benefits'.

After gathering extensive additional data, Abbott resubmitted in March 1995. ... This data was generated at an expense of A\$16 million to the corporation and tracked 2000 patients over a 12 month period (sub. 48, p. 6).

Participants argued that this emphasis on clinical trial data was misplaced, because of the artificiality of the clinical trial environment. Clinical trial conditions are designed to generate scientific information about the therapeutic and safety qualities of a drug. This may involve the use of dosages or combinations of other treatments not likely to be used in practice. The costs measured in this environment are not likely to be very relevant to any measure of cost effectiveness in the 'real world'.

In addition, compliance and patient characteristics will be different in actual practice. Professor Richard Day of the Australasian Society of Clinical and

Experimental Pharmacologists and Toxicologists stated:

Once out into practice ... you're into a population that's not controlled, is not overseen quite as frequently, and the effectiveness and costs will be different (transcript, p. 387).

Similarly, Parke Davis argued that 'actual prescribing patterns are not necessarily the same as data projected from controlled clinical trials' (sub. 121, p. 6).

Langley argued that the emphasis on clinical trial evidence in cost effectiveness analysis was self-defeating:

... their obsession with scientific rigour and the view that randomised clinical trial data are, in a hierarchy of data inputs, preferred, is very much at variance with their recognition that in moving from efficacy to effectiveness, we are forced to move to a modelling rather than a trial based evaluation environment (Langley 1996, p. 10).

PBAC response

The PBAC argued that many of the shortcomings identified by participants were only relevant to trials carried out before cost effectiveness requirements were imposed:

... [trials have been designed] specifically to meet the requirements of regulatory agencies. ... The nature of the questions that are asked in the trials has to change, and they are legitimate changes (transcript, p. 666).

The Commission's view

The Commission considers that there are serious doubts as to whether current Australian methodology and data requirements for cost effectiveness analysis, as reflected in the guidelines, are appropriate.

The Commission notes the comment in the Ontario guidelines that 'currently there is no single best methodological strategy for handling these questions in all circumstances' (DQTC 1993, p. 2).

In addition, the Commission notes that there have been difficulties in selecting appropriate comparators, although this appears to be of less concern than previously.

The incomplete and imprecise nature of much of the data used in economic analysis needs to be recognised. The Commission is particularly concerned at the emphasis placed on costing data collected in a clinical trial context. The artificiality of the clinical trial setting means that the costs generated may be virtually meaningless for cost effectiveness analysis of drugs in actual practice.

Langley concluded that a 'clinical trial plus' interpretation of pharmacoeconomics appears to dominate the PBAC approach. This reflects an essentially clinical view of drug evaluation, with a corresponding emphasis on efficacy rather than effectiveness' (Langley 1996, p. 2).

FINDINGS

The Commission finds that it is more appropriate that cost effectiveness guidelines provide broad principles rather than impose on companies requirements that are too prescriptive.

The Commission finds that the proper application of cost effectiveness analysis requires the estimation of costs incurred in actual practice. Costing information from clinical trials is unlikely to be an accurate indicator of such costs.

10.4 Delays

Participants expressed concern about the costs imposed in meeting cost effectiveness guidelines and the delays they cause in obtaining PBS listing. For example, Pfizer argued that delays in listing have increased since the introduction of cost effectiveness analysis:

The introduction of economic appraisal has substantially increased delays in the PBAC evaluation process. The current minimum time for evaluation for listing is eight months which, with price negotiation and the frequent need for resubmission result in average delay of approximately 12 months. This has a significant commercial impact since the typical effective patent protection period for marketing [is] only seven to eight years (sub. 79, p. 16).

SmithKline Beecham stated that generating the data for cost effectiveness analysis required long lead times:

[cost effectiveness] has severely affected the competitiveness of companies attempting to PBS list new items, in comparison to those listed prior to the new requirements. This is in terms of the long lead times associated with generating the data required to justify cost effectiveness claims (sub. 13, p. 14).

Merck, Sharp & Dohme also argued that evidential requirements delayed listing:

The cost effectiveness guidelines are placing evidential requirements on companies which cannot be achieved within a realistic timeframe (sub. 27, p. 10).

The DSHS rejected any implication that cost effectiveness analysis caused major delays. It argued that new pharmaceuticals did not have a right to be listed as a matter of course:

... the PBS is a Government subsidy scheme where listing must be based on evidence that products are value for money. Processes needed to establish value for money are no more a delay than the time required by a manufacturer of other products to convince customers to purchase those products (sub. 153, p. 1).

The Commission accepts the need to establish value for money before listing drugs but considers that greater recognition should be given to the impact of cost effectiveness requirements on companies and consumers. Cost effectiveness analysis is, by its nature, information intensive and may be costly. It is not surprising that costs and delays will be incurred in collecting and analysing the relevant data. Where cost effectiveness analysis is applied appropriately, these costs are offset by the benefits of a more efficient pricing mechanism. However, as discussed above, there are serious doubts as to whether current Australian requirements are appropriate and whether, as a result, industry may be subject to unnecessary costs and consumers subject to unnecessary delays in access to drugs.

The Commission recognises that, despite the potential efficiency gains the use of economic analysis can provide, the current approach to cost effectiveness analysis appears to impose unnecessary costs on companies and can delay the listing of drugs on the PBS, without providing sufficient offsetting benefits in terms of quality use of medicines and improved health outcomes.

FINDING

The Commission finds that the current application of economic analysis appears to have imposed unnecessary costs on companies and caused delays in the market availability of some drugs.

10.5 Measurement of costs and benefits

The inclusion of indirect costs of disease (or the benefits of its avoidance) in economic appraisal of pharmaceutical products is subject to considerable debate.¹ Similar controversies surround the valuation of intangible 'quality of life' benefits associated with new drugs. Industry has also criticised the current application of cost effectiveness analysis for focusing on the cost of drugs to the PBS and failing to take account of wider health system offsets.

¹ Indirect costs and benefits refer to changes in productive capacity as an outcome of therapy (DHS 1995e, p. 52).

Indirect costs and benefits

The economic literature suggests that it is possible to include a range of indirect costs and benefits in economic analyses, although their inclusion is subject to debate.

Opponents of the inclusion of indirect benefits argue on equity grounds that health care programs or products directed to working people will always generate more gains in production than programs directed at those not in the workforce. Inclusion of indirect benefits could well lead to reduced priority for programs which focus on quality of life for those not in the workforce, such as the mentally or physically disabled and the elderly.

Supporters of including indirect benefits respond that production losses due to illness influence the scarcity of resources and therefore the wealth of all members of society. In this respect there is no difference in assessing direct and indirect benefits—both should be incorporated in economic evaluations of health care programs.

Apart from ethical arguments against incorporating indirect benefits in economic evaluation, objections concentrate on the most frequently used estimation method—the human capital approach. This method defines the indirect costs of disease as the value of production lost to society due to disease. It is argued that estimates of the potential production lost may overestimate the actual production lost because:

- for short term absence, production will be made up on the return to work;
- employers usually have excess capacity in the labour force to cover absenteeism; and
- for long term absence, production will be made up by a replacement worker otherwise unemployed (DHS 1995e, p. 52).

However, various methods have been suggested to address these supposed shortcomings (see Box 10.3).

The APMA (sub. 31, p. 39), Faulding (sub. 46, p. 17), and SmithKline Beecham (sub. 13, p. 30) criticised the current Australian guidelines for placing too little weight on indirect benefits in cost effectiveness analyses. For example, the APMA said that, while arguments may be included in submissions about wider cost offsets in other areas of health care, insufficient weight is given to these and indirect economic cost offsets such as effects on employment and productivity (sub. 31, p. 39). Furthermore, Glaxo Wellcome argued that the Australian guidelines ‘are in complete opposition to guidelines developed in other countries’ (sub. 143, Attachment 1, p. 4).

For example, Ontario's guidelines appear to take a more balanced approach to the inclusion of both direct and indirect costs:

An effort should be made to construct the analysis in such a manner as to present the direct medical costs attributed to the provincially funded healthcare system as a separate analysis from the societal perspective. The societal perspective will include all direct costs, including those borne outside the healthcare system, and indirect costs such as lost wages (DQTC 1993, p. 1).

Box 10.3: Measuring indirect costs—the 'friction cost' method

Koopmanschap *et al* (1995) suggested a new approach for estimating the indirect costs of disease. Their friction cost method explicitly considers economic circumstances that limit production losses due to disease and results in estimates of production loss and costs that are considerably lower than estimates based on the traditional human capital approach.

The friction cost method assumes that production losses are confined to the period needed to replace a sick worker—the friction period.

The actual indirect costs of disease therefore consist of the value of production lost and/or the extra costs to maintain production during the friction period and, if an employee is to be replaced permanently, the costs of filling a vacancy and training new personnel.

Koopmanschap *et al* concluded that the short-term friction costs of disease are considerably lower than estimates based on the traditional human capital approach and better reflect the economic impact of illness.

Source: Koopmanschap *et al* 1995

PBAC response

The PBAC stated that, despite the wording of the guidelines, they did not discourage the inclusion of indirect costs but that until recently the data have not been available:

... if the industry has been unhappy with the treatment up until now it has not been because of an in-principle objection, it has just been the difficulty of accessing adequate data in this respect (transcript, p. 663).

However, the PBAC also noted that the inclusion of indirect costs did not appear to make a great deal of difference to the listing decision:

... the economic analyses that we see are not particularly sensitive to the cost offsets which have been modelled into the analysis ... In the main the cost offsets which are then modelled ... may change the cost effectiveness ratio but they don't

change it to a degree that it would alter the listing recommendation that was made (transcript, p. 662).

Intangible benefits

Participants argued that there are particular problems associated with valuing the intangible or ‘quality of life’ benefits associated with drugs that may have the same therapeutic effect as an existing treatment. It has been claimed that because of difficulties in valuing the benefits, the cost effective prices recommended by the PBAC undervalue such drugs. For instance, Glaxo Wellcome argued that:

... many new pharmaceuticals offer an improvement in the quality of life of patients to a level unachievable with the older therapies. One negative feature of the guidelines is that no account is taken of an enhancement of quality of life when negotiating price (sub. 143, Attachment 1, p. 3).

CSL provided the example of their treatment for psoriasis, the ‘first new product for psoriasis in about 35 years’:

It is very difficult to demonstrate cost effectiveness ... because we’re talking about improvements to quality of life, the fact that it doesn’t stain your clothes, the fact that it doesn’t make your skin irritated, the fact that the lesions heal a little faster ... the damned system makes it near impossible to ever get it listed on the PBS (transcript, p. 1194).

Eli Lilly did not expect to receive a price for its new insulin treatment, Lispro, that reflected its quality of life benefits:

Here is the first innovative insulin product in 30 years. It’s hard to show the difference between using it and using regular insulin in [therapeutic] terms ... but when you watch how patients can use the drug it changes their lifestyle in terms of managing their disease. So it’s a patient quality of life factor ... The cost of this thing is so high, and we think the benefits are very high for patients, that we have got to have some equalisation of the economic return on the product (transcript, p. 357).

PBAC response

The PBAC was inclined to play down the significance of intangible benefits and argued that ‘a lot of those advantages are marketing advantages in many instances’ and that such claims should be substantiated by trial data:

... [It is] up to the company to substantiate a benefit that it’s claiming to justify an increased price ... these are just vague claims that are being made without any substantiation very often (transcript p. 664).

... if the trials show you that your new drug is equally effective and equally safe to an existing drug but you want to charge two or three times more for it, based

on some claims that are going to be made, then it is reasonable that you should be required to substantiate those claims ...

... If quality of life is the issue then quality of life should be measured ... If that is the main claim it should be supported by trial data (transcript, p. 666).

However, the PBAC acknowledged that it had difficulties in valuing some quality of life benefits, and suggested it may need broader input than just clinical trials:

... the real issue is ... how do we make the value for money judgment? I think that is very hard because I don't think we have good processes in place for that and I would like particularly to highlight the need we will have—we already have—for broader input, possibly through community consultation but certainly we need some input into how these judgments should be made (transcript, p. 639).

Wider health benefits

Industry claimed that, although the guidelines request companies to provide estimates of both the financial implications for the PBS and the financial implications for Government health budgets, PBAC evaluation of cost effectiveness analyses focuses too narrowly on PBS costs and ignores wider health benefits such as reductions in hospitalisation and other medical treatments. For example, the APMA stated:

One of the major deficiencies we see in the Australian system is the narrow ... focus ... on cost effectiveness of drugs by comparing them with other drugs rather than cost effectiveness in the overall [health] system (roundtable pp. 229–230).

Faulding argued that 'the fact that the launch of a drug could lead to significant savings in other sectors, especially hospitals, is overlooked' (sub. 85, p. 17). Similarly, Professor Parry argued that 'there is no effective mechanism for taking the whole health budget into consideration' (roundtable, p. 12).

PBAC response

The PBAC argued that rather than being used as a means of cost control, cost effectiveness had actually reduced the extent to which the impact on the PBS budget governs pricing decisions:

I think one of the outcomes of cost effectiveness is that it has swung people's attention appropriately on to health outcomes in terms of evaluating submissions rather than looking at the impact on the PBS budget (transcript, p. 725)

Similarly, the PBAC argued that cost effectiveness analysis was allowing greater growth in pharmaceutical expenditure than a focus on the PBS budget alone would allow:

... economic analysis is not a cost containment mechanism; we are clearly not containing the costs of pharmaceutical expenditure, nor are we trying to. We are trying to justify new expenditure on the basis of perceived or estimated value for money. That really is the purpose of this process. I believe without that it would be more difficult to justify the growth and expenditure at a time when the

Government is clearly trying to limit total expenditure on health (transcript, p. 637).

The PBAC argued that wider cost offsets would be considered, as long as they were supported by adequate data. However, it expressed reservations about much of the available data:

Essentially any cost offset that is claimed to occur as a result of treatment with a new drug compared with the typically older drug will be allowed if it is supported by a reasonable standard of data.

... in many cases the data aren't there so in fact it's a question of evidence rather than any in-principle objection to it. It's just that we know that it's possible to be misled and I emphasise again I'm not suggesting that anybody is trying to mislead us, but it is possible to be misled by what apparently is the evidence on such matters (transcript, pp. 661–662).

The Commission's view

The Commission considers that there are persuasive arguments for including the indirect costs of illness in economic analysis. Although health programs directed at economically active people will tend to show greater indirect benefits, these estimates should be weighed in conjunction with other criteria like direct costs, ethical considerations and equity. An explicit estimate of the extent of indirect benefits is likely to be more helpful in decision making than relying on implicit notions.

In relation to intangible benefits, the Commission is concerned that the PBAC places too much emphasis on evidence from clinical trials to establish quality of life benefits. While the PBAC appears to acknowledge that information from other sources, such as community consultation, can contribute to economic analysis, there are currently no mechanisms in place to provide such consultation.

The PBAC appears to require such a level of certainty before it will consider the inclusion of wider health benefit offsets of drugs in cost effectiveness analyses, that companies have become sceptical about the PBAC's willingness to include such costs at all. The Commission considers that this is further evidence of the overly prescriptive and clinical approach taken to cost effectiveness analysis by the PBAC.

FINDING

The Commission finds that cost effectiveness analysis as required by the Pharmaceutical Benefits Advisory Committee does not appear to account adequately for the indirect and intangible costs and benefits and wider health benefits of drugs.

10.6 Prospective versus retrospective analysis

At present, cost effectiveness analysis for PBS listing must be prospective. It must be based on clinical trials and models designed to predict how economic benefits might apply to the community in general.

Several participants suggested that more accurate judgments of cost effectiveness would be available if evaluations were made after the product was marketed for a couple of years. They suggested that this would overcome the problem that estimates for economic analyses based on clinical trials are often inaccurate because first, the data were unavailable and second, prescription patterns do not necessarily reflect those projected from clinical trials.

To address these concerns, AMRAD suggested that the requirement for cost effectiveness analysis be waived until completion of Phase IV studies during the first two years of marketing a new drug (sub. 24, p. 5). It argued that this would prevent unnecessary delays in the availability of valuable new pharmaceuticals to the community (sub. 24, p. 43).

The major advantage of retrospective cost effectiveness analysis is that it enables the use of patient records to establish the actual consequences of using a particular drug. It thus removes the need for modelling likely costs and benefits. For example, it would be possible to examine the actual costs of prescriptions, hospitalisation and other treatments and whether the patients lost time from work or whether any premature deaths were prevented. Furthermore, retrospective analysis could potentially trace the costs and benefits of the use of a drug outside its permitted indications.

In response to such arguments, the Commission recommended in its Draft Report that:

... companies should have the option of delaying cost effectiveness analysis to allow for two years of marketing if the data necessary to conduct cost effectiveness analysis are unavailable (IC 1995c, p. 235).

This recommendation generated a significant response from participants.

Participants' responses

Many participants endorsed this recommendation and provided several additional arguments in favour of a delay:

- the need for economic analysis could delay listing and hence marketing of important new drugs;
- until cost effectiveness analysis becomes a standard requirement, new drugs will not have conducted Phase III studies with cost effectiveness in mind;

- the choice of comparator drugs may have changed since Phase III trials;
- Phase III endpoints to measure cost effectiveness may not be as appropriate as those available for Phase IV trials;
- Phase IV patient populations may be more appropriate than those in Phase III (AMRAD, sub. 165, pp. 4–5).

The Royal Australasian College of Physicians argued that the possibility of an optional delay ‘is well worth considering’. It did not believe, however, that the Government should allow indefinite subsidisation of pharmaceuticals without careful analysis of the cost benefit implications (sub. 140, pp. 1–2).

The APMA also strongly supported the Draft Report recommendation. It viewed this proposal as an innovative approach to achieving more ‘real-life’ information that would allow greater opportunities for demonstration of cost effectiveness than the cost efficacy substitute analyses that are currently imposed (sub. 119, p. 10).

However, other participants did not support the recommendation. A number of concerns were raised, particularly:

- a perceived implication that companies have a right to subsidy;
- methodological and data constraints;
- at what price to list during the delay; and
- practical difficulties removing drugs found not to be cost effective after two years.

APAC considered that the introduction of a two year delay would ‘place at risk the system of using economic analysis as a mechanism for the efficient use of the community’s resources with respect to drug costs’ (sub. 137, p. 2).

The DSHS interpreted the Draft Report recommendation as proposing that ‘manufacturers have some right of subsidy even without evidence’ and rejected any implication that ‘new pharmaceuticals have a right to be listed as a matter of course’ (sub. 153, p. 1).

The PBAC stated that ‘while accepting that [looking at how drugs are actually used and actually perform in the community] is an attractive notion—it is necessary to have some regard for the methodological constraints that are imposed’ (transcript p. 641).

Dr David Henry identified the following constraints:

- in Australia there are no data bases that allow linkage of data on drug use and outcomes of therapy;

- even where such data bases exist, they are set up primarily for administrative reasons and do not contain much of the information necessary for cost effectiveness analysis;
- linkage of apparent differences in outcomes of therapy to the treatments used is very difficult because of confounding and other forms of bias. Such differences can easily be detected in randomised clinical trials (sub. 170, p. 2).

The PBAC argued that the only way to assess cost effectiveness after listing would be if this were carried out as a randomised trial set up to address the relevant policy questions:

... one response to this is to subsidise these drugs but only within the context of a rigorous randomised trial that answers the policy-relevant questions about the use of that drug (transcript, p. 643).

Some participants questioned how an interim price would be established in the absence of cost effectiveness analysis. They considered that there is no guarantee that the drug would be listed at a price during the initial two years that would be cost effective.

Dr David Henry feared that this would lead to a return to an arbitrary system of price setting which would disadvantage companies with innovative products:

In other words, a new drug, which is often only a marginal improvement over the old drugs, will be recommended to the pricing authority as having a 'minimal advantage'. There is no concept of cost effectiveness in this sort of recommendation. The old drug, probably available at a few cents per day will then be used as the benchmark and that slight advantage will be translated into a price much lower than the company would have got through a consideration of the cost effectiveness of its product (sub. 138, p. 2).

The DSHS also argued that 'it would be unethical and politically unrealistic to subsidise a drug ... then restrict or remove the product after two years if it did not meet claimed outcomes' (sub. 153, p. 14). Similarly, the Victorian Government argued that the proposal for a two year delay would be difficult to administer in practice, particularly because of difficulties in removing from the PBS drugs found not to be cost effective (sub. 182, p. 3).

The Consumers' Health Forum (CHF) also expressed concern at 'the ethical problem with removing a product from PBS listing if the cost effectiveness analysis is unfavourable, given that this may cause very practical problems for consumers who have been using it as their medication of choice for up to two years' (sub. 139, p. 9).

The Commission's view

The Commission considers that all the above problems can be addressed.

The Commission is concerned that some participants appear to have misconstrued the Draft Report recommendation. The Draft Report stated that:

The Commission considers most of the problems of evaluating drugs on the bases of randomised trials and predictive models discussed above could be avoided if the analysis was undertaken after two years of marketing. *Products could be provisionally listed on the basis of their therapeutic value and community need after an appropriate price has been negotiated* (IC 1995c, p. 235).

The Commission did not contemplate that 'new pharmaceuticals have a right to be listed as a matter of course' or that 'manufacturers have some right to subsidy without evidence'.

The Commission explicitly envisaged that the pricing authority would still negotiate a price for the period of the delay but that formal cost effectiveness would not be an input into that negotiation. It is noted that the PBAC negotiated prices without the benefit of formal cost effectiveness prior to the introduction of mandatory cost effectiveness analysis in 1993. These negotiations appeared to result in relatively low prices compared to other countries.

Although there is no guarantee that drugs listed at a negotiated price in the initial two years would prove to be cost effective, the current limitations on cost effectiveness analysis mean that drugs listed at prices recommended by the PBPA may not necessarily be cost effective either.

For example, a 1993 UK study concluded that early economic analyses can lead to perverse outcomes:

[the study]... casts doubt on the viability of establishing regulatory hurdles based on early economic analyses which are often only partial ... Strict application of such criteria lead patients to be deprived of important innovations and may have the perverse effect of directing resources to treatment options which, in the long run, are less cost effective (Matheson *et al* 1993).

Review of cost effectiveness information after two years marketing would not necessarily lead to removal of the product from the market but rather may involve a price review. The PBAC routinely conducts periodic reviews of drugs on the PBS to determine continuing subsidy and products are removed from PBS listing.

A product would not be removed from listing unless found to be not cost effective compared to some alternative, and the Government and company could not negotiate a satisfactory price. In such a case, the comparator or other

substitutes would remain available to users of the deleted product. Other potential solutions such as extended special patient contribution mechanisms could maintain consumer access to these products at a compensated price (although not fully subsidised by the PBS).

The Commission notes that the DSHS, although opposed to a formal two year delay, has recognised that:

... as products reach the market faster, often on a world wide basis, it is not possible always to have data on actual outcomes, hence surrogate measures might be used. On occasions, where effectiveness is based on surrogate measures, products have been subsidised on the understanding that post marketing monitoring will occur so that the listing conditions can be reassessed over time. Even in these cases, economic data are available and increasingly this aspect is part of phase III clinical trials (sub. 153, p. 14).

This practice appears to delay full cost effectiveness analysis pending the collection of more appropriate data in a market setting. Where such arrangements are made, they should be formalised and transparent, and available to all participants.

The Commission remains convinced that the many problems associated with evaluating drugs on the bases of randomised trials and predictive models discussed above could be avoided if cost effectiveness analysis was undertaken after two years of marketing.

However, the Commission cautions that simply delaying the time at which cost effectiveness analysis is done does not address the more fundamental theoretical and methodological issues associated with the current application of the technique. It therefore proposes that these be examined as part of the recommended PBS process review (see Chapter 9).

It is appropriate to grant companies an option of conducting cost effectiveness analysis at any time within the two year delay period. This option provides a means of helping companies adjust to the data requirements of cost effectiveness analysis without imposing unnecessary costs.

However, a company contemplating the expense of a major marketing campaign for a new drug may wish to conduct cost effectiveness analysis before commencing marketing, to ensure a more definite estimate of probable price.

Another possibility is to allow companies greater scope to submit information from trials based on expected actual practice. In either case, administrative arrangements could be introduced to reimburse the Government if the original negotiated price ends up being too high in cost effectiveness terms.

Recommendation 10.1

The Commission recommends that companies should have the option of delaying cost effectiveness analysis for two years to allow for the collection of costing data based on actual use.

The need to continue this option of delayed cost effectiveness analysis should be reviewed in the Commission's recommended PBS process review (see Chapter 9).

10.7 Reliance on cost effectiveness analysis

Participants were concerned that, given the theoretical and practical difficulties associated with cost effectiveness analysis at its current stage of development, it is given undue weight in pricing decisions.

ICI criticised cost effectiveness analysis as 'a pseudo scientific means of cost comparison requiring a sophisticated submission' (sub. 50, p. 2). Parke Davis argued that 'to a large extent' it was all 'window dressing' (transcript, p. 553).

Companies also criticised the conservative approach taken to cost effectiveness analysis by the PBAC. For example, Schering-Plough claimed that the PBAC has a 'tendency to select the worst case scenarios' and that this:

... may have a flow-on effect when a series of assumptions are being made and may even turn a positive cost effectiveness result into a perverse negative cost effectiveness result. Thus a drug product which may save the Government money will be considered to cost the Government money according to the PES's approach of economic analysis (sub. 128, p. 1).

Similarly, Glaxo Wellcome argued that:

Many times, the ESC operates in a pseudo-PBAC capacity and appears to be much more conservative than the PBAC itself. This has obviously limited the opportunities for industry in getting products reimbursed much more than was the case before the ESC was established. The role of the ESC needs to be reassessed as its influence increases (sub. 143, Attachment 1, p. 4).

Langley stated that:

While [the cost effectiveness analysis guidelines] have an immediate appeal to those coming to pharmacoeconomic evaluations from a clinical perspective, the approach taken is unlikely to appeal ... to economists ...

... the use of the term 'economic evaluation' exaggerates the degree of sophistication which is applied (Langley 1996, pp. 1, 8)

PBAC and PBPA response

The PBAC argued that cost effectiveness was ‘fairer’ and led to ‘more appropriate’ prices than the previous ‘arbitrary’ pricing system:

... we believe that cost effectiveness analysis provides a fairer basis for price setting than arbitrary judgments about the relative merits of different competing drugs. I think the evidence—[which] I accept is preliminary—is that the prices that have been awarded and/or agreed to under cost effectiveness provisions are getting closer to whatever one might regard as an appropriate benchmark than they have been in the past.

... where a satisfactory economic analysis has been submitted the companies are very likely ... to receive a price that is very close to the price that they want and very close to the price that has been granted in other countries (transcript, p. 637).

The PBPA acknowledged that there are limitations to using cost effectiveness analysis. However, it assumed that the limitations meant it should aim to achieve lower prices where possible, in order to guarantee cost effectiveness:

Submissions to the PBAC need to make a number of assumptions and the PBAC will advise if a product is of a reasonable or acceptable level of cost effectiveness based on these, often imprecise, assumptions. Any lower price negotiated must improve the cost effectiveness ratio (sub. 201, p. 1).

The Commission asked what relative weight was given to PBAC cost effectiveness recommendations. The PBPA replied:

Although the Authority puts high reliance on the advice from the PBAC, cost effectiveness is one of a number of factors the Authority takes into account. The weight given to cost effectiveness will vary with different drugs depending on issues such as the expected volume, availability of alternatives and drug cost (sub. 201, p. 1).

The Commission’s view

The Commission considers that appropriately designed and administered cost effectiveness analysis can provide a useful input for assessing suitability for listing on the PBS. Its use may also lead to closer correspondence between PBS prices and the real value of medicinal products to the community. There is some evidence, discussed in Chapter 8, that new listings on the PBS are achieving higher prices.

However, despite the theoretical attraction of cost effectiveness analysis as a mechanism for ensuring ‘value for money’ in decisions relating to PBS listing, significant problems remain in its application in Australia. These are:

- theoretical problems with the underlying methodology, such as whether to incorporate indirect benefits;
- practical problems in collecting the data necessary to do meaningful analysis, such as the requirement for clinical trials data; and
- problems associated with the types of value judgments made by the ESC and PBAC based on cost effectiveness analysis.

The present emphasis placed on cost effectiveness analysis goes beyond its practical use. Its accuracy and precision are being exaggerated, given the unresolved technical and measurement issues. The Commission is particularly concerned that it is being used to supplement clinical judgments about small differences in drug therapeutic properties.

Inappropriate application of economic evaluation in decision making can occur. Tools such as cost effectiveness analysis have the seductive property of providing an apparently precise, often single answer to complex questions. Unless the assumptions, methodologies and data deficiencies are understood and taken into account, there is a serious risk of too much weight being given to cost effectiveness estimates because they are wrongly perceived as precise.

FINDINGS

The Commission finds that the use of cost effectiveness analysis in drug listing procedures will contribute to the efficient use of community resources if applied appropriately.

The Commission finds that because economic analysis can only be approximate, undue reliance has been placed on its use in Pharmaceutical Benefits Scheme listing and pricing decision making.

10.8 Review of cost effectiveness analysis

In Chapter 9, the Commission recommends that a number of PBS process issues should be reviewed. There are some particular aspects of cost effectiveness analysis which could also be addressed in such a review.

The DSHS commissioned a consultancy to develop recommendations on how to review the implementation of cost effectiveness (Evans 1995). The consultancy suggested a detailed terms of reference which included the following areas for review:

- the impact of the cost effectiveness requirement on ensuring that cost effective products are listed, timely availability and equity;

- the consistency, transparency, fairness and technical accuracy of decisions, the efficiency of the process and adequacy of resources allocated to the process;
- whether the guidelines should be amended to improve their clarity and incorporate recent theoretical developments; and
- the establishment of an internal quality control system.

The Commission considers that these issues should be examined in its recommended process review. In addition, this review should assess the broader methodological issues raised in this Chapter, examine the skills required to undertake evaluation of cost effectiveness analyses and investigate further the potential of the Commission's recommended two year delay.

11 FACTOR F—AN EVALUATION

This Chapter contains an evaluation of the effectiveness and efficiency of the Factor f scheme. To analyse these issues, the Commission has used a consultancy report from the Bureau of Industry Economics as well as information provided by participants. The Commission has concluded that the scheme may have both under and overcompensated for the effects of the PBS. The efficiency of the scheme was judged on whether it brought net benefits to the Australian community. The results are inconclusive, but it is doubtful that the scheme overall has achieved this because of the way it was designed. Its poor administration has caused concern in the industry.

11.1 Assessment of the Factor f scheme

The Inquiry's terms of reference require the Commission to evaluate the effectiveness and efficiency of the Factor f scheme and quantify the benefits of Factor f scheme assistance (Term of Reference 4b). This is the purpose of this Chapter.

The effectiveness of the scheme describes how well it meets its goals. As discussed in Chapter 5, the Commission considers the aim of the scheme is to restore activity lost due to price suppression.

Efficiency refers to whether the reallocation of resources brought about by the scheme has resulted in net benefits to the community—that is, whether the social benefits exceed the social costs. Ideally, this should be measured on an economy wide basis, but because the industry is small, this is difficult to do. (Section 11.4 outlines some general equilibrium modelling results of the effect of Factor f on broader economic variables.) Consequently, the Commission has chosen to undertake a partial analysis which focuses on the impact of the scheme on the industry and largely discounts the interaction between the industry and the rest of the economy.

This partial approach has its own limitations. Its principle weakness is that while costs can be estimated quantitatively, many of the benefits of the scheme must be described qualitatively. There are many reasons for this.

First, many of the benefits will occur in several years time and are uncertain. For example, the benefits from R&D spending occur many years in the future. Second, other benefits are qualitative in nature and cannot be measured accurately. Some of these qualitative benefits will accrue to the participating companies themselves. Third, there will also be spillover benefits resulting from the scheme, which will accrue to non-participants as well as other companies outside the pharmaceutical industry.

While recognising the inherent limitations of the approach, the Commission has chosen to assess what benefits it can and has described the likely size and value of these benefits. In the broader context, likely changes to the pattern of resource usage and the benefits of these changes are discussed qualitatively.

To help analyse these issues, the Commission commissioned the Bureau of Industry Economics (BIE) to undertake a study based on a survey of pharmaceutical companies. The BIE's 1991 Review of the industry contained a similar analysis. The Commission asked the BIE to update and repeat this analysis, with the advantages of experience, hindsight and an extra four years' worth of data. The BIE's 1995 survey respondents accounted for 70 per cent of Pharmaceutical Benefits Scheme (PBS) sales.

The Commission has used this report as one input into its analysis. In addition, the Commission used information provided by participants about the benefits to themselves and others of participating in the scheme, as well as information from multinational company head offices.

11.1.1 Qualifications to the BIE analysis

There are several points to be borne in mind when using evidence drawn from the BIE survey.

First, some of the survey questions are hypothetical in nature and therefore require non-factual answers.

Second, there may be some scope for strategic responses to some questions. For example, some respondents might have biased their answers to the questions in such a way as to maximise the potential for the Commission to find favourably upon the effectiveness or efficiency of the scheme.

Third, the numbers of companies in each group of respondents is not large, as emphasised by Astra (sub. 141, p. 12). The most extreme example is the group of continuing participants, which contains only four companies.

There are other, broader limitations to the approach that should also be taken into account. As the BIE itself noted, its approach did not take account of:

- any wider economic benefits arising from the elimination of a government distortion; and
- any net gains to tax revenue resulting from such a reallocation of resources (BIE 1995, p. 89).

Also, the analysis takes account of only those benefits arising during the life of the scheme—since some activity is expected to continue once payments are made, then any benefits associated with that activity will also continue.

11.2 Effectiveness of Factor f

As discussed in Section 11.1, the Commission considers the aim of the scheme should be to restore activity lost due to price suppression under the PBS. This means that the scheme should try to recreate the types, levels and pattern of activity that would have occurred in the absence of price suppression.

As discussed in Chapter 5, Factor f can be viewed as both a scheme designed to restore efficient activity that has been lost to Australia because of low PBS prices, or it could be used to promote industry development in its own right. This distinction becomes especially important in determining how effective the scheme is in meeting its aims. The restoration rationale implies that the scheme could overshoot its aim, that is, it could overcompensate for activity lost due to price suppression. Similarly, it could achieve less than this goal in some areas and undercompensate for the effects of price suppression. On the other hand, if industry development is the main criterion, there can be no concept of overcompensation—all activity is counted towards measuring the success of the scheme. The Commission has rejected this latter approach (see Chapter 5).

What the industry would look like in the absence of the price suppression is unknowable in an absolute sense. The following sections analyse the way the scheme has influenced activity.

11.2.1 Potential undercompensation

There are two main ways in which Factor f could have undercompensated for the effects of price suppression:

- by excluding some companies which might have increased their activity if prices were higher; and
- by excluding some types of activities which might have been undertaken under a deregulated pricing environment.

It is likely that undercompensation occurred under Phase II of the scheme because certain companies were excluded. As discussed in Chapter 12, several companies claim that they would have increased their activities in a deregulated pricing environment (although most of the non-participants claimed they would not). In particular, the companies eligible under Phase II of the scheme, but which were denied access to funding, may represent a source of undercompensation.

On the basis of survey information, the BIE also noted that had all of the eligible companies seeking entry into Phase II of the scheme been successful, Phase II would have included virtually all of the companies which claimed they would have increased their formulation and packaging activity if prices were higher (BIE 1995, p. 39).

Regarding R&D, there were several companies which claimed they would have increased their clinical trial activity in Australia in the absence of price suppression. Many of these companies have little or no manufacturing presence in Australia. These companies were excluded from participating in Factor f by the twin eligibility criteria of the scheme. This represents another source of undercompensation under the scheme, caused by the scheme's design features.

The BIE did not identify any source of undercompensation arising due to excluded activities.

However, some companies have suggested that in any future scheme, activities related to health promotion should be included as eligible activities under the scheme. Nevertheless, it is unclear why low PBS prices would be the main impediment to such activity. While there may be a link between low prices, low profits and the amount of money a company can afford to spend on such activities, the Commission considers that it would be more appropriate to encourage such activities through institutions such as the Australian Pharmaceutical Advisory Council and the Rational Use of Medicines Sub-Committee (see Chapter 13).

11.2.2 Potential overcompensation

The BIE (1995) identified two main potential sources of overcompensation in Phase II of the Factor f scheme. These include:

- making payments on activity that would have taken place anyway; and
- inducing more activity than would have occurred under a deregulated pricing regime.

Activity that would have taken place anyway

Factor f was designed to encourage additional activity in Australia. If it made payments for activity that was going to occur anyway, then in effect this was money wasted.

There have been many significant changes in the environment for pharmaceutical companies since the scheme's introduction. Other initiatives, such as the change in patent rules, were introduced through the Pharmaceutical Industry Development Program. Cost effectiveness analysis has been introduced, which has allowed some companies to justify higher prices for some drugs than previously. There have also been changes in the general economic climate, including lower interest rates, labour market reforms, improvements in public infrastructure pricing policies and other elements of general microeconomic reform. These effects may have been expected to have a positive influence on the growth of activity regardless of the Factor f scheme.

However, responses to the BIE's 1995 survey indicated that most of the increased activity planned for the duration of Factor f would not have occurred without Factor f. Although there is significant scope for response bias in these figures, they are supported by other information provided to the Commission.

Many participants in this Inquiry argued that Factor f had a catalytic role in encouraging activity that would not have occurred in the scheme's absence. For example, the Australian Pharmaceutical Manufacturers Association (APMA) stated that:

... there should be no doubt in anyone's mind that the effectiveness and success emanating from Factor f has really demonstrated the willingness and capacity of the pharmaceutical industry to respond positively to a favourable environment for investment (transcript, p. 220).

AMRAD described itself as 'a success story encouraged by the Factor f scheme':

At the time of the Factor f announcement in 1988 AMRAD Pharmaceuticals did not exist. However, the Factor f scheme provided the stimulus for AMRAD and [Merck, Sharp & Dohme] MSD Australia to joining forces to conduct rapid development of selected projects from Australian research (sub. 24, p. 11).

However, some participants indicated that some of their activity would have been undertaken without the payments. This implies that not all of the activity attracting Factor f payments was induced by the scheme.

To gain further insights into the amount of activity that the scheme induced, the BIE examined the responses of the unsuccessful applicants in Phase II. This was to see how their activity without Factor f compared with what they would

have done had they been accepted into the scheme. Appendix M includes these responses to the BIE survey.

The BIE noted that:

Not surprisingly, companies indicated they would carry out more activity under Factor f than they were planning to undertake as non-participants. However, at least some participants were planning to carry out higher activity over this period anyway, so that not all the additional activity that might have qualified for Factor f support was induced solely by the scheme. This suggests that some adjustment to inducement for participants is warranted ... (BIE 1995, p. 43).

The Commission agrees that it would be inappropriate to attribute all increases in activity to the Factor f scheme. While it would seem logical that the more generous a subsidy scheme is, the more activity it will generate, the scheme alone is unlikely to have been the only reason for the increased activity.

The scheme also influenced the behaviour of non-participants and any activity induced in these companies should be considered. Several unsuccessful applicants have claimed that, but for the scheme, they would not have undertaken some projects (see Box 11.1).

Potential overcompensation for continuing participants

It is apparent that the scheme has worked selectively in the way it compensates for low PBS prices. One striking instance is the case of continuing participants. It is likely that the scheme paid for activity that would have occurred anyway because continuing participants were permitted to keep their base year from Phase I. Phase II activity is rewarded on the basis of being an increase over a base year. The smaller the value of activity in this base year, the greater the payments. As the BIE noted:

Any scheme of government support that retains a fixed base for a period as long as twelve years, and rewards all increases in activity over this fixed base at a subsidy of 25 per cent, as under Factor f, appears to be extraordinarily generous (BIE 1995, p. 46).

To some extent, this generosity may be reflected in the concentration of payments to relatively few companies. The four continuing participants will receive up to 68 per cent of allocated Phase II funds (BIE 1995, p. 30). Two participants in the scheme will receive almost half the total support offered in both Phases (BIE 1995, p. 95). However, it should be noted that these companies also dominate activity figures and concentration is not an inherently bad characteristic of the scheme.

Box 11.1: Non-participant activity induced by Factor f

Eli Lilly was one of the companies that applied for Factor f but failed to attract funding due to the budget cap. In order to demonstrate the integrity and potential of the submission, Eli Lilly undertook several activities in advance of Factor f funding approval. This involved:

- limited re-introduction of manufacturing initially via a third party;
- undertaking a major review of Australia's biomedical research expertise;
- progressively building up strategic research and development (R&D) projects in both basic and clinical research; and
- development of detailed strategic options to build a new manufacturing capability or to acquire an existing state of the art facility.

When the decision was made to exclude Eli Lilly from the scheme, all proposed projects were reassessed according to the company's Decision Making Model. Most of the manufacturing and export projects failed to be short listed, since without the Factor f support, they could not generate the required returns. Increased risk of policy instability and uncertainty was also important.

However, the committed or almost committed R&D collaborations were able to proceed because of their long term strategic value and importance. Eli Lilly contends that these projects, including the AZA joint venture with the Garvan Institute, would never have occurred had it not been for the preparation undertaken in the light of a more positive environment created by the Factor f scheme.

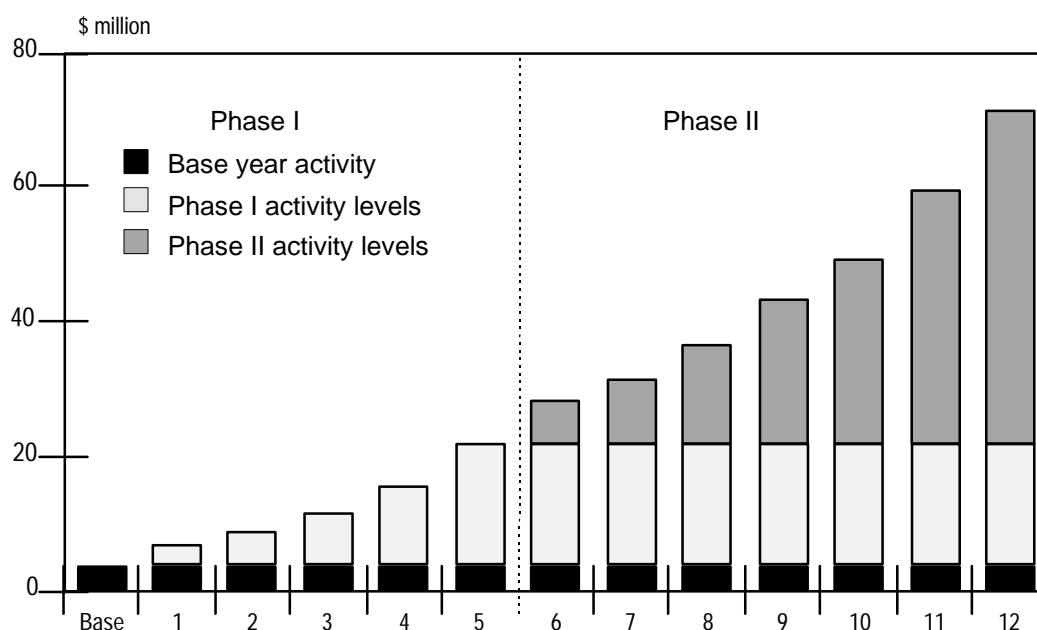
Similarly, SmithKline Beecham was preparing to undertake ten R&D projects in Phase II of Factor f. When it failed to receive funding under the scheme, it reduced this number to three, two of which were with the Macfarlane Burnet Centre for Medical Research.

Bristol-Myers Squibb has also increased investment in Australia on the basis of activity planned for Phase II of the scheme, despite not obtaining funding. The company claims that since the decisions were made in advance of Phase II beginning, the company was locked in to those decisions.

Sources: Eli Lilly sub. 142, pp. 9–12; Macfarlane Burnet Centre for Medical Research sub. 17, p. 3 and transcript, pp. 1065–1066; Bristol-Myers Squibb transcript, pp. 821–822

A description of the effects of the use of the Phase I base year is contained in Figure 11.1. Continuing participants were rewarded for all activity above the base year activity of 1987, indicated by the black area. By the end of Phase I, this activity level gradually increased to equal the pale grey area.

Figure 11.1: Illustrative example of the effects of the base year for payments made to continuing participants, \$ million



Source: BIE 1995, p. 45

When Phase II began, it might have been expected that companies would have maintained activity at the level of the pale grey area even without further payments, especially if this activity was truly internationally competitive. On the face of it, it is unlikely that this level of activity was induced by Phase II payments.

However, some of the larger companies argued that the maintenance of activity levels masks the dynamic process of replenishing activity as product life cycles end and new technology replaces old. For example, Merck, Sharp & Dohme stated that since products have life cycles of only 10 years or so, when products go off patent they are replaced by other products. While the level of activity may appear constant it is supporting a constantly changing product mix (transcript, pp. 402–403). Glaxo Wellcome made similar comments regarding products and technologies (transcript, p. 1299).

Because the maintenance of end-of-Phase I activity levels was important to achieving Phase II targets, it could be argued that at least some of this activity was induced by Phase II payments. However, to the extent that ongoing payments are required to maintain existing activity levels, then these activities might be seen as being footloose and fragile, and possibly not internationally competitive.

Table 11.1 illustrates the difference between how much of the currently eligible export value added and R&D activity would not have been eligible had the base year been the end of Phase I. This shows that the Phase I base year has a significant effect on the amount of eligible activity and hence the payments continuing participants receive.

Table 11.1: Differences in eligible activity if end-of-Phase I activity levels were the base for continuing participants in Phase II

<i>Activity</i>	<i>Phase II increase in activity over end-of-Phase I base year \$m</i>	<i>Phase II increase in activity over original base year \$m</i>	<i>Ratio %</i>
Value added on exports			
Foreign owned	367.8	686.2	54
Australian owned	209.2	346.7	60
R&D			
Foreign owned	40.6	94.9	43
Australian owned	124.7	185.3	67

Source: BIE 1995, p.47

The Phase I base year has the greatest impact on export value added and R&D. Calculations of domestic value added are product specific, which means that this type of overcompensation is unlikely to have occurred.

Two of the four continuing participants' responses to the BIE survey indicated that they would not have done as much activity under Phase II had their base year been their final year of Phase I, rather than their Phase I base year, a point emphasised by Astra (sub. 141, p. 12). This implies that the higher effective rate of payments was needed to induce the activity. However, two companies indicated that they would have done the same amount of activity even with a different base year (and hence with lower payments). This suggests that for these two companies, overcompensation is likely to have occurred.

However, Merck, Sharp & Dohme rejected this proposition, stating that:

In the context of price correction, ... Factor f payments to [Merck, Sharp & Dohme] MSD have not enabled us to move our patented products to [European Community] average prices. In fact many of our product prices are well below the [European Community] average, even after Factor f has been applied ...

In the context of industry development, had Factor f not existed, MSD would simply not have undertaken the local activity on which it embarked (sub. 122, p. 11).

However, this view fails to recognise that the scheme's aim should not be to compensate companies for low PBS prices, but rather to compensate for activity lost due to price suppression. It may not be necessary to raise all prices to European Union (EU) levels in order to 'buy back' this lost activity. Therefore, overcompensation can still occur even though some prices are still below EU average because the aim of the scheme refers to *activity* levels rather than *price* levels *per se*.

On balance, it appears that having different base years for continuing and new participants resulted in:

- making payments more generous than necessary to induce at least some of the activity that occurred; and
- different and unfair treatment of continuing and new participants.

Inducement of more activity than in the absence of pricing constraints

As well as paying for activity that would have taken place anyway, Factor f may have overcompensated companies by inducing more activity than would have occurred in a deregulated pricing environment.

As discussed in Chapter 12, the BIE surveyed companies to estimate the levels and types of activity that companies might undertake in a deregulated pricing environment. The BIE then compared this information with what Factor f participants were actually doing. The BIE found that Factor f appears to encourage more export value added (and to a lesser extent, domestic value added) than would occur in a deregulated pricing environment.

Even for clinical trials, which most companies nominated as the area of R&D which they would undertake more activity in a deregulated pricing environment, the scheme appears to encourage too much activity (see Appendix M) (BIE 1995, p. 49). The BIE raised the possibility that some companies may only be pursuing R&D in order to be eligible for much larger production payments. Without the need for R&D expenditure for Factor f payment purposes, most participants would appear likely to concentrate on manufacturing. The BIE noted that this was less likely to be the case for Australian owned companies, due to the integrated nature of their local activity.

CSL responded to the BIE's survey with an indication that some activity had been induced by Factor f which would not have occurred in a deregulated price environment:

The increase in profits provided by [deregulated pricing] would enable CSL to invest in commercialising local R&D and internationalising our business.

However, not to the extent that Factor f funding has stimulated this activity (BIE 1995, p. 49).

Another piece of evidence which may point to overcompensation is the fact that the Factor f payments amounted to much more than the capital costs of all of the investment required to meet companies' commitments. In fact, Factor f payments under Phase II are around twice the size of all planned investment (BIE 1995, p. 77). Indicative calculations by the Commission show that this is likely to have significantly increased the rate of return on investment, probably to somewhere above the normal rate of return for similar high technology manufacturing industries. This may suggest that Factor f payments were more generous than they needed to be to attract back any investment and associated activity which the PBS may have impeded.

Several participants have responded that even if the Factor f scheme did encourage more activity than would have occurred had prices been deregulated, that this should be seen as an extra achievement of the scheme, not a failing.

However, the Commission considers that assuming the aim of the scheme is to correct for a resource allocation distortion, inducing more activity than would have taken place in the absence of this distortion means that too much money was spent on the scheme. Presumably, lower payment rates would have induced less activity than has occurred under the current scheme. If lower rates could have ensured the scheme *met its aims and no more*, then this would have been a preferable outcome.

Comparative data on the effects of Factor f

The Commission has received information on the comparative performance of participants in the scheme and other companies. This information can potentially shed light on the influence of the scheme on various activities.

The APMA (1995a and sub. 119) provided comparative data based on a survey of members. Respondents reported their expected activity levels up until 1997–98 which showed that, while the activity of Factor f companies did indeed dominate the levels of activity, the rates of growth for Factor f companies and non-participants had often not been as different as might be expected. Given that one group of companies received a subsidy and the other did not, it might have been presumed that the subsidised group would perform more activity and would grow faster than the non-subsidised group. However, this only appeared to be the case for some of the subsidised activities.

Since the Draft Report, the APMA has provided additional information to the Commission regarding the comparative performance of Factor f participants and

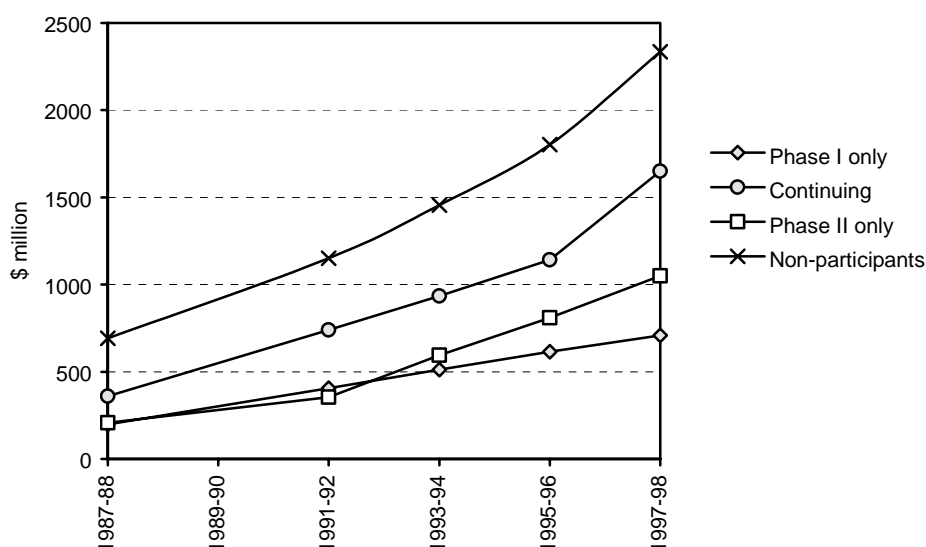
non-participants. Further information is contained in Appendix J. Key comparisons include:

- turnover;
- exports; and
- production value added for PBS-type markets.

Turnover

Both participants and non-participants have experienced strong growth in turnover (see Figure 11.2). This suggests that the same factors affecting market growth (for both imports and domestic production) apply to both participants and non-participants.

Figure 11.2: Turnover by company type, 1987–88 to 1997–98, \$ million

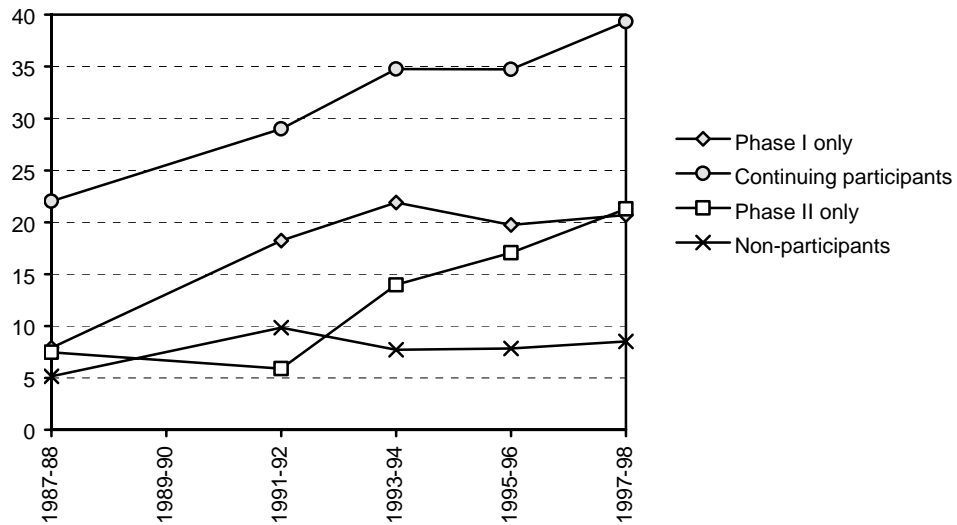


Source: APMA sub. 119, Attachment 1, Appendix A, p. i

Exports

A clear difference between participants and non-participants can be seen in export/turnover ratios. Continuing participants are expected to have the highest ratio of 39 per cent at the end of the decade, while Phase I only and Phase II only companies are expected to have a ratio of 21 per cent. Non-participants, despite starting the decade with a ratio only a couple of percentage points lower than companies in this group, are expecting an export/turnover ratio at the end of the decade of only 9 per cent (see Figure 11.3).

Figure 11.3: Export to turnover ratio, 1987–88 to 1997–98, per cent

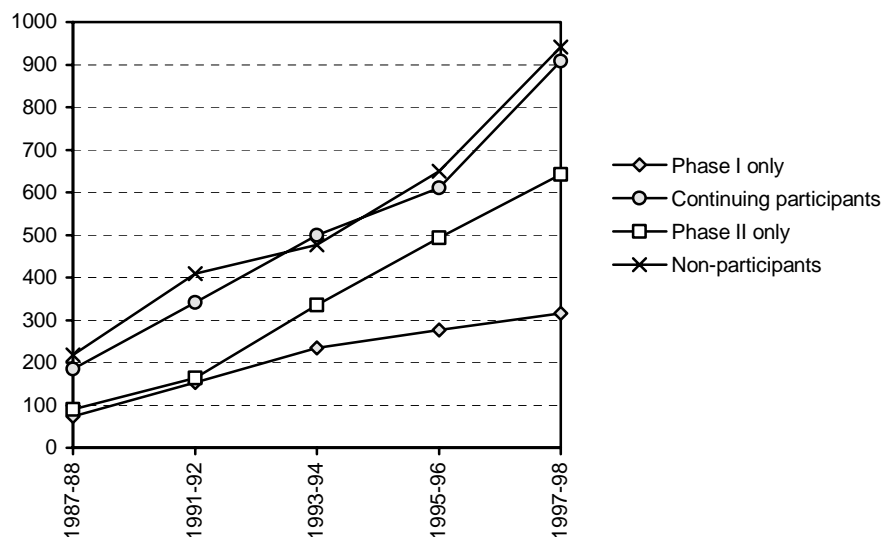


Source: APMA sub. 119, Attachment 1, Appendix A, p. ii

Value added

It appears that all groups of companies are increasing their value added in Australia (see Figure 11.4).

Figure 11.4: Production value added—PBS type, turnover minus imports, 1987–88 to 1997–98, \$ million



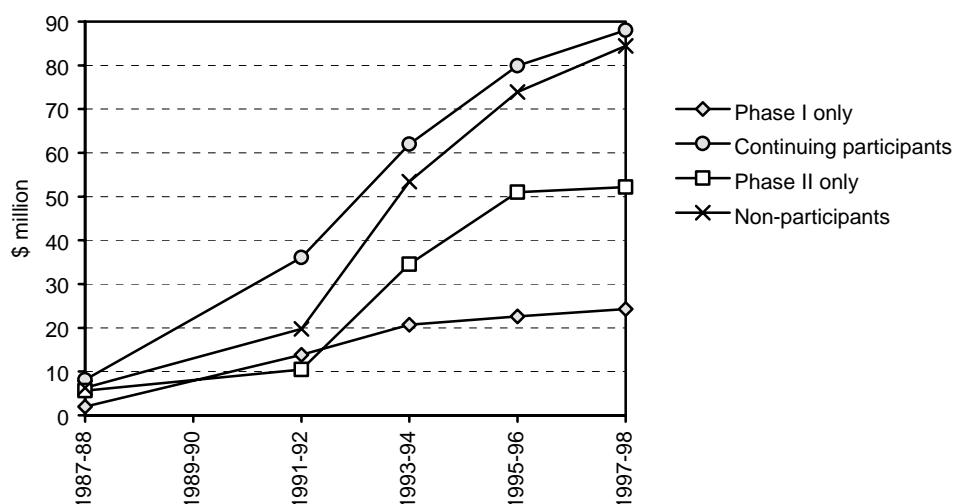
Source: APMA correspondence 12 April 1996

Non-participant growth appears to be as strong as that of participating companies. Phase I only participants' growth has not been as great as continuing and Phase II only participants' growth, or as strong as non-participants' growth. For the PBS-type market, the similarities in growth rates are even more pronounced.

Research and development

Regarding R&D, non-participants are expected to spend more than 13 times their 1987–88 levels of investment in 1997–98 while Factor f companies are expected to increase their spending about tenfold. While the size of R&D spending by non-participants is comparable to that of Phase I only and Phase II only companies combined, it should be noted that the four continuing participants alone account for more than the total of either group throughout the period (see Figure 11.5).

Figure 11.5: Research and Development, 1987–88 to 1997–98, \$ million



Source: APMA sub. 119, Attachment 1, Appendix A, p. ii

Of the non-participating companies, four of those which applied but were unsuccessful in obtaining Factor f funding account for 20 to 30 per cent of the R&D carried out by non-participants. The APMA claims that this R&D was largely set in train in anticipation of Factor f funding. One of these companies has a strong over the counter (OTC) R&D base.

Qualifications

There are several points to bear in mind when drawing conclusions from any of these data:

- Factor f companies started from a higher activity base than non-participants. It may be more difficult to achieve higher rates of growth for large companies than for smaller companies;
- there is the possibility that some non-participants have increased their activity because of the existence of Factor f; and
- the APMA provided data that suggested that the Factor f companies were generally more dependent on the PBS or other Government controlled markets than non-participants. For continuing participants, 95 per cent of turnover is devoted to PBS type markets. Factor f companies on average are 91 per cent dependent on PBS type markets (see Appendix J). The fact that non-participants are less dependent on the PBS means that their growth may not have been hampered to the same extent by low PBS prices as Factor f companies.

It should be noted that the APMA's PBS-type market includes sales to the Repatriation Pharmaceutical Benefits Scheme, hospitals and other Government tenders. If these other markets were excluded from the figures, it would have the likely effect of making participants as a group appear relatively less dependent on the PBS market (although some individual participants are likely to still have an extremely high dependence on the PBS).

It is not clear to the Commission that price suppression in markets other than the PBS has the same impact on the industry as PBS price suppression. Sales to hospitals and other tender systems often reflect competitive pressure among sellers. This is discussed further in Chapters 12 and 13.

Conclusions from APMA data

It appears that while in some areas Factor f companies have been growing more quickly than non-participants, the non-participants have been far from reducing their activities in Australia. In fact, for the most directly comparable data, that of PBS-type production value added, it appears that the Factor f scheme has made little difference to the relative sizes of the two groups' activities.

This could reflect numerous things: a flow-on 'positive environment' effect from the Factor f scheme, a response to an improving (overall) PBS price environment (see Chapter 8), or growth in the OTC market which is not affected

by PBS prices. It could also represent a more competitive environment for manufacturing and R&D in Australia generally.

Perhaps the only safe conclusion that may be drawn from these data is that the Factor f scheme has encouraged greater export orientation in participating companies than in non-participants. This might suggest that low prices are inhibiting exports by non-participants, perhaps due to country of origin pricing fears, although the fact that Factor f only grants notional price increases may reduce the likelihood of this explanation. Since exports are subsidised under the scheme, it may not be surprising that they have risen as dramatically.

It is impossible to know how much activity companies would have undertaken if there had been no scheme at all. However, the Commission has concluded that most of the activity conducted under Phase II of the scheme would not have occurred in the absence of the scheme and there is some evidence that the scheme has had an impact on non-participants. However, because of this uncertainty, the Commission has used a range of estimates for the level of inducement in its assessment of the efficiency of the scheme (see Section 11.3.4 and Appendix K).

11.2.3 Factor f and the balance of trade

The pharmaceutical trade deficit has grown much larger over the life of the Factor f scheme, increasing from around \$340 million in 1986–87 to around \$700 million in 1993–94 (BIE 1995, p. 51). However, this has been during a time of rapid PBS outlay growth. It could be expected that the pharmaceutical trade deficit would have been much larger had domestic production (for both the home market and for export) been lower.

The Commission considers that improving the balance of trade on pharmaceuticals should not be seen as an end in itself. While reducing the current account deficit may be a worthy goal, what is more important in the case of the pharmaceutical industry is to concentrate on activities which provide Australia with the greatest net benefits. It is unclear that a smaller deficit on the balance of pharmaceutical trade results in greater benefits for Australians.

11.2.4 International competitiveness of additional activity

One of the stated aims of the Factor f scheme was to encourage ‘internationally competitive’ activity. This provides another benchmark against which effectiveness can be measured. The BIE examined a number of indirect indicators to form a judgment of the competitiveness of the induced activity:

- its viability without ongoing support;
- how footloose the activity is; and
- how much it encourages exports rather than import replacement.

Viability without ongoing support

The BIE's view of internationally competitive activity was that it could survive in the absence of Government funding.

However, if the original distortion created by low PBS prices still exists when the payments of Factor f are removed, then it may not be surprising that some activity declines. It is unclear that viability without ongoing support is an unequivocal indicator of international competitiveness while PBS prices are still significantly lower than world prices. The APMA argued that:

The focus of the analysis has been upon Factor f providing a 'one-off' solution to the PBS pricing issue, rather than as a second best interim solution to an ongoing distortion in the domestic market for pharmaceutical products (sub. 119, Appendix 2, p. 3).

The BIE cited several examples which suggested that not all Factor f activity would be viable without ongoing support. This would suggest that when Factor f funding ceases, the activity it supported will also be wound down. The BIE survey compared companies' views on their activity levels after 1999 if Factor f continued and if it ceased. The type of activity which was most likely to decrease without Factor f support was R&D. As discussed in Section 11.2.2, there is the possibility that some companies are only undertaking R&D in order to be eligible for the much larger offsetting payments for production.

Footloose activity

If companies were only undertaking activity to take advantage of a subsidy, then this in turn would suggest that Factor f has encouraged a measure of footloose activity, able to leave relatively costlessly once the subsidy ceases. If a company intended to undertake activity in Australia which was only viable with Factor f, and that this activity would last *only* for the duration of the Factor f payments, that company would be likely to make investments which were easily reversed. For example, Pfizer stated:

... my [Head Office] has said to me ... 'we will give you more investment but we are not going to do anything which we cannot get away from. ... We will not build infrastructure ... in terms of R&D; we will get you to work through third parties. ... We will not allow you to build a synthesis plant. You get somebody to do it for you and therefore toll manufacture (roundtable, p. 85).

However, because some activity may be footloose does not necessarily mean that it is not internationally competitive. Footloose activity can occur in any industry where sunk costs are relatively low.

Respondents to the BIE survey claimed that they would operate their new facilities for the duration of their economic lives, although stating that their activity levels would fall if there were no scheme after 1999. The reduction in activity levels might thus represent a failure to capitalise on new opportunities, rather than implying that the original activity was not internationally competitive.

Export orientation

The BIE considered a high degree of export orientation to be a signal of international competitiveness. This is because, overwhelmingly, participants have stated that the global trend in the industry is towards fewer, more efficient plants which service whole regions, if not the world. This suggests considerable economies of scale, common to many manufacturing industries. A plant simply supplying the Australian market would not appear to fit the industry's vision of modern, internationally competitive activity.

One measure of export orientation is the ratio of exports to total company turnover. As discussed in Section 11.2.2, Factor f companies are around three times as export oriented as non-participants. This might imply that their activity is more likely to be internationally competitive, in the sense that these companies might be achieving greater economies of scale than non-Factor f companies.

However, it cannot be assumed that more export orientated plants are necessarily the type of activity that would have occurred in the absence of price suppression. Production for some drugs supplying the domestic market alone may achieve economies of scale for some drugs to a world competitive level.

Since export value added is a subsidised activity, it is not surprising that exports have increased. Moreover, it is unclear that pharmaceutical exports are necessarily internationally competitive in the absence of the subsidy.

11.2.5 Conclusions regarding effectiveness

The Commission considers that a number of design features of the Factor f scheme have operated to reduce its effectiveness.

First, the fact that some companies, which were likely to have increased their activity in a deregulated pricing environment, were excluded from the scheme contributed towards undercompensation.

Second, because of the requirements that companies undertake *both* R&D and production value added, some companies were ineligible. These eligibility criteria reflect industry development objectives rather than an aim to restore efficient activity to Australia. This condition also contributed to undercompensation.

Third, the generous nature of the subsidy offered is likely to have induced more activity than would have occurred in the absence of price suppression. The fact that Phase II Factor f payments are roughly double the size of planned investments under the scheme is strong evidence of this.

Finally, the fact that most continuing participants had the benefit of a base year of 1987 is likely to have contributed to overcompensation. The scheme is likely to have paid for at least some activity that would have been maintained anyway.

FINDINGS

The Commission finds that the effectiveness of the Factor f scheme should be measured according to its ability to restore efficient activity lost to Australia as a result of price suppression on the Pharmaceutical Benefits Scheme.

The Commission finds that the effectiveness of the scheme has been reduced through overcompensation of some participants, particularly those continuing from Phase I and the undercompensation of some excluded non-participants.

11.3 Efficiency of Factor f

The efficiency of the Factor f scheme should be judged by whether or not it makes a net contribution to the welfare of the Australian community. This involves measuring the social costs associated with the scheme and then attempting to see whether the social benefits of the increased activity arising from the scheme outweigh these costs.¹

The BIE consultancy has attempted to examine these social costs and benefits, to determine whether it is likely that the scheme has been welfare enhancing.

The BIE stated that:

¹ Social benefits and costs include benefits and costs imposed on the broader community as a result of the production or consumption of particular goods. These costs and benefits are additional to the usual private benefits and costs faced by individuals and firms.

In most popular discussion, the benefits of Factor f are considered to be the increases in eligible activity—the additional value added on exports, value added on domestic sales, and R&D expenditure carried out—as well as any increases in investment expenditure and employment. But in a social welfare framework, the benefits from a program such as Factor f arise not in the additional activity itself but rather in the benefits that *arise from that activity* (gains in producer and consumer surplus). Clearly, it is much more difficult to measure benefits in the latter sense (BIE 1995, p. 62).

Another important factor used by the BIE in measuring the efficiency of the scheme is estimating the activity *induced* by the scheme. This is the difference between the observed increase in activity and the amount of activity that would have occurred even without the scheme. Benefits arising from non-induced activity should not be taken as benefits resulting from the scheme.

For its 1995 assessment, the BIE developed a social welfare framework, based on its 1991 approach. As in its earlier review, the BIE calculated the benefits required for the scheme as a whole to be welfare enhancing. This is a ‘gap analysis’ approach. Since the costs of a scheme are much easier to measure than the benefits, a benchmark figure is established of how large benefits have to be before the scheme breaks even.

The key difference between the BIE’s 1991 and 1995 approaches is that the required benefits are calculated separately for Australian owned and foreign owned companies.

To make judgments about the efficiency of this scheme it is important to look beyond the pharmaceutical industry. Resources used in one industry could be used in other industries: that is, they have an opportunity cost. If making payments to the pharmaceutical industry means that it can bid away resources from other activities where they would have been better used, there is a net cost to the community. The BIE has identified the following factors to take this into account:

- to the extent that the increased investment in pharmaceuticals is a net increase in investment, the more likely it is that Factor f induced value added is beneficial for Australia. In the case of foreign owned companies, this is more likely if the increased investment comes largely from inflows of foreign capital;
- if it is mainly a reallocation, any gains from increased pharmaceutical activity will be offset to some degree by welfare losses elsewhere. On balance, because the reallocation to the pharmaceutical sector is in response to the distortion imposed by price suppression, the reallocation might be expected to enhance efficiency and a net benefit might be expected. However, because of the offsetting welfare losses elsewhere, the net benefit may not be substantial; and

- if there is little increase in net investment, the benefits of the value added activity induced by Factor f depend predominantly on the likelihood and magnitude of spillover benefits only (BIE 1995, p. 65).

However, the analysis undertaken by the BIE could not capture any of these effects. Such broader effects could possibly be captured in a general equilibrium model. The Commission arranged for the Centre of Policy Studies (COPS) to examine these questions using its MONASH model of the economy (see Section 11.4). Since the industry is so small, this modelling failed to identify any significant changes in the economy generally. Therefore, the Commission can only discuss such broader economic costs and benefits in a qualitative sense.

11.3.1 Estimating costs

The overall social costs of the scheme are determined by:

- the direct budgetary costs of the scheme (payments plus administration costs);
- any tax clawback effects;
- the marginal social costs of taxation;
- the amount of leakage of payments overseas; and
- the inducement rate.

Budgetary costs

The direct budgetary costs of the scheme are identified in Chapter 5.

The administration costs of the Factor f scheme are very small in relation to the size of the scheme, amounting to \$107 000 in 1994–95. Although this is an official Pharmaceutical Benefits Pricing Authority (PBPA) estimate, it does appear to be unrealistically low.

Since companies must provide data to the PBPA, companies also incur monitoring and administrative costs. These costs have not been estimated.

Tax clawback

Since Factor f payments are assessable as income, some make their way back to the Government in the form of taxes. This is known as the tax clawback. These tax benefits of the scheme could partially offset its budgetary costs.

As in its 1991 review, the BIE has used a tax clawback rate of 30 per cent. A rate which was lower than the company tax rate of 36 per cent was used because investment in the pharmaceutical industry may be displacing profitable investment in other sectors, which may also have raised revenue for the Government. A lower tax clawback rate increases the estimated costs of the scheme.

Astra did not agree with this reduction in the clawback rate below the full company tax rate:

The assumption that payments to the Pharmaceutical Industry displace other profitable industries seems to ignore the fact that some industries, and particularly R&D based industries, are characterised by high tax losses or tax minimisation schemes (sub. 141, p. 13).

However, this does not recognise the fact that increased activity in the pharmaceutical industry could be displacing activity in a range of other industries, not necessarily R&D based industries.

Marginal social cost of taxation

Raising taxes distorts resource allocation. Decisions about what people consume, how they invest their savings, how much they work and how they use their leisure time can all be affected by taxes. The resource allocation that results from these altered choices is likely to bring less benefits to the community than otherwise. This loss of benefits is known as the excess burden or deadweight cost of taxation. Because of this extra social cost of raising tax revenue, the benefits of governments spending a dollar must exceed the value of that dollar.

The BIE used an estimated marginal excess burden of 20 per cent.

Calculations in the Commission's previous report on Research and Development (IC 1995a) used an estimate of the social costs of taxation of 33 per cent. The Commission has recalculated the BIE's model using this figure. This has the effect of increasing the benefits required for the scheme to be welfare enhancing.

Leakage of payments overseas

A key element in the BIE's analysis is the different treatment of Australian owned and foreign owned companies. This recognises that even if activity was not induced by the scheme (that is, it would have occurred anyway), payments to Australian owned companies are transfers of wealth from taxpayers to other Australians—the money remains in this country. However, in the case of foreign owned companies, there is scope for some of the Factor *f* payments to leak

overseas in the form of repatriated profits and returns to other foreign owned resources.

Estimating the proportion of Factor f payments which might have leaked overseas first requires breaking down the payments according to whether they accrued to domestic or foreign owned companies. These data are presented in Table 11.2.

Table 11.2: Share of Phase II Factor f activity and payments—by type of recipient, per cent

<i>Factor f payments</i>	<i>Australian owned</i>	<i>Foreign owned</i>
Payments on export value added	25	75
Payments on domestic value added	20	80
Payments on all value added	22	78
Payments on R&D expenditure	62	38

Source: BIE 1995, p. 71

Having discovered the proportion of payments accruing to foreign owned companies, the BIE survey elicited information on possible sources of leakage such as payment of dividends to foreign shareholders and interest payments on foreign borrowing (loans from parents/affiliates). From this information, the BIE estimated an average rate of leakage on non-induced activity of Factor f payments overseas as being around 50 per cent. For induced activity, the BIE assumed a 100 per cent leakage rate: that is, the BIE assumed that all payments (net of any tax clawback) for induced activity was a social cost.

The Commission considers that it is more appropriate to consider the leakage of subsidy payments to foreign owned companies in a different way. Payments on *non-induced* activities that would have occurred anyway represent a straight increase in profits. Apart from the proportion of profits that Australia can capture in tax or that companies decide to reinvest in Australia, all of this payment could be considered a leakage. Since payments that are recaptured through taxation have already been taken into account, the Commission has chosen to recalculate the model assuming a 100 per cent leakage on non-induced activity, net of any tax clawback. It should be borne in mind that this is a maximum rate of leakage, since it does not take account of companies which choose to reinvest profits in Australia. The result of this changed assumption is to increase the benefits required for the scheme to be welfare enhancing.

Regarding *induced* activity, the Commission does not agree with the BIE's use of 100 per cent of the payments to induced activity as a social cost. Only the

profit component of such activity that is repatriated overseas should be taken as a social cost, not the entire payment. The Commission has recalculated the model with lower leakage rates for induced activity, such as 50 per cent, 20 per cent and 10 per cent. The result of these recalculations is to reduce the benefits required for the scheme to be welfare enhancing (see Appendix K).

Astra recalculated the BIE model with a zero leakage on non-induced activity. However, it is extremely unlikely that none of the Factor f payments would leak overseas. Even where this may be delayed while a subsidiary reinvests in Australia, eventually foreign shareholders will require a return on Factor f investments.

Estimates of inducement rates

The BIE concluded that most of the activity being assisted by the Factor f scheme was induced by the scheme. It should be noted that there is no way of proving ‘correct’ inducement rates. There is no way of knowing what activity would have taken place had it not been for the Factor f scheme. Therefore, any estimates of inducement rates are purely speculative.

For new participants, the BIE estimated inducement ratio for exports and R&D is 90 per cent, while for continuing participants, the estimated ratio is much lower. The ratios for continuing participants were calculated by assuming that only activity over and above the end-of-Phase I levels was induced by the scheme. The BIE points out that these are *minimum* estimates of inducement, because there were two companies which indicated that they would have done less activity had the base year been higher (although they did not indicate how much less activity they would have undertaken).

For domestic value added, all participants were assumed to have a 90 per cent inducement ratio.

In the light of evidence regarding the relative performance of Factor f and non-participants, the Commission considers these inducement rates to be overly generous. The Commission’s recalculations of the BIE model have used a range of lower inducement rates (see Section 11.3.4 and Appendix K).

The then Department of Industry, Science and Technology (now the Department of Industry, Science and Tourism) (DIST transcript, pp. 807–808) claimed that some companies were required to undertake some ‘extra’ non-eligible activity in order to meet their broad quantitative criteria targets, and that this activity ought to be taken into account as induced activity. However, it appears that much of this activity would have taken place anyway, that is, it was not induced by the scheme. Therefore, any benefits arising from this activity cannot be counted as

a benefit of the scheme. Also, even if such activity was induced by Factor f, such activity is ineligible because the perceived benefits to Australia arising from the activity are very small. In this case, including such ‘extra’ activity will not affect the conclusions that the Commission has drawn from its analysis of the efficiency of the scheme.

11.3.3 Benefits required for Factor f to be welfare enhancing

The BIE’s estimates of the required benefits for Factor f to be welfare enhancing are presented in Table 11.3 and set out more fully in Appendix K. They are estimated separately for export value added (EVA), domestic value added (DVA) and R&D. These benefits are assumed to be either spillover benefits (benefits accruing to parties other than the participants themselves), or else benefits which are not captured by the BIE’s model. These benefits might include greater returns to Australian resources due to a more efficient allocation of resources into the pharmaceutical industry.

Table 11.3: BIE estimates of benefits required per dollar of induced activity for Factor f to be welfare enhancing, \$

	<i>Export value added</i>	<i>Domestic value added</i>	<i>R&D</i>
Foreign participants	0.27	0.20	0.22
Australian participants only	0.05	0.04	0.04
All participants	0.22	0.17	0.11

Note: Payment rate is 25 per cent.

Source: BIE correspondence 3 April 1996

The BIE concluded that the benefits required per dollar of induced activity for foreign companies was much larger than for Australian based companies.

However, for Australian owned companies, the only social costs measured by the BIE are the distortion costs of raising the taxes to pay the subsidy—not the level of required taxes. The BIE’s calculation for domestic companies would have been the same regardless of the industry in which the money was spent. This highlights the important qualification to this analysis that the BIE itself acknowledged, that it does not measure any of the gains (or losses) from a change in the patterns of activity in the economy more generally.

These results are broadly similar to the results of the BIE's 1991 study, although the earlier evaluation did not differentiate foreign and Australian owned companies.

An alternative view of the break even point is to estimate the benefits required per dollar of Factor f money spent. Under the BIE's assumptions, these break even points are contained in Table 11.4.

Table 11.4: Benefits required per Factor f dollar for break even, \$

	<i>Export value added</i>	<i>Domestic value added</i>	<i>R&D</i>
Foreign participants	0.73	0.81	0.70
Australian participants only	0.14	0.14	0.14
All participants	0.59	0.67	0.35

11.3.4 Calculations under different assumptions

The Commission conducted some sensitivity analyses on the BIE's model (see Appendix K). The aims of the recalculations were:

- to test the robustness of the BIE's results under a range of assumptions; and
- to change some assumptions that the Commission considered inappropriate.

To summarise, the altered assumptions were:

- the social cost of taxation was changed to 33 per cent, rather than 20 per cent, in line with previous Commission work;
- a 100 per cent leakage on non-induced activity;
- a range of lower rates of leakage for induced activity; and
- a lower DVA inducement rate was used to reflect the fact that DVA activity has increased for participants and non-participants at roughly the same rates.

The results of these combined changes are similar to those found by the BIE (see Table 11.5).

Table 11.5: Benefits required per dollar of induced activity for break even, revised assumptions^a, \$

		<i>Export value added</i>	<i>Domestic value added</i>	<i>R&D</i>
Foreign participants	IC estimate	0.25	0.22	0.22
	BIE original	0.27	0.20	0.22
Australian participants	IC estimate	0.08	0.08	0.07
	BIE original	0.05	0.04	0.04
All participants	IC estimate	0.22	0.20	0.13
	BIE original	0.22	0.17	0.11

^a Assumptions include a 33 per cent marginal social cost of taxation, a 100 per cent leakage on non-induced activity, a 50 per cent leakage on induced activity and a 70 per cent inducement rate for domestic value added.

Source: BIE correspondence 3 April 1996

These calculations show that the BIE results are robust under a broad range of assumptions. These changed assumptions tend to slightly reduce the benefits required for foreign owned participants to break even, and to slightly increase those for domestic companies. Overall, the revised assumptions slightly increase the benefits required for DVA and R&D to break even.

The relatively high benefits required for the scheme to be welfare enhancing reduce if lower payment rates are applied. The Commission has recalculated the model assuming 20 per cent, 12 per cent, 10 per cent and 5 per cent payment rates. The results per dollar of induced activity are reported in Table 11.6.

The results show that reducing the payment rates significantly reduces the benefits required for break even roughly proportionately, that is, if the payment rate is halved, the benefits required are halved. For the same amount of activity, it appears much more likely that the scheme could have been welfare enhancing had it paid a lower subsidy rate.

Table 11.6: Benefits required per dollar of induced activity with lower payment rates^a, \$

<i>Payment rate</i>	<i>Benefits required per dollar of induced activity</i>	<i>Export value added</i>	<i>Domestic value added</i>	<i>R&D</i>
20%	Foreign participants	0.16	0.15	0.18
	Australian participants	0.07	0.07	0.07
	All participants	0.14	0.14	0.11
15%	Foreign participants	0.12	0.11	0.13
	Australian participants	0.05	0.06	0.05
	All participants	0.11	0.10	0.08
12%	Foreign participants	0.10	0.09	0.11
	Australian participants	0.04	0.04	0.04
	All participants	0.09	0.08	0.07
10%	Foreign participants	0.08	0.08	0.09
	Australian participants	0.04	0.04	0.03
	All participants	0.07	0.07	0.05
5%	Foreign participants	0.04	0.04	0.04
	Australian participants	0.02	0.02	0.02
	All participants	0.04	0.03	0.03

a Assumptions were a 33 per cent marginal social cost of taxation, a 100 per cent leakage rate on non-induced activity, a 20 per cent leakage on induced activity and the same inducement rates as assumed by the BIE except for a reduction in the domestic value added inducement rate to 70 per cent.

11.3.5 Estimating benefits

Estimating the benefits brought about by increased activity under the Factor *f* scheme is significantly more difficult than measuring the costs. Some of the benefits cannot be measured at all, and others only imperfectly (see Box 11.2).

Box 11.2: Benefits to Australia of greater pharmaceutical activity

The benefits Australia receives from new investment by a foreign owned company may be explained by an example. Say a company built a new factory that cost \$50 million and employed an extra 100 people. The cost of the factory included \$30 million in equipment purchased from overseas. The remaining \$20 million was spent on Australian

contractors. There are a number of benefits that Australia might receive from such an investment:

- *Employment benefits:* since the industry mainly employs skilled labour, many of the people employed in the industry may move from other jobs rather than from a period of unemployment. The benefits to these people would be the extra wages they earned, if any, from working in the new factory, adjusted for any extra effort they must provide in their new jobs. If the overall effect on employment is a net gain in the number of people employed, there is also a benefit to Australia in terms of a reduced demand for social security and the intangible benefits, including improved morale and increased skills, deriving from greater employment.
- *Skill benefits:* both the people employed at the new factory and the contractors who helped design and construct it may learn new skills which they can use outside that company.
- *Payments to contractors:* whether the payments to contractors is considered a benefit depends on how scarce the contractors skills were at the time. If contractors were scarce, the fact that the pharmaceutical industry is using these resources may mean that another industry has to wait. These costs need to offset the benefits to the contractors.
- *Equipment:* the full value of the equipment installed at the plant (purchased from overseas) is not a benefit to Australia. The equipment is owned by the foreign shareholders of the company and any return to this investment flows to them.
- *Taxes:* any tax revenue earned in Australia from profits accruing to foreign owned capital resources is a benefit to Australia, which may be ongoing.
- *Overall:* these benefits must be set against the total benefits that might have occurred in the economy if the tax used to pay for Factor f had either not been raised at all, or had the tax money been used for something else (for example, increased hospital or education funding).

The BIE described the types of benefits which could potentially fill the ‘gap’ for the scheme to be welfare enhancing. The main types of potential benefits include:

- the benefits arising due to increases in net investment;
- the impact on profitability; and
- qualitative benefits, including spillovers.

Net investment

The gains from Factor f activity are greater if it involves a significant amount of *net* investment. If investment in the pharmaceutical industry displaces investment in other sectors, the welfare gains are limited to any marginally higher gains from putting resources into this industry compared with another. However, benefits flowing from investment which has not displaced other activity is pure gain.

Around 55 per cent of the investment encouraged by Factor f has come from multinational companies, and around 50 per cent or more of this investment comes from inflows of foreign capital (BIE 1995, pp. 76–77). The BIE noted that:

... irrespective of whether participants financed the new facilities on the basis of loans from parent companies or from earnings generated by local activity, the new investment carried out under Factor f is actually being funded by Australian taxpayers—proposed Factor f payments of more than \$800 million are around twice the size of the planned investment expenditure. Because taxes have to be higher than they otherwise would be to fund the Factor f payments, this means that elsewhere in the economy expenditure on new investment is likely to be lower than otherwise.

... In effect, through the Factor f payments, taxpayers have fully funded (in aggregate) all participants' new facilities and plant upgrades—at the individual company level, the Factor f payments for each Phase II participant exceeds the planned investment expenditure in all but one case (BIE 1995, p. 78).

As discussed earlier, Factor f payments have been large in comparison to the size of planned investments. This might suggest that a lower rate of payments may have been more appropriate.

However, the benefits of increased investment might last for considerably longer than the period of Factor f payments. For example, SmithKline Beecham, despite not obtaining funding in Phase II of Factor f, recently won the right to supply South East Asia with oral penicillins. The company claims that this was primarily because of the investment that took place in Phase I of the scheme (sub. 115, pp. 3–4).

Similarly, the benefits resulting from investment in Australian R&D may continue well beyond 1999. Any ongoing benefits Australia receives through royalties or experience should also be offset against scheme costs. Moreover, many companies now have a better idea of the capabilities of Australian researchers and have developed relationships with them. This may result in more R&D activity in the future that is not subsidised by the scheme, but may be an indirect benefit of the scheme.

Impact on profitability

One of the benefits that might arise from the Factor f scheme is an increase in the profitability of pharmaceutical companies. For Australian owned companies, part of the increase in profitability will represent a transfer of wealth from taxpayers to the company, which is not a welfare benefit to Australia of itself. However, if profits increase because of Factor f but by more than the quantity of the Factor f payments, then this does represent a gain to Australia. Any offsetting reductions to profits elsewhere in the economy have already been taken into account through the reductions in the tax clawback rate from 36 per cent to 30 per cent. That is, the tax clawback rate was reduced to take into account the fact that tax revenues might be reduced elsewhere in the economy because pharmaceutical activity might be displacing other profitable activity. Therefore, this effect does not need to be taken into account again.

Similarly, if foreign owned companies become more profitable due to Factor f (but excluding the Factor f payments), this might also bring gains to Australia. However, this amount is smaller than for a domestic company, since only the proportion of profit which is captured by tax is a direct welfare gain to Australia. Indirect welfare gains might arise if a company retains earnings in Australia to reinvest.

For example, Astra stated that it has only recently begun repatriating profits, preferring instead to reinvest profits locally (sub. 141, p. 13). This new investment might be a source of future taxable profits, as well as further increases in skill levels and other qualitative benefits.

The BIE survey requested information on the importance of Factor f on company profitability for continuing participants. A representative picture of new participants could not be obtained because typically Factor f payments increase markedly over time.

The BIE found that Factor f payments had made a significant contribution to the profitability of continuing participants:

The results testify to the importance of the Factor f payments in improving company profitability. For ratios of 100 per cent or more, the Factor f payments are at least as great as the company's overall pre-tax profit (apart from the payments) in that year. This was the case for three of the four continuing participants in one year, and for one participant on four of the five years (BIE 1995, p. 83).

This suggests that the profitability of the continuing participants has not generally been enhanced by more than the Factor f payments themselves. Therefore, any welfare gains to Australia deriving from increased profitability are likely to be small.

Qualitative benefits to Factor f participants

The BIE survey and submissions to this Inquiry shed light on the qualitative benefits that might arise in the participating company itself. These benefits are not spillover benefits (that is, they do not accrue to others outside of the participating company). However, they may be benefits of the scheme which may rightly be used to offset its costs, at least to the extent that they do not flow overseas to foreign shareholders.

The BIE (1991) cited a number of possible qualitative benefits resulting from increased activity under the Factor f scheme including:

- improved product quality and delivery reliability—to meet the stringent demands of export markets;
- a significant attitudinal change among overseas head offices about Australia as an investment location;
- an appreciation in overseas markets that Australia is a high quality source of products; and
- greater ability for Australian subsidiaries to gain credibility within their multinational companies as a competitive supplier to export markets (BIE 1991, p. 96).

The BIE (1995) sought specific information on these types of qualitative benefits, to see whether they in fact existed, and how important they were.

The qualitative benefit most commonly rated as ‘very important’ was the potential of Factor f to enhance the credibility of a company as an internationally competitive unit within the overall corporate structure.

Other highly rated benefits were the development of key competencies and the acquisition of new technologies and skills. There is potential for these benefits to spill beyond the participating companies, for example by a demonstration effect and as staff move from one company to another.

The development of collaborative links, especially with research institutions, but also with other pharmaceutical companies, was also rated highly by many participants. It is important not to double count the benefits of linkages and the eligible activity of R&D activity under the scheme. Many companies fulfil their Factor f R&D obligations through third party organisations. The R&D conducted through this linkage is not an *extra* benefit of the scheme in itself, since it is a subsidised activity that has already entered into the calculations.

However, the creation of such a linkage could create the likelihood of *further* collaborations of benefit to both parties. This is both a qualitative benefit to the

participating company as well as a spillover benefit to the third party research organisation. Such benefits could be sizeable.

Spillover benefits to other pharmaceutical companies

Some of the benefits of the Factor f scheme might flow to non-participant pharmaceutical companies. These benefits are known as intra-industry spillover benefits.

It is also possible that the scheme has a negative impact on non-participant companies (intra-industry spillover costs). These wider industry benefits and costs should also enter the calculations of whether the scheme was welfare enhancing as a whole.

DIST cited the following as ‘secondary benefits’ of the scheme:

- non-participants can use the scheme as evidence of Government support for the industry; and
- linkages with Australian active manufacturers, local packaging companies and local medical research institutes (sub. 56, p. 30).

A case of a positive intra-industry spillover is the strategic alliance between Pfizer and the Institute of Drug Technology Australia to manufacture an active raw material.

DIST (sub. 56, p. 31) claimed that Factor f induced linkages have had a demonstration effect on non-participants, who have been able to observe the benefits of such linkages. DIST cited the example of the joint venture between Eli Lilly, a non-participant, and the Garvan Institute.

Responses to the BIE survey, however, indicated that most non-participating companies did not perceive any significant benefit from the participation of other companies in the scheme (BIE 1995, pp. 83–84).

The BIE asked non-participants whether they experienced any extra costs due to the fact that subsidised companies were in a position to buy more scarce resources, thus pushing up the price for everyone.

Most non-participants responding to the BIE survey did not identify significant problems arising because of a crowding-out effect due to increased costs of resources, except for R&D in some instances.

The most significant negative effect on non-participants appears to have been a perceived reduction in competitiveness compared with Factor f companies. Some non-participants noted that Factor f companies had been given greater resources and could afford more aggressive marketing campaigns.

Spillover benefits to other industries

The Factor f scheme may have created benefits for industries outside the pharmaceutical industry. For example, increased investment and activity in the pharmaceutical industry may have passed on skills and technology that are new to Australia.

Glaxo Wellcome offered several examples of how increased investment in the pharmaceutical industry has developed skills and opportunities in upstream industries. In particular, Glaxo Wellcome cited several companies involved in the construction of its manufacturing and product development facilities, especially companies involved in installing its blow-fill-seal operations:

All of these companies, to varying degrees, have indirectly benefited from involvement in Glaxo Wellcome capital projects, in terms of developing export related activities and/or acquisition of skills to support development of new business opportunities in other high technology industries.

The most tangible examples of these flow-on benefits from participation in capital projects related to the Factor f scheme are the establishment of new 'export' pharmaceutical construction/design activities, especially in the Asia Pacific Region (sub. 144, Appendix 2, p. 1).

The range of examples of ways increased investment in the pharmaceutical industry has developed skills and opportunities in upstream industries given by Glaxo are listed in Box 11.3.

Box 11.3: Flow-on effects from Factor f investments

Glaxo Wellcome provided the following examples of spillover benefits:

- Hooker Cockram and Andrew Kings (contractors in the design and construction of Glaxo Wellcome's blow-fill-seal facility) are now using knowledge gained in those activities to design and construct pharmaceutical factories in Asia.
- Three of the four contractors shortlisted to build SmithKline Beecham's factory in China are Australian companies with previous experience in design and construction of Australian pharmaceutical factories.
- Burns Bridge Australia, which designed Glaxo Wellcome's product development facility, claims that the experience gained in Australian Factor f related projects has greatly increased its chances of exporting its skills to Asia.
- Norman, Disney & Young, which provided consulting engineering services for Glaxo Wellcome on a range of Factor f related projects, claims that these experiences expanded its skills in areas such as process engineering, specialist laboratory services and quality assurance and validation procedures. This knowledge is exportable as well as applicable within Australia.
- Cleanroom Technologies (Australia), a small multi-disciplinary building services consulting engineering company, with experience from projects for other Factor f companies, claims that it has gained the skills and experience to international standards. The company is now exporting its services to several Asian countries.
- CMPS&F, an Australian technology and management group, was the design manager for Glaxo Wellcome's tablet production facility and has worked for other Factor f and non-participants. The company specialises in master planning, and has exported its services to pharmaceutical companies in Asia and Oman. This company has been working with GroPep, a Cooperative Research Centre for tissue growth repair, to create a recombinant growth factor production facility. This requires the application of Codes of Good Manufacturing Practice for traditional facilities to commercialise new drug/hormone manufacturing using Australian biotechnology.
- Newpulse Systems is a design engineering and contractor specialising in process and piping systems. The company's first project was involved in Glaxo's blow-fill-seal facility. Newpulse has used the experience gained on this and other Glaxo Wellcome projects to expand into other high purity piping projects in the semi-conductor, solar cell and optical fibre industries. One major new project is to commercialise new solar cell technology developed by the University of New South Wales. The company is developing plans to export its services.

Source: Glaxo Wellcome sub. 144, Appendix 2, pp. 1–5

Box 11.4 contains information regarding further spillover benefits to contractors identified by CSL.

Box 11.4: Spillover benefits to contractors

CSL provided evidence of spillover benefits to contractors associated with Factor f investments.

- Leighton Contractors, associated with building CSL's state of the art bioplasma plant has now developed a Process Engineering Division which is well placed to carry out pharmaceutical projects in China and in other Asian countries.
- Alpha Laval now market a 'zero dead leg' (hygienic) valve for the pharmaceutical and food processing industries.
- Centreline Engineering now markets a plasma cutting machine internationally;
- Industrial Control Technology, a major supplier of instrumentation and control automation to CSL, recently received an Engineering Excellence Award.
- Birrus Engineering now has expertise in the flow conveying of powders under sterile conditions which they offer to the pharmaceutical industry.
- Sheddon Pacific Engineering designs pipe work systems related to sanitary applications for the pharmaceutical industry.
- CMPS&F and Hooker & Cockram have expanded their capabilities in project management and knowledge of clean room technology and design as a result of their involvement in the construction and commissioning of CSL's sterile antibiotic dispensing facility.
- Newpulse Systems has developed a three dimensional computer aided design system to facilitate the installation of CSL's new 'Prostak' filtration system in its influenza production facility. Newpulse is now in a position to offer this system to other pharmaceutical manufacturers.

Source: CSL sub. 118, pp. 23–24

Another large source of spillover benefits is the collaborative links created through Factor f with research organisations. Factor f eligible R&D activity conducted through third parties is not in itself a spillover. However, there can be wider benefits created through such linkages. For example, the Australian Association of Medical Research Institutes stated that:

... I would argue that there's a spillover factor in the sense that funding which is provided by [a multinational company] for a particular project will support

scientists who may have ideas outside of that project which ultimately are going to lead to additional intellectual property (transcript, p. 1070).

CSL has also identified several skills and other advantages that research collaborators have gained from working on Factor f funded projects:

- Advice and assistance in identifying and defining the commercial applications of an academic researcher's ideas;
- Establishing a solid base in intellectual property protection to ensure that commercialisation can proceed and that the maximum benefits are returned to the research unit and its other collaborative partners;
- The introduction of sophisticated project management and Good Laboratory Practice techniques which ensure that all procedures and processes within the researcher's unit are appropriately documented. *Inter alia*, this avoids work being duplicated later in order to support a regulatory package;
- The injection of funds to quickly build up core expertise and critical mass within the research unit to enable the collaborators to remain internationally competitive;
- Giving the research unit access to CSL's scale up, development expertise and capabilities; and
- The provision of regulatory, clinical and health economic advice from the earliest stages of the project's development (sub. 118, pp. 22–23).

CSL also stated that its suppliers and contractors benefited from being forced to achieve Good Manufacturing Practice standards. For example:

... CSL educates staff in abattoirs around Australia in techniques to preserve the quality of animal by-products. Besides providing CSL with quality raw materials, this training has assisted the meat industry to lift its exports of animal by-products including enzymes, hormones and bile salts (sub. 118, p.24).

A broader spillover may encompass any improvements to the health system which arise because of the presence of a pharmaceutical industry in Australia. These may arise, for example, due to increased expertise in particular fields of medicine as a result of basic research and clinical trials. Companies may also prove to be helpful in achieving other health objectives, such as the rational use of medicines, through education and other health related activities (although there is little evidence that this resource is being utilised as a result of Factor f).

11.3.6 Conclusions regarding efficiency

The Commission has received considerably more information regarding the benefits resulting from the scheme than the BIE had access to at the time of its report. This information relates to the spillover benefits to non-participants and

ongoing benefits to participants themselves. While this information helps fill the ‘gap’ identified by the BIE, it does not invalidate its conclusions.

In a partial sense, it appears that the Factor f scheme has created many benefits for the participants themselves, for some non-participating companies (as well as some costs) and for other upstream industries. However, considering the size of the benefits required for the scheme to break even, it is unlikely that the current scheme has been welfare enhancing.

However, the Commission is required to take an economy wide viewpoint of the scheme and take account of the pattern of activity across the economy. From this broader viewpoint, the Commission considers that the scheme would have the greatest chance of bringing efficiency benefits to the community if it encouraged the same patterns and levels of activity that the market itself would have done in the absence of the PBS distortion.

The fact that some companies were excluded from the scheme (both those which met the criteria and those which did not, due to the twin quantitative guidelines) is likely to have inhibited a shift in activities towards an outcome likely to bring net benefits to the community.

Similarly, the fact that the scheme appears to have encouraged more activity than had been inhibited by low prices would also operate to reduce benefits. This indicates that the payment rates were probably too high.

The Commission concludes that the scheme would be more likely to have been welfare enhancing if it had lower payment rates, more flexible criteria, and open rather than competitive access.

FINDING

The Commission finds that Phase II of the scheme is unlikely to have been welfare enhancing largely due to poor scheme design, especially overly generous payment rates.

11.4 General equilibrium modelling results

Another source of information about possible inter-industry effects of the Factor f scheme is the study commissioned from COPS (see Appendix L). Activity encouraged by Factor f does not occur in isolation from the rest of the economy, nor from those parts of the pharmaceutical industry not covered by the scheme. Although industries upstream and downstream of the pharmaceutical industry may be stimulated, payments to participants need to be funded and increased competition for scarce resources may adversely affect the growth of other sectors in the economy.

The aim of this modelling exercise was to estimate the industry and economy wide effects of Phase II of the Factor f scheme using the MONASH model. MONASH is a general equilibrium model that provides a highly disaggregated representation of the Australian economy. The model has been used for policy analysis to provide annual forecasts of the economy with and without a policy change. A comparison of the forecasts of a base case scenario and an alternative scenario provides an estimate of the effect of the policy change on industry specific and aggregate levels.

According to the model, Factor f is financed by an increase in income tax rates which contributes to an increase in wages. Wages also increase because the supply of labour is fixed, and an increase in demand for labour in the pharmaceutical industry pushes up its price. This in turn affects the costs of production across all industries and the prices of final outputs. This effect is assumed to be small but widespread in the economy. Because of this increase in labour costs and the subsequent increase in the price of outputs, the Factor f scheme may lead to some contraction in some export-oriented industries, such as agriculture and mining, minerals processing, food processing and tourism. It may also adversely affect those industries most exposed to import competition (such as the textiles, clothing and footwear sector).

The model also shows that the industries supplying the pharmaceutical industry with inputs might expand due to Factor f. These industries include commercial printing, glass and plastic products and wholesale trade.

According to the model, the macroeconomic effects of the Factor f scheme are extremely small. This is because even with the sizeable expansion projected under the Factor f scheme, the pharmaceutical industry represents a small proportion of Gross Domestic Product (GDP). The model finds a small (0.01 per cent per annum) increase in real GDP to result from Factor f by 1998–99 and no impact on employment.

The model found that pharmaceutical activity would be lower in the absence of Factor f. Some manufacturing activity was lost, but the major impact was on R&D expenditure, which was found to decrease markedly. On this basis, part of the industry appears to be highly dependent on Factor f. This is corroborated by evidence that for some companies, payments are large and can significantly contribute to their bottom lines in some years.

It should be noted that *none* of the results of the COPS modelling should be interpreted as *welfare gains or losses*. These projections do not make any allowance for any externalities (spillover benefits) which arise because of extra pharmaceutical industry production or R&D.

11.5 Administration of Factor f

The administration of Phase II of the Factor f scheme appears to have suffered from a number of problems. There are two main areas of concern:

- problems associated with the selection process; and
- the lack of transparency in decision making.

As discussed in Chapter 5, the Australian National Audit Office examined the administration of Phase I and found it to be satisfactory overall. The Commission's comments focus on Phase II of the scheme.

11.5.1 Selection process

Problems associated with the selection process for Phase II raised by some companies include:

- the rules for selection changed midway through the process;
- the selection process is perceived to have been unfair; and
- there was an apparent lack of communication with companies, particularly when the funding cap was applied.

Changing rules

It is evident that the grounds for selection changed midway through the process. Parke Davis stated that:

... we believe that the rules were changed midstream—unannounced, unknown, unheralded, unsung—and that they were very unfairly changed (roundtable, p. 67).

According to Bristol-Myers Squibb:

When Phase II funds began to dry up the PBPA decided (August 14, 1993) to review proposals remaining on 'relative merits' but didn't tell the industry. All prior submissions were reviewed on individual merits against the guidelines (sub. 78, p. 3).

Research organisations that planned to receive funding from companies participating in Phase II were also affected by the funding cap. The Association of Australian Research Institutes stated that, while dealing with uncertainty was a normal part of National Health and Medical Research funding:

I think it was the opaqueness of the competitive process and apparent capriciousness of the competitive process that upset everybody and there was the additional ... psychological problem that we were led to believe—obviously

incorrectly—that the funding was there, only to find out that it wasn't, so it was bad psychology as much as anything (transcript, p. 1065).

The Commission has observed that all companies which were able to meet the Phase I eligibility criteria gained admittance to the scheme. However, in the case of Phase II, it appears that only initial submissions were assessed on this basis. Some later applicants which met the eligibility criteria were accepted while others were denied access to the scheme. The basis for such decisions has not been made public.²

The PBPA stated that since the process of selecting companies to participate in the scheme is currently the subject of legal action, it was inappropriate to comment on this matter (sub. 145, p. 2).

Fairness

Participants have argued that the selection process for Phase II was unfair because it did not assess all applications in the same manner. While all participants may have known that an initial sum had been allocated by the Government to Phase II, they were not aware that this budget cap would eventually result in a change in the way applications were assessed halfway through the selection process.

According to Bristol-Myers Squibb:

The PBPA pricing guidelines include Factor f as one element of setting prices for all companies. Including some and excluding others is unfair and places recipients at a very significant competitive disadvantage. How do you think [Bristol-Myers Squibb] ... (which met the Phase II criteria) feels when its four biggest competitors all received Phase II allocations. ...

PBPA should have reviewed all applications, decided all on the same basis, determined the Factor f payment for each company and passed all recommendations to the Ministers. [Bristol-Myers Squibb] believes PBPA should not have changed the approval criteria to 'relative merits' part way through the program (sub. 78, p. 3).

The Commission observes that the exclusion of some companies and special arrangements for others appears to be unfair.

Lack of communication

The Phase II selection process appears to have suffered from a lack of communication with some companies. This applies to the period prior to

² It should be noted that not all companies that were denied Phase II funding were actually eligible under the criteria.

applications being received, as well as during the selection process. The Factor f guidelines were also inadequate in that they did not indicate that a company meeting the eligibility criteria could be denied access to the scheme due to funding constraints.

There is no mention of 'relative merit' in meeting the aims of the scheme. The guidelines state that eligibility according to the criteria does not guarantee entry to the scheme. However, the only stated reason for possible non-admittance is:

Approval of price increases is dependent on the assessment of the international competitiveness of the proposed activity and of the net benefits which will accrue to Australia from the activity (PBPA 1992, p. 7).

There is no publicly available evidence of any objective analysis by the PBPA to measure the likely 'net benefits' arising from Factor f proposals, nor the international competitiveness of that activity. This adds another element of non-transparent discretion to the administration of the scheme.

Bristol-Myers Squibb stated that:

DIST made no attempt to advise the industry of the status of Phase II allocations. Statements such as 'funds are being rapidly taken up' are useless for decision making. Companies approved and total (not individual) funds allocated should have been notified.

Rumours of funding and funds available cannot be considered as an adequate communication to companies which are about to make significant decisions. ...

... If fixed dollars are to be set for allocation this should be in the guidelines. In fact the guidelines clearly imply that a company meeting the criteria will receive price increases (sub. 78, pp. 2, 3).

A case study illustrating all of these problems is presented in Box 11.5.

The Commission observes that the industry was not sufficiently informed of how the selection process was to be run. When it became obvious that the rules were to be changed, some companies argued that they were not properly informed of how the process would be changed.

Companies were not advised of the status of their applications. When bids were rejected, adequate reasons were not given as to why these bids were seen as being inferior to those that were accepted.

Box 11.5: Views of an unsuccessful applicant—Parke Davis

We submitted an application for entry into the Factor f scheme based on replacing import of a product that we were importing not fully finished, in bulk, and repackaging locally. We were going to manufacture it here. The proposition was approved by our parent company based on receipt of Factor f or being entered into the Factor f scheme. I won't go through all the gory details, because it is a sad situation, but it was based on us exporting to South East Asia. We would be eligible for Factor f and also to increase our R&D activities here in Australia.

Ultimately we were not invited to join Factor f, but it wasn't until very late in the piece that we received the news that we weren't to be invited. By that time we had invested the capital and we were producing the product here to meet our commitment, which started 1 January 1994. We were advised in December 1993 that we wouldn't be entering the scheme.

Factor f was a means of justifying two things: (1) local production and export of this particular product, which wasn't a huge product, to South East Asia and making Australia the sourcing location. What that did, though, was to carry Australia as a potential source for a whole range of other products. That then carried the proposal that we were going to expand our facilities here and invest US\$51.5 million. That was approved. When the Factor f disappointment—we think that f stands for fiasco—finally sank in, our parent company then started asking questions like, 'What are we doing?' and we said, 'Well, we are now in a position to export out of Australia.'

We haven't exported this product to any great degree because it doesn't make sense. From our total corporate company's point of view it is not an economic consideration without the Factor f benefits. What it created and generated was a growing sense of unease.

Source: roundtable, p. 66

Outcomes

The poor handling of the Phase II selection process has contributed to uncertainty about the operating environment, particularly for companies excluded from Phase II. Three of the companies which missed out on Factor f funding are involved in Federal Court proceedings against the Commonwealth Government over the issue.

SmithKline Beecham stated that:

The uncertainty and ultimate exclusions of [SmithKline Beecham] Australia from Factor f Phase II sent mixed messages to the parent company regarding the Federal Government's commitment to the future of the pharmaceutical

manufacturing industry in Australia. ... Continued lack of clarity in this area will impact adversely on future investment decisions in Australia (sub. 13, p. 7).

The failure to secure Phase II funding meant that SmithKline Beecham missed out on supplying Tagamet, an anti-ulcer drug, to Japan, representing \$33 million in value added processing over five years. A decision was taken by the company's head office to continue to joint venture manufacture the product in Japan (sub. 13, p. 7).

One of the crucial aims of the scheme was to address the perception of Australia as a 'hostile' environment. Having companies which met eligibility criteria and which expected to be entitled to payments turned away due to lack of funds cannot have improved Australia's reputation internationally.

This is not to say that the scheme needed greater funding—rather that the criteria and the process ought to have ensured that companies knew all of the ground rules before they applied. If companies were going to be excluded, even though they met the criteria, there should have been an understanding initially that applications would be assessed in order of merit or receipt. As it is, there is no clear understanding within the industry of how the decisions were made.

The ill-will created by the selection process has been recognised by Government. As the then Minister for Industry, Science and Technology acknowledged:

... I believe it is only fair to acknowledge that Phase II of the scheme has caused a degree of angst in sections of the industry.

The Government is fully aware of these concerns. We will maintain close consultations with the industry to ensure that these problems don't arise again (Cook 1995, p. 4).

11.5.2 Lack of transparency

There are other serious weaknesses associated with a lack of transparency in the administration of the scheme in addition to those associated with a lack of communication with industry during the selection process. These include:

- the lack of publicly available information about payments to individual companies, and what they are doing in return;
- the lack of publicly available information on the performance of individual companies throughout the life of the scheme; and
- the lack of documented reasons for administrative decisions.

Payments to companies

Much of the information about the Factor f scheme is protected as ‘commercial-in-confidence’. This includes information about how much money has been allocated to each company and what exactly they are doing in return. It also includes information regarding the products for which companies receive notional price increases and the data justifying the size of these price increases. A fundamental principle of transparent Government administration is that where public money is being granted to companies, this should be publicly recorded. This general principle should only be breached where there are legitimate commercial reasons for keeping information confidential.

It could be expected that companies concerned with benchmark and country of origin pricing risks would want the information on notional prices made available on the public record.

The size of the total Factor f payments combined with the small number of participants indicates that the payments to at least some companies must be substantial. Very few companies volunteered this information publicly in submissions. Merck, Sharp & Dohme was an exception and stated that it had received \$56.6 million in Factor f payments up until August 1995 (sub. 27, p. 15).

The PBPA stated:

With regard to transparency, particularly as it relates to company programs, activities and payments, the Authority is conscious of the highly sensitive and competitive nature of the pharmaceutical industry. Most of the material supplied to the Authority for Factor f purposes is on a commercial-in-confidence basis. It is the responsibility of the Authority to ensure that the nature of this material is respected and that it cannot otherwise be used to the commercial detriment of the company concerned. This applies equally on a prospective and retrospective basis ... (sub. 145, p. 1).

While the Commission agrees that information about future activities might be commercially sensitive, it does not agree that old information needs to be kept secret. With the passage of time, competitors have been able to observe participants’ activities in the marketplace.

There appears to be no good reason why the Government ought to have undertaken to keep such information secret after payments were made. However, since the Government has agreed to keep such information about the current scheme commercial-in-confidence, any retrospective change to this policy now is inadvisable as it would suggest that past dealings with the Government cannot be relied upon. This would be costly to Australia, as such perceptions could spread to other industries besides the pharmaceutical industry.

Nevertheless, in any new scheme, the Commission sees no reason why information about payments to companies should be kept commercial-in-confidence (see Chapter 13).

Performance of companies

The Factor f Secretariat has provided no publicly available information on the performance of individual companies throughout the life of the Factor f scheme. This is another example of the serious lack of transparency in the administration of the scheme. This issue is particularly important since participating companies were selected by the PBPA in preference to other companies which were excluded despite meeting the eligibility criteria.

Publicly documented reasons for decisions

There were many puzzling decisions taken in the administration of the scheme, the reasons for which are not publicly available. These include:

- why the PBPA exercised its discretion to offer some companies less than the maximum 25 per cent rate of payments for value added on some activities;
- how the PBPA estimated whether the proposed activity was indeed internationally competitive and the likely net benefits to the community resulting from such activity;
- why some companies are subject to slightly different ‘catch up’ provisions than others; and
- the basis of the judgment that some companies should be admitted to the scheme while others were rejected.

However, the Commission recognises that the Secretariat is aiming to provide more complete documentation of its activities than has occurred in the past.

The PBPA responded to the Commission’s concerns in the Draft Report by emphasising the discretion given to the Authority in the guidelines and mentioned by the then Ministers for Industry, Science and Technology and Community Services and Health:

... there will be circumstances where judgment rather than quantitative rules will be more appropriate (Button & Blewett 1988, p. 1).

The PBPA stated:

The Draft Report ... does not reflect a full appreciation of this aspect of the scheme. The use of discretion and judgment for example, does not constitute a lack of regard for appropriate administrative procedures. Neither does it suggest

that the Factor f scheme is not transparent ... or that reasons for decisions are not documented (sub. 145, p. 1).

The Commission agrees that discretion does play a large part in the administration of Factor f, and that this was part of the design of the scheme. However, the Commission observes that there is no publicly available information regarding the basis for decisions. Discretion combined with secrecy about the basis for decisions and the results of those decisions is highly undesirable. The Commission has not been persuaded by the PBPA that the scheme has been managed well.

An alternative approach to future intervention discussed in Chapter 13 is far less discretionary than the current scheme and would be much more open and transparent.

FINDING

The Commission finds that the Factor f scheme has suffered from severe administrative problems and has not operated in a transparent manner. These problems have contributed to uncertainty about the operating environment, particularly for companies excluded from Phase II.

11.6 Interim arrangements

The Commission considers that there are two outstanding issues in relation to the current scheme:

- whether companies should be allowed to extend their Factor f contracts, to give them more time to fulfil their commitments; and
- whether companies should be able to take their payments as actual rather than notional price increases.

Regarding the first point, two Australian companies have argued that the distribution of Factor f payments through time under Phase II of the scheme may present difficulties for them. It is in the nature of the scheme that payments increase gradually. When companies complete their contractual obligations under the scheme, payments cease. The sudden ending of payments, it has been argued, creates problems for these companies.

Faulding stated:

Faulding has met commitments under the Phase II scheme for the first two years and anticipates a slight shortfall in the financial year ending June 1995. Achievement of future years' commitments will provide challenges due to the time period between research and final commercialisation of product. The

question of increasing PBS prices over time and discontinuing the Factor f scheme will require a period of transition with careful phasing.

Therefore we strongly recommend that the present scheme is extended ... The total cost is approximately the same and the scheme allows more time for increasing PBS pricing and for companies to adjust while still developing a genuine integrated Australian base (sub. 46, pp. 14–15).

This suggestion involves spreading payments over a longer period of time at the same net present value as the present payment stream.

Not all participants agreed with this suggestion. AMRAD said that it can see no benefit in extending the scheme over a longer period of time (roundtable, p. 268).

The Commission is doubtful about the merits of this suggestion. If payments are delayed, so are benefits. Since companies themselves drew up their Factor f proposals, they should bear the risks of not being able to complete their commitments on time. If the Government allows companies to extend the time period to fulfil their commitments, this may send a negative signal to the industry that over bidding will be accommodated. It may also be unfair to those companies which missed out on Phase II funding if such extensions were granted. However, a rigid scheme which does not take account of the commercial realities is not to be encouraged, either. There may be good reasons why a company cannot meet a commitment in a given year, but could make up for this in later years. The Factor f scheme's current 'catch up' provisions appear to offer the right amount of flexibility in this regard (see Chapter 5).

There is nothing presently in the contracts between DIST and participating companies which gives any flexibility beyond the contracted finishing date. Given the doubts about the net benefits of the scheme, the Commission considers it inappropriate to give special consideration to extending the time period for completing performance targets.

FINDING

The Commission finds that there is no basis for extending the current Factor f scheme for any company now in the scheme beyond its contractual finishing date.

Regarding the second point, the Commission is mindful of the problems for activity and availability that low actual prices can represent (see Chapters 8 and 12). Actual rather than notional price increases would help overcome these difficulties.

However, there are a number of difficulties associated with actual price increases, such as flow-on effects to wholesalers' and pharmacists' margins, as

well as possible competitive disadvantages for products with substantially higher prices than those of close substitutes.

To overcome the first of these difficulties, the Government could seek to ensure that margins are not passed on through the distribution chain. If this is not possible, then companies could repay the Government any higher margin costs.

Competitive disadvantage would be best judged by companies themselves, and they would only be willing to take actual price increases if the perceived benefits outweighed the costs.

Recommendation 11.1

The Commission recommends that companies should have the option of taking their remaining Factor f payments as actual rather than notional price increases.

11.7 Further analysis

The Commission has concluded that the current Factor f scheme incorporates a number of design features that hamper its effectiveness and reduce its ability to efficiently create more benefits for the Australian community than costs.

Chapter 12 re-examines whether there is a rationale for further Government intervention in the pharmaceutical industry.

Chapter 13 discusses the Commission's conclusion that broad front reform of the PBS is what is required to solve the growing problems facing the industry, taxpayers and consumers. Given the structural and administrative problems associated with the current Factor f scheme, its continuation is not considered as an option.

12 PHARMACEUTICAL BENEFITS SCHEME— THE CASE FOR INTERVENTION

In this Chapter, the Commission considers the effects of the PBS on activity undertaken by the pharmaceutical industry. Based on its findings on the impact of the PBS on activity and availability of drugs, the Commission examines the case for Government intervention in the PBS. A distinction is made between general Government intervention, which refers to reform of PBS processes and policy with the aim of improving the PBS environment, and financial intervention, which refers to compensating industry for the adverse effects of the PBS.

12.1 Introduction

In Chapter 8, the Commission considered the effects of the Pharmaceutical Benefits Scheme (PBS) on the availability of drugs to the Australian community. This Chapter examines the effects of the PBS, in particular low PBS prices, volume constraints and listing delays, on the level of pharmaceutical activity.

The case for Government intervention in the PBS depends in part on whether the PBS is adversely affecting the supply of drugs to Australian consumers and also on whether the PBS reduces efficient pharmaceutical activity undertaken in Australia.

The Government can intervene at a general level in the PBS to reform its processes and policy. Alternatively, it can intervene financially by compensating industry for the impediment represented by the PBS. The Factor f scheme is an example of this latter approach. Approaches to Government intervention are considered in Chapter 13.

12.2 Effects of the PBS on activity—a theoretical perspective

In Chapter 8, the Commission found that PBS drug prices are significantly lower than drug prices in other developed countries. In addition, the limiting of indications for which drugs are listed, the application of authorisations for some drugs, and delays in listing may adversely affect sales volumes of

pharmaceutical companies. Hence, overall, the PBS is likely to have reduced companies' sales revenue in the local market.

The effect of lower sales revenue on efficient activity will depend on:

- whether the market is competitive (in which case companies do not have much market power) or monopolistic (in which case companies may have significant market power);
- whether short or long run effects are considered; and
- whether local activity can be differentiated from global activity.

Market structure

In a competitive market, sales revenue will be closely related to the costs of production, and these costs will be subject to competitive pressure. If companies are not able to generate sufficient revenue to cover production costs, their operations may not be sustainable. In this type of market the PBS, by reducing companies' sales revenue, could be expected to lead to a loss of efficient activity. In contrast, in a market in which companies have significant market power, sales revenue more than covers the costs of production and the effect of lower sales revenue, within limits, will be to reduce profits rather than production. In this market, the PBS may reduce companies' sales revenue, but may have little or no effect on efficient activity.

The market for pharmaceutical products is complex. As described in Chapter 8, prescription drugs fall into one of four categories, depending on their stage in the innovation cycle. As drugs move through the innovation cycle, they will occupy different positions in a number of different sub-markets, each with its own market structure. A company with numerous drugs will occupy a number of different positions in the market simultaneously. It may have significant market power in the case of patented breakthrough and innovative drugs, reduced but possibly significant market power for patented drugs where there are similar drugs available, or very little market power for out of patent drugs.

For this reason, at any time, sales revenue for companies may embody some degree of transitory market power. It is, therefore, difficult to know whether a reduction in sales revenue from the PBS will reduce activity below its optimal level.

Short or long run

The Commission considers that, in the long run, the pharmaceutical industry is competitive (see Chapter 2). The nature of competition in the industry flows in

part from the patent system, which grants a monopoly position to originator products in the short run to promote competition through innovation in the longer run. That is, in the short run, originator drugs can be highly differentiable and may provide a company with market power for considerable periods of time. Over time, however, this market power will be gradually eroded as competitors innovate around the patented molecule to produce their own close substitutes or ‘me too’ drugs. While brand advertising and ongoing brand loyalty may continue to provide producers of originator drugs with some market power over competitors even after their patents expire, in the long term, the pace of innovation and the capacity of companies to supply a variety of sub-markets will ensure that companies are acting in a competitive manner.

In the long run, companies must generate sufficient sales revenue to cover all costs of production, which for this industry include large, fixed and sunk research and development (R&D) costs. In particular, sales revenue must provide the source of funds for future product development. While any reduction in sales revenues may appear to be efficient in the short run because it erodes market power and monopoly rents, it may be inefficient in the long run because it erodes incentives to innovate and compete.

Global or local markets

If sales revenue is reduced globally and companies cannot cover their long run production costs (including R&D costs), companies may not be able to sustain their operations and efficient activity may be lost. However, Australia is a small part of the global market and it is unlikely that price suppression in such a small market would have any significant effect on the global level of efficient activity.¹

The question for this Inquiry is whether price suppression under the PBS will have an effect on efficient activity undertaken in Australia. It is difficult to get a clear answer to this question.

First, multinational enterprises (MNEs) are able to generate revenue from subsidiaries located in a number of different countries. They may be able to segregate markets and ‘price discriminate’ to generate sufficient revenue across all markets to cover their production costs.² For example, a MNE may charge

¹ This may not apply to companies whose sales are heavily dependent on the Australian market.

² ‘Price discrimination’ refers to a situation where companies are able to segment their markets and charge each segment a different price depending on its willingness to pay.

higher prices in one market to subsidise lower prices charged in another market if it considers that it is possible and profitable to do so.

Second, in a competitive market, a reduction in sales revenue would be expected to affect supply and activity. To date, the Government has been able to suppress revenues without a significant effect on the supply of drugs (see Chapter 8). In fact, the market outcome of buying power exerted by the Government through the PBS is extremely difficult to identify or predict. While it is clear that price has been affected, there is limited evidence of an effect on supply. To date, the latter has materialised mainly in the form of the Government limiting indications for some drugs to a sub-class of their availability overseas. However, there is an increasing risk of the situation worsening in the future (see Chapter 8).

Given the complexity of the pharmaceutical market, it is not clear whether the PBS is suppressing sales revenue below long run marginal costs or, on the other hand, reducing monopoly profits. Hence, there is no clear cut theoretical case that the reduction of sales revenue from the PBS affects efficient activity undertaken by the industry.

MNEs can, and do, separate out issues of supply and production. Given a favourable operating environment, a MNE may be willing to manufacture and conduct R&D in Australia, but may be unwilling to supply some drugs to the local market at the low prices under the PBS. However, activity may be affected if the PBS has additional negative effects on the companies' operating environment. This is discussed below.

12.3 Effects of the PBS on activity—a practical perspective

The Commission considers that a practical case for Government intervention in industry is to address market failure by offsetting impediments to normal industry development (see Chapter 1).

The industry has argued that the PBS represents the major impediment to its growth and development (see Chapter 7). In particular, the industry has claimed that price suppression, volume constraints, and listing delays under the PBS are significant impediments.

However, to recommend Government intervention on this basis, the Commission must be convinced that the impediment is real—that the PBS does create an actual distortion to the allocation of domestic resources or inflow of foreign resources.

The Commission has examined:

- evidence on activity that may have been ‘lost’ due to the PBS; and
- possible direct and indirect links of the PBS to a lower level of efficient pharmaceutical activity.

12.3.1 Evidence of ‘lost activity’

It is difficult to quantify the effects of the PBS on pharmaceutical activity. First, it is impossible to know ‘what might have been’ if companies had been operating in a deregulated environment without a PBS. Second, it is difficult to separate out the negative effects of the PBS from other negative influences on companies’ operating environment. Nonetheless, the Commission has drawn on evidence from a number of sources, including:

- the 1995 Bureau of Industry Economics (BIE) survey (BIE 1995);
- indirect evidence based on the companies’ responses to the Factor f scheme;
- information provided by companies in their submissions; and
- evidence from overseas.

With respect to these sources, it is important to note that much of the evidence available to the Commission is reported by companies. The implications of this are discussed below. In addition, with the exception of the information provided by some companies in their submissions, much of the evidence has focused on activity that may have been lost as a result of low PBS prices, rather than volume constraints and listing delays. However, to the extent that the latter may have a similar effect on sales revenues and hence the sustainability of the companies’ operations, it is likely that they will have a similar or compounding effect on activity.

BIE survey

To assess the magnitude of any ‘lost’ activity due to price suppression under the PBS, the 1995 BIE survey asked companies how different their local activity would be in 1999 if the Government had not continued the Factor f program beyond Phase I, but instead had deregulated PBS prices (BIE 1995, p. 12). With respect to the companies’ responses, the BIE qualified its results by stating:

Because companies’ perceptions were sought in relation to a hypothetical scenario, there will be some uncertainty associated with their responses. Indeed, in cases where respondents expected their activity to be higher or lower than presently, an estimate of the percentage change over the period was also requested. However, not all respondents were able to provide such estimates—in some cases, even broad perceptions were uncertain (BIE 1995, p. 12).

The companies' responses on their perceived behaviour in a deregulated pricing environment are summarised in Table 12.1. The BIE indicated that respondents answering 'not relevant' tended to be pure importers.

Table 12.1: Impact of deregulated environment on local activity, per cent

Activity	% of firms indicating change over period 1993 to 1999			
	<i>Not relevant</i>	<i>No significant change</i>	<i>Higher</i>	<i>Lower</i>
Volume of domestic sales	3	14	72	10
Volume of export sales	21	21	55	3
Average prices	7	17	72	3
Local profits	7	10	76	7
Employment	3	21	66	10
Formulation of final products	28	28	34	10
Packaging of final products	21	31	41	7
Production of active ingredients	55	41	3	-
Overall manufacturing capacity	28	28	38	7
Research into new chemical entities	38	38	17	7
Research to enhance existing chemical entities	38	28	34	-
Clinical trials	10	21	59	10

Source: BIE 1995, p. 13

The BIE concluded that, in a deregulated pricing environment:

- 34 per cent of respondents would increase formulation activity;
- 41 per cent of respondents would increase packaging activity; and
- 38 per cent of respondents would increase overall manufacturing capacity (BIE 1995, pp. 14–15).

It appeared that, while greater pricing freedom would encourage some more basic R&D, clinical trial activity would increase significantly:

- 17 per cent of respondents would carry out more basic research into new chemical entities; and
- 59 per cent of respondents would increase clinical trials.

Subject to its qualifications on results noted above, the BIE made a rough estimate of 'lost' activity through price suppression. In particular, it estimated

the additional formulation and packaging activity that may have been carried out in a deregulated price environment as:

- more than \$200 million of additional formulation activity—some 16 per cent of the formulation activity carried out by all survey respondents in 1993–94; and
- more than \$120 million of additional packaging activity—or around 30 per cent of 1993–94 packaging activity of all survey respondents (BIE 1995, pp. 15–16).

The BIE concluded:

Overall, these findings confirm ... that PBS pricing policies appear to result in lower activity than would take place in a deregulated pricing environment (BIE 1995, p. 16).

Response to Factor f

The response of pharmaceutical companies to the Factor f scheme provides some indirect evidence that Australian activity is lower than the level which could be achieved if sales revenues under the PBS were higher.

The Factor f scheme was designed, in part, to compensate Australian companies for the negative effects of the PBS on domestic activity (see Chapters 5 and 11). Participants in Phase I of the scheme have significantly increased exports, domestic value added and R&D expenditure. Phase II participants have also committed to significant increases in these areas of activity (see Chapter 5). To the extent that the scheme was instrumental in generating this additional activity, this evidence suggests that the PBS may have been impeding activity and growth.

However, while the evidence may imply some form of link between prices and activity levels, there have also been substantial reforms in the wider economy over this period which could also have contributed to increased productivity and output (see Chapter 5).

Moreover, because Factor f payments are tied to performance, activity generated by the scheme may not necessarily be indicative of how companies might have responded to higher prices with no activity ‘strings’ attached. The BIE noted:

... the fact that companies have responded to the support (notional price increases) available under Factor f by increasing local activity is not necessarily evidence to support such a claim of low prices impeding activity. This is because the Factor f Scheme is a *tied* compensation scheme—that is, companies are *required* to increase activity in order to qualify (BIE 1995, p. 5).

Therefore, companies may be simply responding to the conditions of financial assistance through the Factor f scheme.

In addition, the Commission notes that some participants and non-participants in Phase II indicated that they were planning to carry out significantly higher activity over this period regardless of the Factor f scheme (see Chapter 11).

Similarly, the 1995 Australian Pharmaceutical Manufacturers Association (APMA) survey demonstrated that the activity of both participants and non-participants in the Factor f scheme showed strong rates of growth (APMA 1995a). While Factor f participants are more export oriented than non-participants, and hence may have economies of scale that are important in an environment of rationalisation, there is very little difference between growth rates in R&D activity. In fact, on a number of criteria, the APMA survey suggested that activity is not being suppressed by the PBS as much as might have been expected (see Chapter 11).

It is possible that additional activity by non-participants in Factor f may be caused by a 'demonstration effect', flowing on from successful Factor f companies. Moreover, even companies that do not receive Factor f payments may regard the existence of the scheme as evidence that the Australian Government is not 'hostile' to companies. This could increase the attractiveness of investment in Australia.

Evidence from participants

The Commission requested evidence from participants on 'lost' activity that could be attributed to the PBS. Pharmaceutical companies responded with examples of activity that had been, or could be, lost not only due to the PBS but also due to non-participation in the Factor f scheme.

As noted in Chapter 5, the operation of the PBS in the 1980's may have been associated with declines in activity and actual or threatened departure by some pharmaceutical companies. This was observed in previous reviews of the industry by the Industries Assistance Commission (IAC, 1986) and the BIE (BIE, 1991). It was also noted by the Department of Industry, Science and Technology (now, Department of Industry, Science and Tourism) (DIST) in its submission to this Inquiry (sub. 74). The IAC concluded:

Participants from local industry provided information on declines in activity and employment in specific sections of the industry which they said were directly attributable to [the] PBS (IAC 1986a, p. 97).

There is evidence from participants that price suppression, volume constraints and listing delays under the PBS are still having a similar effect. With specific reference to listing delays, Sandoz stated:

From the Company's perspective, the delay to listing on the PBS has meant that we are disadvantaged in the marketplace. This has contributed in part to the decision announced recently to cease manufacturing in Australia (sub. 93, p. 1).

Other companies provided examples of the effect of 'lost' activity on specific products. Abbott provided an example of activity that it claimed had been lost because of low prices:

The impact that ... [low price expectations under the PBS] has had on the Australian affiliate is that regional manufacturing for clarithromycin has been assigned to the UK and Italy where the domestic selling price is up to double what would be expected in Australia. This has given both countries a substantial volume base to be able to offer a viable cost of goods to countries within the Pacific/Asian region (sub. 109, p. 1).

Eli Lilly provided general examples of activity that it claimed had been lost:

Prozac and Ceclor account for over 60 per cent of ELA's [Eli Lilly's] sales by volume in the Australian market place. The combination of price suppression, volume restriction and listing delays severely affect ELA's performance relative to that of affiliates in other markets.

... These examples ... show how low market prices and other related Government distortions ... act to inhibit the level of value adding activity in Australia.

... all the key investment proposals in ELA's revised strategy ... had to be re-assessed against the ELC Decision Making Model. In the manufacturing and export area, in particular, most projects failed to be short listed. This was largely because in the absence of Factor f compensation for low prices, they could no longer generate the necessary returns (sub. 142, pp. 7, 11).

Glaxo Wellcome provided specific examples of both activity that had been, or could be, lost:

The following are some examples of the impact on manufacturing activities of poor PBS price offers.

- Zinnat. A poor PBS price offer has seen Glaxo refuse to PBS list one of its products, Zinnat, or even make that product available in Australia ... this poor PBS price offer led eventually to the closure of the antibiotics facility at Boronia and the loss of potential export activity.
- Imigran. The continuing unwillingness of the PBS system to allow Glaxo Wellcome a listing price for Imigran that even approaches the European average has seen that product remain on the private market since its marketing approval in March 1992, with postponement of the intended local manufacturing of that product.

- Aerosols. Poor PBS listings have constrained domestic sales of the new products Serevent and Flixotide to such levels that the planned local manufacture is no longer viable. This fact, when combined with the low prices that are being received for older products such as Ventolin, Becotide, and Becloforte, weaken the case for the necessary replacement of the aerosols manufacturing line at Boronia with new manufacturing technology as an alternative to future importing of aerosol products (sub. 143, p. 4).

Glaxo Wellcome stated that it had lost opportunities to supply Zantac to some export markets due to fears of country of origin pricing and parallel exports from Australia (transcript, p. 1303).

Some companies claimed that past disinvestment due to the PBS had been partly offset since the introduction of the Factor f scheme and, hence, the potential to receive higher prices on some products:

[As an example] of suppression of local activity due to the PBS operating environment in Australia ... [Eli Lilly] as a company which disinvested in the mid 1980's, but reinvested in the early 1990's in preparation to participate in the Factor f scheme [and, hence, gain compensation for low PBS prices] ... provides a relevant case study. While ELA's [Eli Lilly's] application [to the Factor f scheme] was unsuccessful, the additional local activity that has occurred (and which may still occur) is directly attributed to the leverage and signals generated by the Scheme (sub. 142, p. 8).

Other companies provided examples of specific activity that had occurred only because higher prices were obtainable through the Factor f scheme. For example, SmithKline Beecham stated that the decision to use an Australian plant (instead of Singapore) to supply Japan, Australia, New Zealand and South East Asia with oral penicillins was driven entirely by Factor f which supported investment in a larger more productive supply plant in Australia (sub. 115, pp. 1, 3–4).

Companies have provided evidence of 'lost activity' due to the negative influence of the PBS on their head offices' perceptions of the Australian operating environment. They also noted the importance of the Factor f scheme in offsetting this influence in actual investment decisions. For example, Merck, Sharp & Dohme stated:

Even though the Factor f payments did not fully compensate for low PBS prices (for example, the price increase which was notionally applied to a patented product, Pepcidine, meant that the product only reached 67 per cent of world average price), head office perceptions of Australia changed because of the Government's positive signals.

If the Factor f scheme had not existed, this local activity would simply not have occurred. [Merck, Sharp & Dohme's] presence in Australia would slowly be

eroded, as the economic life of its existing operations came to an end (sub. 122, p. 2).

Some companies have indicated that the negative impact of the PBS on manufacturing activity would be compounded through flow on effects to their R&D activity. Even though Australia supports R&D generally, through measures such as the 150 per cent tax concession, Glaxo Wellcome indicated that full use would not be made of its R&D expertise unless it retained a manufacturing presence. Glaxo Wellcome stated:

Sometimes the ability to even access and work with local researchers on the research and development is because you do have manufacturing and development capability here and you have the right technical people that could help guide their commercial people in deciding what is the potential of the product, what is the risk—helping the communication. So I think you need an integrated approach and you need all of the elements supported if you're truly going to have the ability to retain some of the commercial benefit of the innovation within Australia (transcript, p. 1282).

Evidence from overseas

The experience of overseas countries provides some evidence that low prices for drugs may contribute to a reduced level of activity.

As noted above, Pfizer claimed that it decided to stop manufacturing in New Zealand because of a failure to secure acceptable prices, as well as a fear of benchmark pricing by the US. Glaxo Wellcome has commented on the general decline of the New Zealand industry and indicated that it will also stop manufacturing in New Zealand based on two main influences:

... the review of operations as a result of the Glaxo Wellcome merger, and the 'increasingly hostile operating environment in New Zealand' including a 'blanket refusal' by Pharm to fund new medicines.

... a decade ago ten research based pharmaceutical companies had manufacturing operations in New Zealand, and that with its closure none will remain (*Scrip*, 8 August 1995 in Victorian Government, sub. 80, Attachment 4a).

While companies have cited price as the main reason for disinvestment and departure from New Zealand, these decisions may also reflect international trends toward global and regional rationalisation of plants in which case factors such as market size and production efficiency will also have an effect.

In Spain, the predicted disinvestment and departure of pharmaceutical companies over the long term has been also attributed to low prices for pharmaceuticals. A Spanish publication, *Tribuna Médica*, surveyed the concerns of several industry executives:

Laboratorios Novo Nordisk executive president ... noting recent price cuts and devaluation, says that unless conditions improve, Spanish industry will be limited to producing generics, and R&D is likely to disappear gradually. The only solution for local firms would be new Government policies, and alliances with multinationals ...

Grupo Synthelabo managing director ... also sees a bleak future unless Spanish drug prices are brought more into line with those in the rest of Europe—plant closures, cancelled investments, and possible delays in the marketing of new products ... executive vice president of Solvay Pharma, agrees, saying that low prices discourage companies from investing in R&D in Spain, and that plants will close because of the lack of incentives from the Spanish authorities, and falling profit levels (*Scrip*, 1 December 1995, p. 4).

The experience of these two countries seems to indicate that companies may respond to negative features in their pricing environment by reducing activity.

Commission's view

As noted above, it is difficult to quantify the effects of the PBS on efficient pharmaceutical activity. In particular, because it is difficult to know the level of activity that might have been undertaken in a deregulated environment, it is difficult to determine the benchmark to measure 'lost activity' against.

The Commission has had to rely on self reported evidence by companies about activity that had been 'lost' due to the PBS, hypothetical expectations of future levels of activity and, to a lesser extent, activity that had been 'regained' by the Factor f scheme. However, it is difficult to rely on this evidence alone. First, self reported and hypothetical evidence by companies may not be objective. Second, because higher prices under the Factor f scheme are tied to activity, evidence on activity 'regained' may not be indicative of the activity that might have been undertaken in a different environment.

The Commission has had access to a range of evidence relating to 'lost activity' with respect to manufacture and export. However, the scope of the problem is unclear in terms of the number of products and companies affected. Nevertheless, it is apparent that a significant number of companies operating in Australia, both participants and non-participants in the Factor f scheme, are expanding although it is unclear whether their full potential is being reached under the PBS (see Chapter 11).

At the same time, any 'lost activity' could be significant if Australia is not taking advantage of any comparative strengths it may have as a pharmaceutical investment location (see Chapter 7).

12.3.2 Direct links between the PBS and ‘lost activity’

Despite limited objective evidence, a number of direct links between the PBS and a lower level of efficient pharmaceutical activity might be assumed. For example, the importance of price suppression in influencing many companies’ activity decisions could be explained by the existence of country of origin pricing policies in overseas markets. For some companies, the combined effect of price suppression, volume constraints and listing delays on local profitability could be influential. These factors may be particularly important for producers of uniquely Australian drugs, such as some anti-venoms.

Country of origin pricing

Country of origin pricing refers to the practice by purchasers in export destinations of restricting their price for an imported product to the price it commands in the country from which it is sourced (that is, its country of origin). If this occurs, MNEs, which typically have alternative sources of supply, will prefer to export from countries where prices are higher. This practice, or the threat of this practice, may impede export development. In addition, because economies of scale are often dependent on export volumes, it may also impede the development of manufacturing for the local market.

Evidence of country of origin pricing

There is limited evidence of country of origin pricing policies operating in practice. The 1991 BIE survey concluded that, with the exception of Japan, it was difficult to prove that such policies operated in Australia’s major export markets. However, it noted that country of origin pricing may not be practised openly or explicitly (BIE 1991, p. 159).

The companies’ responses to the 1995 BIE survey on whether country of origin pricing policies operate across a range of Australian export markets are summarised in Table 12.2.

Table 12.2: Prevalence of country of origin pricing

Country	Number of companies exporting to country	Number of companies reporting whether country of origin pricing operates		
		Yes	No	Not known
New Zealand	20	2	11	7
Hong Kong	8	2	2	4
Malaysia	6	2	2	2
Singapore	5	-	2	3
UK	3	-	3	-
Canada	3	-	3	-
Other countries	21	2	11	8
All countries	66	8	34	24

Source: BIE 1995, p. 8

In respect of these responses, the BIE noted:

... companies reported that country of origin pricing operated in only a very small proportion of cases—around 12 per cent. But there was also considerable uncertainty on the part of many respondents as to whether country of origin pricing operated, and there were differing views for some countries' (BIE 1995, p. 7).

The 1995 BIE survey concluded that, overall, there was scant evidence of country of origin pricing in Australia's key export markets (BIE 1995 p. 7).³

However, due to its focus on Australia's key export markets, the BIE may have underestimated the extent of country of origin pricing. In this respect, the BIE stated:

... the survey findings cannot rule out the possibility that the reason why companies export to these markets is that country of origin pricing typically does not operate (BIE 1995, p. 7).

It concluded that it is possible that country of origin pricing may discourage any exporting to some markets.

The Commission sought information from participants about the existence of country of origin pricing.

In its first submission, Merck, Sharp & Dohme stated:

³ The countries included in Table 12.2 account for around 60 per cent of all pharmaceutical exports from Australia—New Zealand alone represents around 30 per cent (BIE 1995, p. 7).

In most of the Asian markets to which MSD exports, and the Middle East, Governments are explicitly or implicitly focusing on the price in the country of origin (sub. 27, p. 6).

In a subsequent submission, Merck, Sharp & Dohme advised that country of origin pricing was formally practiced in Saudi Arabia, the Middle East and Taiwan (sub. 95, p. 1). With specific reference to the pricing policies of Taiwan, it stated:

[Merck, Sharp & Dohme] Taiwan has asked us to obtain official documentation from the Australian Government ... to assist it in pricing negotiations with the National Health Insurance Bureau (NHIB). The NHIB is using the country of origin price as the major criterion for setting the domestic reimbursement price of an MSD product in Taiwan (sub. 122, p. 2).

It indicated that governments in other Asia-Pacific countries (such as China, Korea and Hong Kong) had conducted international price comparisons but was unclear how these were used in local pricing and reimbursement decisions (sub. 95, p. 1).

Pfizer had also been advised by its sister operation in Taiwan that Taiwanese health authorities practise country of origin pricing (sub. 133, p. 12). However, it was not able to provide actual evidence. Its first batch of new products for export to Taiwan was not likely to be approved until mid 1996 (sub. 133, p. 12). In addition, based on evidence provided by its international head office on European export markets, Pfizer submitted that country of origin pricing was practised in Austria, Ireland, Portugal, and Switzerland (with premiums up to 25 per cent) (sub. 97, p. 1). It indicated that it could not preclude its operation in other European countries where governments conduct inter-country price comparisons, such as Belgium, France, the Netherlands, Spain and Sweden.

Glaxo Wellcome claimed that country of origin pricing was widely practised in the Middle East and parts of Eastern Europe, stating that:

It is the general approach in most Middle East countries (for example, Saudi Arabia, United Arab Emirates and Cyprus, etc) that the local price cannot exceed the country of origin price (sub. 144, p. 10).

Other companies documented the negative effect on activity from country of origin pricing but did not provide direct evidence of its existence. For example, Faulding stated that:

... [while it] generally sells products at higher prices overseas than in Australia

.... country of origin pricing affects exports. Low PBS prices in Australia seriously erode ability to market price in other countries (sub. 46, p. 3, 13).

Astra stated:

Country of origin pricing will increase ... as countries develop, cost containment and benchmark pricing (or the threat of it) increases, there will be little incentive for multinational companies to fully develop pharmaceuticals in countries where it is likely that there will be a low initial price (sub. 141, p. 6).

Based on the limited formal evidence submitted to the Commission, it would appear that country of origin pricing, at present, is not a common practice. In particular, it is uncommon in Australia's key export markets.

Threat of country of origin pricing

Many companies argued that it is not just the actual practice but also the potential for country of origin pricing that affects trading and investment behaviour. Glaxo Wellcome stated:

Formal evidence of country of origin pricing in other regions of the world is difficult to identify, as the Commission has discovered. What is important, however, is that the perception of this occurring is a very real concern and issue within international and regional management, and if widely practiced would have very significant adverse implications for a pharmaceutical company. For this reason, a cautious view is adopted by Head Office when evaluating the acceptability of proposed PBS prices ... This is not a formalised benchmarking mechanism but the views expressed have been done in regional management meetings, leading to pressure on Glaxo Wellcome Australia to reject PBS price offers too far below prices in other countries in the near geographic vicinity and have resulted in lost export supply opportunities for Australia (sub. 144, p. 10).

Further, Pfizer stated:

... I know the Commission has heard a lot about this country of origin pricing and [struggled] to find some hard data ... a lot of the barriers in terms of what we define as country of origin pricing are internal within company.

... [for example] the managing director of Pfizer's business in Taiwan has the right to ensure that he gets the best possible return on the products that he has in his marketplace.

If he believes ... that an in-the-market price of X is going to compromise his in-the-market price he has every right to say to some other Pfizer location, 'Can you please give me your in-the-market price and can I register you as a source of supply?' So much of what you hear I suspect is lost in the internal negotiation within company, across borders, but let me assure you it is very real and it's tangible, and just recently, I can assure you, we lost an opportunity for a sizeable export to a particular market because of that. Germany has won the export and we lost it (transcript, pp. 502–503).

Pfizer noted that, until recently, companies had manufacturing facilities that serviced national, as opposed to regional or global, markets. Hence, domestic companies provided the source of supply, and country of origin pricing was not an issue. However, with global and regional rationalisations and, hence, import

replacement of home manufactures in some markets, this issue has become material (transcript, p. 504).

The threat of country of origin pricing was also raised as a significant concern by Astra (sub. 141, p. 6) and Bristol-Myers Squibb (sub. 25, p. 30).

The Commission considers that companies could reasonably expect that buyers in export markets will take account of pricing practices in other countries in their pricing negotiations, especially in the case of a low priced, developed country such as Australia. Hence, companies could consider this possibility when making decisions about supply sources.

FINDING

The Commission finds that there is little formal evidence of country of origin pricing. However, it accepts that the threat of country of origin pricing may affect decisions about the location of production.

Profitability

In Chapter 8, the Commission concluded that the overall impact of the PBS is likely to have reduced pharmaceutical companies' sales revenue. Hence, the PBS is likely to have reduced the profitability of companies operating in Australia. This may have an effect on activities funded out of local cash flow.

In many cases, companies focused on the effect of low PBS prices which would affect local profitability. However, it could be assumed that volume constraints and listing delays would have similar effects on profitability, and hence, on activity.

The Australian companies have argued that the impact of the PBS on profitability had directly affected their ability to expand and export. CSL stated:

The generally low prices in the Australian market act to slow down CSL's capacity to generate funds from its home market base for the necessary investment in capital equipment, technology, research and market development required to 'carve out' a sustainable international position (sub. 39, p. 5).

Faulding went further and stated:

The inadequate reimbursement for products on the PBS will prevent establishment of a viable sustainable industry (sub. 46, p. 2).

The Australian companies also argued that reduced profitability had directly affected R&D activity. The companies claimed that higher revenues and profitability were necessary to fund expensive and high risk pharmaceutical R&D. Further, lower profitability reduced their ability to develop innovative products. At the public hearings, AMRAD stated:

To assist in the finance of this [long term and extensive] R&D program, AMRAD requires revenues generated through its sales of products on the PBS and therefore we have a keen interest in the link between any future Government incentive or compensatory scheme and the recovery of low prices in Australia (transcript, p. 1242).

In addition, AMRAD indicated that increased revenue under Factor f had enabled greater investment in R&D (transcript, p. 1241) while other companies indicated that it had led to collaborative arrangements with research organisations, and greater investment in Cooperative Research Centres (CRCs) and research syndicates.

Likewise, MNE subsidiaries argued that lower local profitability had reduced their discretionary expenditures on all activities which are partially or wholly funded from profits on local sales, and that R&D had been particularly affected.

With respect to the first point, Glaxo Wellcome stated:

... [higher profitability due to higher prices under the Factor f scheme] relieves financial pressure locally and allows one to do more activity locally, fund more activity locally, before the necessity arises to bring in the bigger brother in the group (roundtable, p. 273).

With respect to the second point, Pfizer stated:

Low prices directly affect R&D decisions, which are influenced significantly by local market conditions (sub. 79, p. 27).

In both its 1991 and 1995 reports, the BIE provided evidence that many companies would increase clinical trials if price controls were removed (for example, BIE 1995, p. 15).

With respect to significant R&D projects, the effect of reduced local profitability on R&D activity undertaken by MNE subsidiaries is less clear. For these companies, revenue from PBS sales will represent only a small proportion of total international sales revenue. If a research project in Australia was likely to earn an attractive rate of return, it would be unlikely that a MNE would stop this project just because its local subsidiary had been earning low profits. Eli Lilly stated:

... we will continue to take advantage of clinical skills in the country ... one of the bright sides of having a cost-effective health care system is you can also do clinical trials cost-effectively, and you can do them for very high quality.

... On the side of the research agreements, I think we will continue to be very proactive and prospective about finding good clinical research ... [the question is] do we set a development unit up in Australia to develop the fruits of that research ... If there is no reward for that, then we're economically minded in that regard and we will move on (transcript, pp. 342–343).

However, the returns from most research are not predictable and Australian researchers have to compete for funds with researchers in other countries. MNEs will be more likely to fund Australian research if they have profitable Australian operations.

The Commission acknowledges that the impact of the PBS on cash flows is likely to have an adverse effect on investment and activity for companies operating in Australia. However, for subsidiaries of MNEs or Australian companies with significant export markets, this effect is likely to be reduced with globalisation and rationalisation in the industry. In this environment, strategic plants will be selected to service regional or global markets and the Australian market will comprise only a relatively small proportion of a company's overall market. Hence, compared to a situation where an operation is predominantly dependent on domestic sales revenue, the effect of the PBS on

a company's total sales revenue and profitability will be reduced. Further, the PBS is likely to have an equal effect on the profitability of any company selected as a strategic site to service the Australian market, regardless of the location of its production.

With globalisation and rationalisation in the industry, the PBS becomes only one of a number of factors determining a company's profitability. Some MNE subsidiaries have indicated that there has been a greater emphasis on factors that affect the cost efficiency of local operations in the location and investment decisions of their head office including labour productivity, R&D infrastructure, and taxation policy (see Chapter 7). In particular, Upjohn stated:

Price is important. ... absolutely, but [we're] judged on profit, not price. I'm judged on in-company profitability and other aspects of running the business (roundtable, p. 100).

The 1995 BIE report also noted that some MNEs were focusing beyond price and taking a broader view of other factors affecting the overall operating environment (BIE 1995, pp. 9–10). In this context, the PBS becomes more important when there are only marginal differences in cost efficiencies between possible investment locations.

For companies for which the Australian market represents a large proportion of total sales revenue, the effect of the PBS may be to impede their growth relative to other companies.

FINDING

The Commission finds that there is limited evidence of a direct link between low company profitability resulting from price suppression under the Pharmaceutical Benefits Scheme and lower levels of activity, including research and development activity. However, any effect is likely to be greater for Australian companies than subsidiaries of multinational companies.

Uniquely Australian drugs

Where Australia is the sole market for a drug, the local market will provide the only opportunity for pharmaceutical companies to generate revenue to recover substantial fixed and sunk R&D costs associated with the development of new products. In this case, the adverse effects of low PBS prices, volume constraints, and listing delays on revenue are likely to provide a disincentive to undertake such activity.

However, there are only a few drugs developed in Australia for unique Australian needs. Perhaps, the only drugs which fall into this category are some anti-venoms or vaccines. Traditionally, in these areas, R&D has been directly

subsidised by the Government (for example, through the Commonwealth Serum Laboratories).

The 1995 BIE report concluded that:

... the quantitative importance of the Australian specific needs category is likely to be very small (BIE 1995, p. 6).

Commission's view

The limited evidence available to the Commission suggests that country of origin pricing practices are likely to be uncommon in Australia's key export markets, and that the actual impact of reduced local profitability is difficult to ascertain. On this basis, it is difficult for the Commission to substantiate the existence of direct links between the PBS and a lower level of efficient activity.

12.3.3 Indirect links between the PBS and 'lost activity'

Given the limited evidence of 'lost activity' under the PBS and direct links between the PBS and lower levels of efficient activity, the practical case for intervention depends, at least in part, on the indirect influence of the PBS on pharmaceutical investment and location decisions. Indirect links between the PBS and a lower level of efficient activity will depend on the impact of price suppression, volume constraints and listing delays, taken together, on company perceptions of the operating environment as well as benchmark pricing policies in overseas countries.

Company perceptions

As noted in Chapter 7, investment decisions by MNEs are complex and multidimensional. They are based not only on a range of specific economic factors (such as prices, costs and tax rates) but also on perceptions of the head office about the overall operating environment. The 1991 BIE report noted:

While locational decisions are clearly influenced by commercial considerations such as relative costs of supply, the decisions of multinationals also depend on their perceptions of how 'hospitable' or unfavourable the policy environment in a particular location is (BIE 1991, p. 84).

Glaxo Wellcome stated:

There are numerous factors taken into account by multinational pharmaceutical companies when taking investment decisions as to where to locate strategic R&D, manufacturing and export operations ...

The overriding key influence in the decision to invest, however, is the overall assessment by head office of the attractiveness of the local climate for investment.

... In ... an environment [of global rationalisation], the challenge for Australian policy makers is that the domestic operating environment must be sufficiently attractive, in an ... increasingly competitive global environment, if local pharmaceutical companies can hope to retain existing activities or attract new activities (sub. 144, pp. 3, 4).

The 1995 APMA survey ranked 'PBS pricing' and 'PBS listing/prescribing restrictions' as first and second respectively in the list of negative factors cited by pharmaceutical companies as impeding business development and new investment (APMA 1995a). In their submissions to this Inquiry, companies have claimed that low prices, volume constraints and listing delays under the PBS have adversely affected company perceptions of the Australian operating environment and negatively affected investment decisions. Glaxo Wellcome referred to these three features of the PBS as 'the three ugly sisters' of the Australian operating environment. Eli Lilly stated:

ELA's [Eli Lilly Australia's] experience indicates a more complex picture of how the PBS depresses returns in the market through a mix of actions which often involve one or more of:

- Price suppression;
- Volume constraints (for example Authority listings); and
- Time delays (for example listing, the pricing decision making by Government, removal of authority listings, changes in indications).

These factors affect ELA's comparative performance measured against other affiliates. Ultimately they feed back into the [Eli Lilly Corporation] decision making model when evaluating investment opportunities (sub. 142, p. 5).

While noting the significance of the other features of the PBS, a number of companies highlighted the particular importance of PBS prices in investment decisions. For example, Merck, Sharp & Dohme stated that its investment decisions were based on:

... price, price, price and patents (transcript, p. 426).

Similarly, CSL stated that:

... I still feel like a bit of a real estate person. At the end of the day it's position, position, position. In our industry it's price, price, price (transcript, pp. 1182–1183).

Some of these companies have indicated that low PBS prices are the most important indicator of a generally 'hostile' attitude to the pharmaceutical industry. Glaxo Wellcome stated:

The Commission is correct to focus on the issue of price. Apart from the direct impact of price upon the viability of local operating companies, the price of a product is extremely visible to other parts of a multinational pharmaceutical company and to foreign reimbursement authorities (sub. 144, p. 7).

In addition to specific negative features of the PBS, companies have also argued that the Government's approach to the PBS has led to frequent changes in policy, and a high level of uncertainty. Merck, Sharp & Dohme stated that 'arbitrary and *ad hoc* decisions ... undermine industry's confidence' (sub. 27, p. 13).

In this respect, the 1995 APMA survey ranked the 'overall health system/environment' sixth in the list of negative factors cited by companies as impeding business development and new investment (APMA 1995a). According to the APMA:

In particular the industry is stressing the importance of a policy framework which is consistent, stable and has a long term focus if new business investment and activity is to be attracted to Australia in an increasingly competitive global pharmaceutical environment (APMA 1995a, p. ii).

However, it is difficult to isolate the adverse effects of PBS pricing, process and policy from other features of the operating environment which may also be negatively affecting companies' perceptions and, hence, their investment and location decisions.

It is clear that Government controls, in general, may influence companies' perceptions of the operating environment. For example, Merck, Sharp & Dohme noted that it is Government pricing and reimbursement policies as well as marketing approval regulations and the intellectual property protection regime:

... [which] enable multinational companies such as [Merck Sharp & Dohme] to realistically compete, against their sister subsidiaries, for a greater share of the worldwide Merck business in both manufacturing and export (sub. 27, p. 1).

Further, the Canadian experience with compulsory licensing to import medicines is an example of the effect that government controls perceived as 'hostile' can have on companies investment decisions (see Chapter 7).

In addition to the PBS, companies have noted that there are other Government controls that are having a substantial negative effect on the perceptions of their head offices and, hence, on investment decisions. Among the more significant concerns were:

- a patent regime that is less generous than in the US and Europe (see Chapter 16);

- administration of transfer pricing policies by the Australian Taxation Office (see Chapter 7 and Appendix G); and
- the lack of a ‘whole of government’ approach toward industry leading to inconsistent treatment by different Government Departments.

With respect to the last concern, Bristol-Myers Squibb argued that:

Inconsistent and frequently changing Government policy creates a cautious attitude toward investment in Australia (sub. 25, p. 22).

SmithKline Beecham stated:

The pharmaceutical industry, by its very nature, is heavily reliant on long-term planning. Such planning must be made in the context of the business environment within which we operate. The Australian long-term planning environment is made difficult by the instability of Australian Government policy (sub. 13, p. 22).

Based on the evidence, low PBS prices, volume constraints and listing delays do appear to be having a negative effect on the companies’ perceptions of the Australian operating environment. Together with other factors that are negatively affecting companies’ perceptions on the operating environment, this may represent an increase in sovereign risk. Since Australia may have only marginal attractions over other possible investment locations, even a small increase in the implicit costs of risk could tip the scales against Australia as an investment location.

FINDINGS

The Commission finds that low prices, volume constraints and listing delays under the Pharmaceutical Benefits Scheme, combined with other policy and process uncertainties are likely to play a part in corporate decisions about whether to locate activities in Australia. However, the weightings given to these factors by individual companies may vary.

These factors add to an impression of an unfavourable environment and therefore indirectly reduce the attractiveness of investing in Australia, particularly where there are only small cost and quality variations between Australia and other countries.

Benchmark pricing

In Chapter 8, the Commission found that, while there was limited formal evidence of benchmark pricing, the threat of benchmark pricing may affect decisions about the supply of drugs to Australia and that this threat is likely to increase.

As noted in Chapter 8, benchmark pricing is more likely to affect the range of drugs available under the PBS, rather than directly affect the level of pharmaceutical activity. However, there may be indirect effects. For example, a refusal to accept prices below the international price, causing a long delay in listing, may lead to lower than expected revenue. In turn, domestic manufacturing could be postponed or shifted permanently offshore. Similarly, a reduced range of listed indications on the PBS, curtailing domestic volumes, may affect location decisions.

Glaxo Wellcome provided the example of Flixotide. As noted in Chapter 8, a refusal to negotiate on price, due to the threat of benchmark pricing by other countries with Australia, led to negotiation on volumes. For Glaxo Wellcome, this led to revised expectations on revenue which may also affect future investment in asthma research in Australia, aerosol manufacture and export supply (Glaxo Wellcome correspondence 16 February 1996).

Pfizer provided the examples of Zolofit and Carduran. As noted in Chapter 8, Pfizer was concerned that the threat of benchmark pricing by the US with other countries including New Zealand and Australia could jeopardise the prices of these drugs in the significantly larger US market. Pfizer claimed that this was a major contributing factor in its decision to cease operating in New Zealand:

Obviously, for an R&D-based drug producer, being unable to launch new and innovative products into a national market makes manufacturing and other investment in that market unsustainable. Pfizer closed its manufacturing facility in NZ in 1990 ... Because of the Zolofit situation [in 1992], our experience with Carduran [in 1990], and the poor prospects of adequate prices for new Pfizer products in NZ in the future, Pfizer totally closed its NZ operations in 1995. Withdrawal from the NZ pharmaceutical industry was completed in March (sub. 79, p. 14).

Pfizer submitted that its actions in New Zealand ‘demonstrate plainly the close relationship between pharmaceutical prices and the sustainability and potential for investment in pharmaceutical activities in individual countries’ (sub. 79, p. 14).

The Commission accepts that the threat of benchmark pricing may indirectly affect company decisions about the location of activity.

Commission’s view

Inevitably, the nature of such indirect evidence makes it difficult to draw objective conclusions. It is not only difficult to separate out the negative effects of the PBS from other negative features of the Australian operating environment (for example, policy uncertainties and inconsistencies or other Government controls) but these effects must also be weighed against other more positive

features (such as, high quality labour and management, and R&D infrastructure). However, on balance, the effect of the PBS on companies' perceptions is important.

FINDING

The Commission finds that, based on available evidence, low prices, volume constraints and listing delays under the Pharmaceutical Benefits Scheme appear to be depressing pharmaceutical activity below the level that might be achieved in a deregulated environment, and impeding industry development.

In the following Sections, the Commission considers the likely effects of the PBS on pharmaceutical activity together with likely future health and budgetary outcomes to determine whether there is a case for Government intervention in the PBS.

12.4 The case for general Government intervention

While the Government has in the past dealt with the problems facing the pharmaceutical industry via financial intervention in the form of the Factor *f* scheme, it could deal with these problems at a more fundamental level, by reforming the PBS. The Commission refers to this as general Government intervention. There would be a case for general intervention if it is clear that some elements of the PBS were not serving the best interests of the community generally. This involves looking at the interests of all stakeholders—consumers, taxpayers and the industry.

The Commission has examined issues such as delays, volume restrictions, complex and inefficient administrative processes and problems with cost effectiveness analysis (see Chapters 8, 9 and 10). These issues would not only affect the industry, but also reduce the welfare of consumers, by denying them timely access to some drugs and rationing their use. These problems, while not grave at present, appear to be worsening. On the basis of its findings, the Commission has recommended a review of PBS processes and has suggested a review of PBS policy settings.

This Chapter went beyond the questions of the effect of the PBS on sales revenues and drug availability to examine in more detail the likely effects of the PBS on pharmaceutical activity. The Commission has found that, overall, the PBS is likely to have lowered domestic activity below that level which might have been achieved without the PBS, largely through its influence on company perceptions about the Australian operating environment. This implies that Australia's resources have been misallocated.

However, if there were benefits to taxpayers and consumers that outweighed any negative effects on the industry, there would be no case for general Government intervention. But it appears that the PBS is not serving the

interests of taxpayers and consumers as well as it used to. It is becoming apparent that the interests of all of the stakeholders may not be adequately met in future.

In deciding whether there is at least a *prima facie* case for Government intervention in relation to the PBS it is useful to examine the likely impact of no intervention at all. The likely effects on all stakeholders is considered below.

12.4.1 The effects of no Government intervention

The Government may decide not to intervene at this stage to address the emerging problems of the PBS. Pursuit of this approach will mean that low PBS prices would continue and the Factor f scheme would not be renewed. With this approach, the Government must be willing to accept possible future costs to activity and drug availability, together with increasing budgetary pressures.

Effects on industry

In its submission, the APMA provided a worst case future scenario based on an assumption of no Government intervention whatsoever. This scenario would have serious industry effects for Australia (see Box 12.1).

Several other participants also offered their views on the likely effect of no further intervention, particularly the discontinuation of the Factor f scheme.

According to Glaxo Wellcome, due to the negative signals transmitted to its head office, there would be both immediate and secondary effects on its investments. The immediate effect would be a reduced opportunity for new investment in Australia. The secondary effects would occur as decisions for existing investment in Australia are reviewed. With respect to the latter, Glaxo Wellcome stated:

For something like the aerosol example, rightly so the world requires us to replace the CFCs [chloro-fluorocarbons] in them. You could lose that just like that, even though the products may be early in their life cycle, the need to change a component alone could trigger an investment decision.

... We have one of the most efficient manufacturing sites for many of our technologies within the Glaxo Wellcome world.

But there may come a point ... when ... we may fall below the line. ... With the slow decline ... you are losing the volumes. You are not replacing equipment with state of the art faster equipment. You are not going to be able to remain competitive (transcript, pp. 1306, 1307).

Taken to the extreme, there could be some disinvestment or departure by some pharmaceutical companies. As noted above, the companies have claimed that the disinvestment and departures in the 1980's were directly attributable to the operation of the PBS.

Box 12.1: APMA prescription sector worst case scenario

Assumes that if the policy environment provides:

- increasingly demanding requirements for PBS listing of new products, confined to very narrowly defined sub-categories of patients in whom the drugs are known in advance to achieve major clinical improvement;
- continuing insistence on low prices through cost effectiveness comparisons with increasingly older therapies; and
- discontinuation of a Factor f type scheme to compensate for low prices, and a negative approach to basic, developmental and industrial R&D.

This would lead to:

- international disillusionment with Australia as a centre for pharmaceutical activity;
- some growth in the dollar value of the local market;
- many new products would be subject to major delays in availability and some would be denied to the Australian public, where the price was relatively high and the Government was unwilling to subsidise its costs through the PBS or some other mechanism;
- manufacturing facilities would gradually close or be directed at a decreasing range of products and markets. State of the art manufacturing facilities which now exist would disappear as the economic life of these facilities ends;
- declining exports would focus on products that were sustainable without the introduction of new technologies or plant upgrades;
- disinvestments would gradually lead to a reversion of the export/import ratio to 1980s levels; and
- much of the interaction and support from the pharmaceutical industry for a huge range of academic, research, public health and educational initiatives would disappear and the broader benefits provided by the 'vitality' of the current industry in Australia would decline.

Source: APMA sub. 199, Attachment A, p. 4

For the Australian companies, which are more dependent on the local market to generate revenue, reduced profitability would lessens their ability to innovate, expand and export. For the MNE subsidiaries, lower profits would be likely to reduce their discretionary expenditure on local activities. It is likely that Factor f companies would undertake less R&D. In a worst case scenario, important links to Australian research institutes and investment in CRCs could be lost.

However, it is unlikely that all activity generated under the Factor f scheme would cease. Indeed, it is likely that activity undertaken by some companies would continue and expand.

For example, based on the stimulus for investment provided under Phase I of the Factor f scheme, and despite its failure to receive funding under Phase II, SmithKline Beecham has recently won the right to supply oral penicillins in all South East Asian markets, Japan, Australia and New Zealand. SmithKline Beecham stated:

The decision was in favour of Dandenong because the initial Phase I investment gave us the support needed to put in place a larger and more productive supply centre than might otherwise have been the case (sub. 115, p. 4).

In addition, strong growth rates have recently been observed in companies that have not received any financial assistance through the Factor f scheme (see Chapter 11). In particular, while Factor f companies are likely to be more export oriented, non Factor f companies have performed strongly in areas such as R&D and domestic manufacturing. This suggests that there are features of the Australian operating environment that are advantageous to pharmaceutical investment. If this is the case, some investment and activity is likely to continue or disinvestment is likely to be more gradual.

Adverse effects are most likely to be felt by:

- employees of pharmaceutical companies which gradually reduce their scope of Australian activities;
- members of the research community which have reduced potential to work with the pharmaceutical companies—this may affect both their incomes and the benefits they receive from the knowledge and expertise found within such companies;
- companies which are involved in contract manufacture of actives; and
- industries which supply the pharmaceutical industry (for example, glass products manufacturers).

Effects on drug availability

In a worst case scenario, pharmaceutical companies are likely to become even less willing to negotiate on drug prices.

In the face of budgetary constraints, the Government is likely to continue to negotiate on drug volumes by restricting the range of indications for which subsidies are available to Australian consumers. If companies are willing to negotiate on the latter, consumer access to important applications could be restricted. If companies are not willing to negotiate, consumer access to important drugs could be denied altogether.

As documented in Chapter 8, the reduced willingness of companies to negotiate on price is becoming apparent. Chapter 8 provides evidence of drugs for which PBS listing has been significantly delayed (in some cases, up to nine years after their marketing approval dates), while Chapter 8 provides evidence of drugs not listed on the PBS due to unsatisfactory price offers and marketing restrictions.

The threat of country of origin pricing policies and benchmark pricing policies in overseas markets is likely to accentuate current trends. In addition, in a worst case scenario of diminished industry presence, Australia may become more dependent on importers for drug supplies. The companies have argued that importers are even less willing than local producers to negotiate on price. Eli Lilly stated that, as a local subsidiary to a large MNE, it provides an advocate in head office that puts forward the best possible case for low PBS prices:

... I always have to get prepared when I make a phone call to Indianapolis when I tell them that [a price reduction] has happened. I usually take a day, sit back, figure out how I'm going to tell them, so it doesn't look so negative. ... I think we're trying to build a business in Australia, and those signals come back very negatively, so we sit down and think about how we're going to put this so it doesn't look so negative, and in essence that makes us an advocate of Australia in doing that and of achieving those growth goals we would like to have and believing that the investments are the right things to make still, but it's a very tough one (transcript, p. 363).

Along with restricted access to important pharmaceutical products or applications, the Australian public could also be denied important health promotion or education campaigns currently undertaken by industry. In particular, the negative effects of the PBS on sales revenue and, hence, cash flows are likely to reduce industry funding of these activities. While the Government already provides a substantial proportion of overall funding in these areas, there may be some important services that are dependent on industry support.

Budgetary pressures

As noted above, in a worst case scenario, companies are likely to become even less willing to negotiate on drug prices. At the same time, consumers are likely to demand timely access to drugs for the same range of indications available to consumers overseas. Community pressure could force the Government to pay the higher drug prices demanded by pharmaceutical companies.

Under current copayment arrangements, the Government's spending on drugs could substantially increase. Indeed, if the Government was forced to pay international prices for all drugs, Government expenditure on drugs could increase significantly.

As noted above, there could also be additional budgetary pressures from reduced industry funding of important health promotion or education campaigns which the Government may be forced to replace.

12.4.2 Conclusions

In the past, the PBS has substantially enhanced the welfare of consumers and the community more generally by providing broad availability to drugs at low cost. However, based on its findings in this Inquiry, the Commission considers that there are problems with the PBS and these are likely to worsen. In its current form, it will become less likely to ensure positive health outcomes for consumers and budgetary outcomes for the Government and taxpayers in the future. It is also likely to continue to adversely affect activity undertaken by the pharmaceutical industry in Australia.

Based on its findings on the emerging problems of access described in Chapter 8, in combination with the likely effects on activity described in this Chapter, the Commission considers that there is a case for Government intervention in the PBS. While the Government could decide not to intervene, the Commission considers that the negative effects of such a decision on all stakeholders could be substantial.

FINDING

The Commission finds that there is a case for general Government reform to improve the Pharmaceutical Benefits Scheme environment.

General Government reforms to improve the PBS environment are discussed in Chapter 13.

12.5 The case for financial intervention

In the past, the Government has addressed the impediment of the PBS to industry development through financial intervention in the form of an industry compensation scheme. As noted in Chapter 5, the Factor f scheme was designed, at least in part, to compensate for the effects on activity of low PBS prices.

The case for further financial intervention to support the industry would depend on whether:

- the PBS was likely to represent an impediment to the continuing development of the industry;
- it would be inappropriate to deal with this impediment at its source; and
- financial intervention was likely to bring about net benefits to the community.

The Commission has already found that the PBS was likely to affect the normal development of the pharmaceutical industry.

However, there appears to be good reasons for dealing with the impediment at its source. As described above, there are a number of problems with PBS processes and policy settings that affect consumers and taxpayers as well as the industry.

The next question is whether financial intervention is likely to bring about net benefits to the Australian community.

The continuation of a Factor f scheme will undoubtedly improve the welfare of companies—one of the stakeholders. Companies have claimed that the current Factor f scheme has been instrumental in attracting activity to Australia, largely through its positive influence on company perceptions of the Australian operating environment. Subject to the qualification that other economic reforms are likely to have also contributed to a higher level of investment and output, participants in the Factor f scheme have significantly increased exports, domestic value added and R&D (see Chapter 5).

A continued Factor f scheme should not be seen as a solution to the industry's problems in their entirety. The Factor f scheme was only designed to compensate for the effects of low PBS prices, which is just one aspect of the PBS impediment to industry development. As noted above, the companies have argued that volume constraints and listing delays are other significant features of the PBS that have impeded their growth. While financial intervention, by increasing sales revenue, can partly offset this negative impact, it does not address the PBS impediment at its source. In particular, it does not directly

address the substantial problems for companies from price suppression, volume constraints or listing delays.

Financial intervention will not address the problems facing consumers. These issues affect a much larger proportion of the community than the issue of industry development. For this reason, financial intervention is only likely to deal with a small section of the broader PBS problems.

Of greatest concern, financial intervention could relieve pressure on the Government to address the PBS impediment directly. In particular, it could relieve the immediate pressure for significant reforms to PBS process and policy to improve the PBS environment and hence, address health, budgetary and industry pressures simultaneously.

At present, the PBS represents a cost saving to Government and taxpayers of about \$860 million each year.⁴ This largely represents a transfer of wealth from foreign shareholders to Australian taxpayers and consumers. It is unlikely that any costs in terms of lower pharmaceutical activity or availability will outweigh these benefits.

Nonetheless, it may be possible to design a scheme which only marginally reduces the Government's cost saving under the PBS and yet could attract pharmaceutical activity to Australia which has substantial benefits to the community. However, it is unlikely that this has been achieved by the current Factor *f* scheme (see Chapter 11). It is impossible to design a scheme that guarantees a positive return to the community.

Finally, if, as expected, companies become less willing to negotiate on price in the future, and volume constraints and listing delays become even more severe, financial intervention will become less of a solution to industry's problems. At the same time, health and budgetary pressures are likely to become substantially more significant for Government, consumers and taxpayers.

Financial intervention would only ameliorate the problems facing one of the stakeholders—the industry. Consumers are unlikely to receive substantial benefits from the scheme. Even from an industry perspective, financial intervention is essentially a 'stop-gap' measure that does not address the real impediments to development. While it may increase pharmaceutical activity in the short term, there are no guarantees that this activity will last beyond the period of the subsidy while the underlying impediments have not been addressed.

⁴ Assuming PBS prices are 70 per cent of world prices and Government expenditure on the PBS is \$2 billion.

FINDING

The Commission finds that there is no clear cut case for financial intervention to compensate companies for low Pharmaceutical Benefits Scheme prices and other impediments.

12.6 Commission's view

In the Commission's view, the overall impact of the PBS including low prices, volume constraints, and listing delays is likely to affect adversely the availability of drugs to the Australian community and the level of efficient pharmaceutical activity undertaken in Australia. On this basis, the Commission considers that there is a case for Government intervention. While the Commission has found that there is a case for general Government reform of the PBS processes and underlying policy to improve the PBS environment, the case for financial assistance to industry is less clear.

Future Government intervention could take three forms:

- reform of PBS processes alone;
- reform of PBS processes plus reform of PBS policy; or
- compensate for impediments associated with the PBS through financial intervention.

Approaches to Government intervention are considered in Chapter 13.

13 APPROACHES TO FUTURE INTERVENTION

This Chapter considers how the Government should address the problems associated with the PBS faced by the pharmaceutical industry, consumers and taxpayers. It concludes that these problems are best addressed at their source, by reforming PBS processes and reviewing its policy basis. The Commission considers the continuation of the Factor f scheme is not the best way to address the underlying problems with the PBS.

13.1 What should the Government do now?

Chapter 12 concluded that there was a case for general Government intervention in the pharmaceutical industry.

This conclusion was based, in part, on the findings in Chapters 8, 9 and 10 that Pharmaceutical Benefits Scheme (PBS) outcomes such as delays and limited listed indications were beginning to affect drug availability to consumers. Some of these problems arise from companies' increasing unwillingness to negotiate on price because of benchmark pricing and country of origin fears. Such pricing pressures are likely to increase because of expanded international trade in pharmaceuticals with global rationalisation, and greater incentives for drug purchasers to scrutinise foreign drug prices for use in their own price negotiations. Delays and limited listed indications also affect the revenue that companies are able to earn in Australia. Other problems were identified with PBS processes, such as the methodology used to undertake cost effectiveness analysis. A review of PBS processes was recommended, and a review of PBS policy suggested.

Chapter 12 added to the case for a review of PBS processes and policy by examining more closely the impact of the PBS on pharmaceutical industry activity. It was found that while there was little direct evidence of a link between the PBS and activity, it was likely that the PBS did affect some investment and activity decisions. However, it was concluded that the case for financial intervention (for example, Factor f) in the industry is less clear.

Chapter 12 noted that the Government response could take three forms:

- reform of PBS processes alone;
- reform of PBS processes and policy; or

- financial intervention to compensate for impediments associated with the PBS.

Because the balance between the interests of taxpayers, consumers and the industry no longer appears to be appropriate, the Commission's preferred approach is for the Government to tackle the problems associated with the PBS directly. Consequently, the best course of action is fundamental reform of PBS processes and policy, rather than the continuation of an interim financial measure such as the Factor f scheme.

13.2 Reform of the PBS

The PBS has served consumers and taxpayers well in the past. It has provided the Australian community with a wide range of drugs at relatively low cost. The low prices of drugs negotiated under the PBS have represented a substantial transfer of wealth from foreign-owned companies to Australian consumers and taxpayers. However, this favourable situation is unlikely to be sustainable. Problems are now evident in both PBS processes and underlying PBS policy (as noted in Chapter 9).

Reform of the PBS could be narrowly focused on processes or it could be broader and involve changes to PBS policy as well.

13.2.1 Process reform

Regardless of any policy changes to the PBS, it is evident that there is widespread support for changes to PBS processes (see Chapters 9 and 10). It was suggested that a review of PBS processes could examine both organisational and methodological issues. Among the methodological issues to be examined are the application of cost effectiveness analysis and the way in which the pricing factors are used. Organisational issues requiring review include the structure of the listing and price setting institutions, including the establishment of an independent pricing authority, and ways of streamlining processes to minimise delays.

There are many likely benefits of PBS process reforms. Such reforms are likely to improve the timely availability of drugs to consumers as well as improving the operating environment for pharmaceutical companies.

Cost effectiveness analysis, properly applied, may justify broader access to drugs for consumers and higher prices to companies under the PBS. Delays may also be reduced and transparency improved through streamlined processes.

Modified organisational arrangements could ensure a more rational allocation of responsibilities between the PBAC and the pricing authority, especially for cost effectiveness analysis, and clearer guidelines for the pricing authority in setting prices might ensure that cost containment objectives are not given undue weighting over other health and industry goals. Such guidelines would also give greater certainty to the industry.

Example of formalised weightings of pricing factors: overseas prices

In formalising the weightings applied to different pricing factors it may be appropriate to explicitly focus on overseas prices. This would represent an administrative change to the way prices are negotiated, as well as a policy change involving modifying the use of market power in some circumstances. Box 13.1 illustrates how greater weight might be placed on overseas prices.

Box 13.1: Example of a single pricing criterion—European prices

Features of such an approach could include:

- at the time of the initial listing, if a drug is found to be cost effective at the EU price for all its registered indications, it could be listed at the EU price;
- price increases could apply to new category 1 and 2 drugs only on a product by product basis; and^a
- after an initial period, price reviews could be undertaken based on a wider range of criteria.

Advantages:

- Companies could respond to market-based signals when making activity decisions.
- Benchmark and country of origin pricing problems would be addressed.
- This approach is relatively simple and could lead to reduced delays.

Disadvantages:

- Unlike a Factor f program, companies that do no activity in Australia would still receive higher prices. This would increase Australia's import bill for no apparent benefit.
- Defining Category 1 and 2 drugs may be difficult.

^a discussed in Chapter 8, drugs may be divided into four categories. Category 1 drugs are unique, breakthrough drugs with no real comparator. Category 2 drugs are the first in a new therapeutic class. While they may not show any large efficacy improvements compared to other treatments, they have significant advantages in terms of side effect profiles and quality of life benefits.

It would be inappropriate to increase the prices of all drugs currently on the PBS to levels in other developed countries. The budgetary costs would be very large, while few company decisions are likely to be affected by increasing the prices of old drugs. However, giving greater weight to overseas prices for some new,

important drugs would improve the operating environment for companies as well as possibly ensuring faster and broader access to drugs for consumers.

At one extreme, European Union (EU) price could become the sole criterion for determining the listing price of Category 1 and 2 drugs. Cost effectiveness could continue to play a role in determining the extent of Government subsidy. By negotiating prices similar to those found in the EU, benchmark and country of origin pricing issues would be addressed. As ‘me too’ and generic copies gradually enter the market, competition would be expected to reduce these prices.

13.2.2 PBS policy reform

PBS process reform, while a worthy goal in itself, is unlikely to address the full range of problems facing consumers, taxpayers and the industry.

As discussed in Chapter 8, the Government’s response to the rising cost of new drugs and increasing PBS expenditures appears to have been a series of rationing mechanisms. These may not have always been in either the industry’s or consumers’ best interests. Delays while prices are negotiated, which can sometimes last for years, are another cost of an apparent imbalance between the interests of the stakeholders.

As discussed in Chapter 8, there are three major themes justifying intervention in the PBS.

First, there are numerous pressures placed on the PBS. Most importantly, companies appear to be less willing to negotiate on price than in the past, due to country of origin and benchmark pricing concerns. While demand continues to rise exponentially, the Government has tried numerous *ad hoc* methods to contain costs, such as economic authorities and limiting the indications for which drugs are listed (see Chapter 4). This in turn has created further uncertainty in the industry, and reduced or delayed access to drugs for consumers.

There may be increasing pressure on the Government to provide access to drugs that is commensurate with that provided by governments overseas. Consumers may be able to bring pressure to bear on the Government to provide such access, even at higher prices than Australia has been accustomed to paying. There are also changes in the way in which healthcare is provided internationally, which may be capable of delivering equivalent (or better) health outcomes at lower cost. A review of PBS policy would represent an opportunity to examine these alternative models of healthcare provision.

Second, there are the concerns expressed by companies about the PBS. Some companies have a perception of Australia as hostile and uncooperative because of its pharmaceutical-related policies. A number of participants suggested a number of PBS policy issues for review in addition to process issues—for example, the PBAC suggested that:

... if there is to be a review we would like to see it look at broader issues and to properly involve the committee and other interested people.

Some more difficult situations that we would like to see advice and thought about are, for example the subsidy of drugs for relatively minor medical conditions, how to make value for money judgments, and the issue of how many ‘me too’ drugs in particular classes, for example, might be subsidised under the scheme (transcript, p. 636).

Third, COAG has identified health care as an area in which greater integration and cooperation is required. It would seem appropriate to examine PBS policy together with other health programs to ensure individual needs are met at lowest costs to the community. This would involve not only a focus on the quality use of medicines, but the better use of all other health care services. This may involve greater use of patient and prescriber data generated by Medicare and the PBS.

If reform of the PBS is not undertaken, it is likely that it will continue to have a negative impact on the pharmaceutical industry. While prices appear to be increasing for newer drugs, the trend towards listings for narrow sets of indications, increased listing delays and the mechanisms such as the authority system are likely to suppress revenues and send negative messages about the desirability of Australia as an investment location. Such revenue constraints are likely to affect the growth of Australian based companies in particular, at least in the short run.

If the normal rate of growth of the industry were to be threatened, its potential role as a partner in achieving health objectives would also be under threat. Pharmaceutical companies have a good deal to offer to promote the quality use of medicines.

For these reasons, there is a need for a close and careful examination of the PBS, to determine whether the scheme is still able to strike a balance that best serves the Australian community.

For example, at present the only compromise between a full subsidy (minus standard copayments, or sometimes a brand premium for some out of patent drugs) and no subsidy at all is the extremely limited Special Patient Contribution system (see Chapter 4). In all other cases, where companies and the

Government cannot agree on a price, access is denied to the community except at the full price as a private prescription.

In Chapter 8, the Commission suggested extending the Special Patient Contribution arrangements so that the Government paid up to what it considered to be the cost effective price, while consumers had the choice of paying the difference between the subsidised and market prices if they considered it worthwhile. In these circumstances, consumers would receive some subsidy. This would provide consumers with greater choice and access where listed indications are currently limited though an ‘all or nothing’ approach. Similarly, companies would be able to earn larger revenues under such a system, providing they can convince consumers and prescribers that their drug is worth the extra out of pocket expense.

It appears to be time to re-examine other elements of PBS policy, such as which drugs and which consumers should qualify for the subsidy, the price signals it sends to consumers and companies, the way it deals with the increasing demand for and cost of new drugs (see Chapter 9).

The terms of reference of the Inquiry do not allow the Commission to make recommendations on the PBS. However, the Commission feels obliged to draw attention to need to go beyond process reform and to review formally the social and economic policy underpinnings of the PBS itself. This is necessary in order to strike a better balance between the interests of taxpayers, consumers and the industry.

The Commission draws attention to the fact that it is necessary for the Government to undertake a review of PBS policy in order to strike a better balance between the interests of taxpayers, consumers and the industry.

13.2.3 Timing

Reviewing and reforming PBS processes could be done relatively quickly. As noted in Chapter 9, there is overwhelming support for such reform.

The Commission recognises that the review and reform of PBS policy is a major task. Such reform would require consultation with consumers, health professionals, the industry and other arms of Government. These groups have divergent interests that have to be addressed. It is unlikely that such important reform can be achieved quickly.

However, if the Government were to make a strong commitment to policy reform, significant change could be made within two years, that is, before the end of the current Factor f scheme.

The Government's intention to undertake such reviews should be announced as soon as possible. This would provide certainty for both companies and the broader community.

13.3 Financial intervention: the continuation of Factor f?

It was concluded in Chapter 12 that the rationale for financial intervention to support the viability of the pharmaceutical industry is not strong.

First, the continuation of Factor f would only deal with the problems facing one of the relevant stakeholders: the industry. It would not deal with the broader problems of rapidly rising costs to taxpayers and the resultant reduced availability of drugs to consumers. Since these problems are likely to grow worse, action to resolve them is required now.

Moreover, the continuation of a Factor f type scheme would fail to address adequately the problems facing the industry. Such a scheme would always be viewed as a 'stop-gap' measure: a panacea rather than a cure. As Pfizer stated:

Whilst Factor f as a part of the current development plan has provided a short term stimulus to the industry, it is clearly little more than a palliative that does not satisfy the broad economic requirements of either Australia or the pharmaceutical industry. Indeed, there are many features of Factor f which actually cause it to be a burden on the positive environment development of Australia, ie potential export markets do not recognise the subsidies provided by Factor f and instead look at a list price. Pfizer believes that a market based pricing system will be in the best interests of optimal healthcare and is essential for future development of the pharmaceutical industry (sub. 79, p. 5).

For as long as a Factor f type scheme is in operation, companies will have doubts about its continuation, while the rest of the community cannot be assured that they are receiving value for money. Since no scheme can be designed that would be guaranteed to give a positive return to the community, such schemes will always be under threat.

Second, the Factor f scheme was designed to improve the viability of the industry in relation to only one impediment: low prices for products. It does not directly address the other impediments to industry development, listing delays and volume restrictions. The Commission considers that, while there is a trend for prices to improve, these other problems are growing proportionally larger.

Therefore, the Commission's preferred approach is not to implement another 'stop gap' scheme designed to maintain some industry capability while other underlying problems continue to worsen. As described in Chapter 12, the Commission considers that the only approach that is likely to address the full range of problems facing all stakeholders in a lasting way is fundamental reform of the PBS and its processes.

Significant progress in improving PBS processes would require as a minimum that the pricing authority, operating independently, would place appropriate weighting on the range of pricing factors. These would include prices in overseas markets and the real value of drugs to the community as reflected in the proper application of cost effectiveness analysis principles. If progress can be made in these areas there would be no need for another Factor f type scheme.

If the Government decides that reform of PBS processes is either not a current priority or likely to take considerable time to implement, it could choose to introduce a Factor f type scheme as an interim measure.

The Commission has designed a new scheme that avoids many of the design problems inherent in the current scheme that were described in Chapter 11. The benefits of this revised scheme are more likely to exceed the costs than in the current scheme. This is described in the following Section.

13.3.1 Structural issues

A revised scheme, with improved structural features, could be implemented immediately for non-participants in the current Factor f scheme.

The main features of the Commission's revised Factor f scheme are described in Box 13.2. A brief explanation of these features is contained below, and a more detailed discussion is contained in Appendix N.

Such a scheme should not be implemented as a substitute for broad reform of the PBS, nor should it be used as an excuse to postpone PBS reform.

Products eligible for price increases

Only patented products, innovative versions of old drugs and non-patentable new drugs should be eligible for price increases. The prices of these products are likely to have the greatest impact on company perceptions. The prices of other out of patent drugs are not shown to be suppressed by the PBS, given the fact that companies are permitted to apply a brand premium. The fact that average brand premia are low denotes competition rather than a misuse of monopsony power by the Government.

Automatic entry

Companies should not have to compete against each other to enter the scheme. This raises the potential to generate distortions among companies and creates scope for inflated bids for funding that are not achievable in reality. As discussed in Chapter 11, both of these elements are apparent in the current scheme. The current scheme was also marred by a selection process that was unclear, and since its rules changed throughout the process, unfair. Automatic, rather than competitive, entry reduces the scope for maladministration.

Box 13.2: Revised Factor f scheme

The main design features of the Commission's revised Factor f scheme are:

- Price increases apply to all patented products plus non-patented innovative products.
- The scheme is open to all companies.
- Payments are transformed into price increases. Price increases are limited by EU prices. Companies have the choice of taking a notional or actual price increase.
- Eligible activities are value added production and research and development.
- The same payment rate applies to all eligible activities (lower than the current rate of 25 per cent, say, 15 per cent).
- An administrative threshold applies to limit the number of claims received by the administrators. This threshold is a minimum amount of payment due to the company in a given time period.
- Only incremental activity is paid for.
- Incremental activity is measured against a three year moving average.
- The scheme should be reviewed after five years of operation to assess its effectiveness and efficiency.

Advantages:

- Price increases are only granted to companies undertaking additional activity in Australia. Prices of imports are not increased.
- To the extent that actual prices are used, they would help resolve country of origin and benchmark pricing issues.

Disadvantages:

- It is only a temporary solution.
It focuses on activity rather than impediments to activity, including availability and delay issues.
- It is unlikely to recreate the levels, types and patterns of activity that would exist in a deregulated pricing environment.

Price increases

Price increases should be limited to average EU prices, as in the current scheme.

Companies should also be given the choice of taking their price increases as an actual or a notional price. The Government should ensure that price increases do not translate into higher wholesalers' and pharmacists' margins. Actual prices would deal with country of origin and benchmark pricing issues more adequately than notional prices. However, they may create difficulties in the marketplace where competitor products have lower prices.

Eligible activities

As in the current scheme, eligible activities should be R&D and value added production. Although some participants suggested that health promotion activity should be included, there is little evidence that low prices are impeding such activity now, and that institutional changes are required before companies will be able to achieve their full potential in this regard. Such activity is best encouraged by bodies such as the Australian Pharmaceutical Advisory Committee and the Pharmaceutical Health and Rational Use of Medicines Sub-Committee.

Base year arrangements

Given the Commission's comments on the current base year arrangements (see Chapter 11), incremental activity should be judged on increases over a three year moving average. This would ensure that all participants are treated in the same manner, and that payments would not be too generous.

Payment rates

Payment rates should be lower than the maximum 25 per cent of the current scheme. The Commission suggests that a rate of, say, 15 per cent would be more appropriate.

The same payment rate should apply to both R&D and value added production.

Quantitative criteria

The current quantitative criteria should be replaced by a simple administrative threshold on eligible activity, to avoid processing small claims and to ensure that companies have made a reasonable commitment.

There should be no criteria requiring companies to undertake *both* R&D and value added production.

Review

As for the current scheme, any new scheme should be reviewed after five years to assess its effectiveness and efficiency.

13.3.4 Estimated costs

The Commission has undertaken some preliminary costings for a Factor f scheme with the design characteristics outlined above. The Commission estimates that the most likely cost to the Government of such a scheme would be around \$235 million over five years and around \$700 million over 10 years. These figures rely upon a number of assumptions:

- current non-participants are permitted to accrue eligibility for payments from 1996, to be paid in 1999;
- six ‘average’ sized companies enter the scheme¹ in addition to the current 11 Phase II participants;
- companies grow at 75 per cent of their current growth rates;² and
- a 15 per cent payment rate is used.

Upper and lower estimates, based on different assumptions, are contained in Appendix N.

13.4 Conclusions

Throughout this Inquiry, the Commission has been aware that the Factor f scheme has supported the industry at a time when the PBS is likely to have

¹ ‘Average’ sized companies were assumed to be the simple average of the size of current participants in Phase II of Factor f. Since there are 11 current participants, the size of an average participant is assumed to be one eleventh of the total size of the current participants.

² Growth rates for domestic value added were calculated from data provided by the APMA (sub. 119, Appendix 1, p. 3). Growth rates for export value added were calculated from data on external trade in the APMA survey (APMA 1995a, p. 7). Growth rates for R&D were calculated on R&D/Turnover ratios provided by the APMA (sub. 119, Appendix 1, p. 3). It was assumed that new participants to the scheme grew at non-Factor f rates up to the year where they entered the new scheme, and then grew at Factor f rates. A lower growth rate than the current rate was used since some large companies are unlikely to be able to continue to grow at their current rates and because payment rates are lower, offering a smaller incentive to undertake activity.

represented an impediment to its normal growth and development. However, Factor f has been a ‘band aid’ and the Commission believes that the best policy is to attack the underlying problems. Not only is the PBS likely to pose ongoing problems for the industry, but there are signs that the PBS is not serving the interests of consumers as well as it once did.

Fundamental reform of the PBS is required to inspire lasting confidence in Australia as a desirable location for long term investments. The continuation of a Factor f approach may not achieve this end. The Australian Pharmaceutical Manufacturers Association survey provided evidence that the impact of the current scheme on company perceptions declined markedly once all funds were allocated (APMA 1995a, p. 21).

Furthermore, a new Factor f scheme would tackle only part of the problems facing the industry. It may encourage activity in the short term, but there is no guarantee that this activity would last much beyond the period of the subsidy. Reforming the PBS is the most efficient way of removing the impediments to industry development.

More importantly, it is likely that another Factor f type scheme may even act as an impediment to further reform. For the decade that the scheme has been in place, there have been few major changes to the way in which the balance between the interests of taxpayers, consumers and the industry has been addressed. The current Factor f scheme also may have reduced the pressure on Government to deal with the emerging problems of the PBS.

The Commission concludes that without fundamental reform of the PBS, it is likely to continue to have a negative influence on the growth of the industry. Furthermore, in the absence of change, the interests of consumers, taxpayers and the industry are unlikely to be balanced as well as might be possible.

14 REGULATORY ISSUES-DRUG APPROVAL

In Chapter 3, the rationale for government control of the safety, efficacy and quality of pharmaceuticals was discussed and Australia's complex regulatory arrangements described. This Chapter takes up the major issues identified by participants in relation to the drug approval regulatory regime. General issues of interest to all participants such as the role and structure of the Therapeutic Goods Administration, and the integration of Australia's regulatory regime with overseas arrangements are addressed.

14.1 Introduction

As discussed in Chapter 3, the development, production and sale of therapeutic products are subject to a high level of government regulation. The Baume Review (Baume 1991) addressed one important area of this regulation—the pre-market approval of new pharmaceutical products by the Therapeutic Goods Administration (TGA).

However, pre-market approval is only one aspect of the regulatory process and a number of general issues remain to be resolved before Australia achieves a unified and internationally competitive regulatory system. Ongoing concerns include appropriate institutional arrangements for the national regulation of pharmaceuticals and integration of Australia's drug approval processes with the rest of the world.

14.2 Performance of the Therapeutic Goods Administration

The Commission received considerable evidence that the implementation of the major recommendations of the Baume Review has led to improvements in the timeliness of pre-market evaluation of pharmaceuticals. In addition, participants commented favourably on the transparency of the TGA administrative processes and improvements in their working relationship with that agency.

For example, Glaxo Wellcome, reflecting a widely held view of the industry, commented that:

... the drug approval system ... has been significantly improved since the Baume Review. This improvement has assisted the timely availability of medicines in Australia. and is a credit to those associated with the reform of the system (sub. 143, p. 2).

In its submission to the Inquiry the TGA stated:

All of the Baume recommendations have been effectively put in place and all of the targets have been generally met.

The backlog of drug applications has been eliminated, the new target times are being achieved, and a productive and co-operative working relationship has been achieved with industry (sub. 16, p. 6).

Notwithstanding recognition of improvements in drug evaluation, some participants suggested that some difficulties remain. Schering-Plough, for example, commented that there are still a number of data requirement and administrative obstacles to be removed. It listed these as an inability to supplement data, -a continuing requirement for individual animal data, the need for prior approval of product information modifications and an embargo on contacting the Australian Drug Evaluation Committee (ADEC) Secretariat after its meetings. Moreover, drawing on some recent experiences, Schering-Plough commented that 'there is a tendency for the TGA to evaluate applications academically and conservatively' (sub. 49, p. 9). It also expressed concern that the TGA appears to be 'hostile' to the industry when compared with the MCA' [UK Medicines Control Agency] and stated:

While the MCA is demanding in its requirements, it tends to go for the big scientific/clinical issues; whereas the TGA is often seen to be focusing on 'trivial' issues such as issues of academic interest (sub. 146, p. 2).

The Proprietary Medicines Association of Australia (PMAA) noted a lack of consistency in the information requirements for some non-prescription medicines and in the resultant labelling and information provided to the consumer. It considered this arose from the current division of responsibility for over the counter (OTC) products between the Compliance Branch and Drug Safety and Evaluation Branch of the TGA (sub. 120., p. 7). Schering-Plough had similar concerns (sub. 128, p. 5).

The Nutritional Foods Association of Australia drew attention to a number of regulatory impediments in relation to products, such as food supplements, 'which are deemed to be safe and in many cases are freely available in other countries' (sub. 108, pp. 16-17).

The PMAA noted that 'an area where there has been some progress, but not enough, relates to TGA's consultation with industry' (sub. 120, p. 2).

The Commission is not in a position to judge whether these concerns detract significantly from the improved performance of the TGA. However, it is important that such concerns are addressed in the pursuit of continuous improvement by the TGA.

14.3 General issues in drug approval

In addition to the performance of the TGA, participants commented on ongoing general regulatory issues:

- the lack of a nationally uniform legislative framework,
- the need to retain a local capability for independent evaluations;
- the potential for further integration of Australia's regulatory system with overseas arrangements;
- benchmarking of TGA performance;
- TGA independence; and
- regulation of exports.

These issues are discussed in the following Sections.

14.3.1 A nationally uniform legislative framework

As discussed in Chapter 3, the regulation of therapeutic goods is shared between the Commonwealth and State¹ Governments. The *Therapeutic Goods Act (Cwth)* 1989² does not attempt to 'cover the field' in a constitutional sense, but rather, preserves the underlying State laws. It relies on the Commonwealth Government's constitutional powers over corporations, interstate or international trade or commerce, pharmaceutical and repatriation benefits and the Commonwealth or authorities of the Commonwealth.

Consequently, the Act does not apply to unincorporated entities which operate within a single State. In practical effect the Act does not extend to the point-of-sale availability of pharmaceutical products, which is separately and independently, regulated by scheduling arrangements under State drugs and

¹ State refers to State and Territory.

² Hereafter referred to as 'the Act'.

poisons legislation, and State regulation specific to pharmacy and other health professions.

The Act was intended to lay the foundation for a nationally uniform system of regulation. In introducing amendments to the Act in 1993, the Parliamentary Secretary to the Minister for Health explained the arrangements as follows:

Uniform regulation over the quality, efficacy and safety of therapeutic goods manufactured for supply and use in Australia cannot be achieved without the establishment of corresponding State and Territory laws that will adopt the Commonwealth's regulatory requirements in respect of appropriate standards including manufacturing and advertising standards, for therapeutic goods. The States and Territories have agreed to set up complementary legislation to complement the *Therapeutic Goods Act 1989*. It is anticipated that State complementary legislation will be in place as early as 1994. When this occurs, the amendments to the principal Act dealing with complementary legislation will be activated by proclamation (sub. 71, p. 54).

Notwithstanding this expectation, as of 1996, only Victoria had enacted complementary legislation (the *Therapeutic Goods (Victoria) Act 1994*). The Victorian statute mirrors the Commonwealth legislation, but it requires specific amendment to implement each change to the Commonwealth legislation.

The Australian Pharmaceutical Manufacturers of Australia (APMA) agreed with the Draft Report recommendation that all States pass complementary legislation, and suggested a deadline of July 1997 (sub. 119, p. 4).

The National Co-ordinating Committee on Therapeutic Goods (NCCTG) is presently developing proposals for model State legislation to complement the Act. In the meantime other States have proposed to adopt the Act and its future amendments using a number of different legislative mechanisms. New South Wales has proposed a model that will adopt the Commonwealth legislation by reference. The Department of Human Services and Health (DHS), now the Department of Health and Family Services (DHFS), favoured this proposal, arguing that it avoids the possibility of delays in adopting future amendments to the Commonwealth Act (sub. 153, p. 24).

The Commission has not received evidence that failure by the States to implement complementary legislation has had a major impact on most large manufacturers and suppliers. Nonetheless, the Commission considers that all States should introduce complementary legislation to the *Therapeutic Goods Act 1989*. This would accomplish the original intent of governments to provide for co-operative, national, uniform regulation of therapeutic goods.

The proposed New South Wales approach of adoption by reference provides the simplest and most efficient means of achieving this end.

Recommendation 14.1

The Commission recommends that all States and Territories pass complementary legislation to broaden the application of the *Therapeutic Goods Act 1989* by adopting its provisions and future amendments by reference.

14.3.2 Retention of capability for independent evaluation

The TGA's drug evaluations are conducted, to a large extent independently of similar evaluations undertaken elsewhere in the world. A threshold question is whether it is in Australia's interest to undertake independent evaluations of drugs seeking marketing approval.

Independent evaluation has a number of costs. In addition to the administrative costs of maintaining a drug evaluation system, costs are imposed on consumers through any 'incorrect' exclusions of drugs from the market and delayed access to drugs which are ultimately approved for marketing.

An alternative approach would be for the TGA to approve for marketing in Australia any drug approved for marketing in one, or more, of a list of designated overseas countries with comparable regulatory standards. Singapore evaluates drugs in this way. A similar approach is adopted in New Zealand, where drugs may be approved for marketing following a brief assessment of approvals by overseas regulators regarded as having adequate standards and expertise.

However, Australia has resisted the automatic recognition of overseas agency approval decisions. For example, the Baume Review rejected a 1986 Industries Assistance Commission (IAC) recommendation that provisional approval to market in Australia be given to products approved elsewhere in the world. Baume argued that there was merit in Australia making its own decisions-that 'the Australian public is entitled to a sovereign evaluation and decision making process which takes proper account of Australian interests', and noted that 'those interests are not always the same as the interests of other countries' (Baume 1991, p. 16).

Arguments advanced for an independent Australian drug evaluation and registration capability, include:

- the existence of unique Australian interests reflecting Australian attitudes to risk,

-
- demand from the Australian community for more rigorous regulation than that provided by overseas regulators; and
 - the need to maintain Australian sovereignty.

Unique Australian interests

It has been argued that the Australian community has unique interests in the control of the safety and efficacy of pharmaceuticals. However, it is not apparent what these peculiarly Australian interests are, and why Australia's interests differ from those of comparable countries.

It may be that Australian attitudes towards the acceptability of levels and types of risks differ from those held in other countries. However, little research has been undertaken into Australian community attitudes towards pharmaceutical risks and the acceptable trade-offs between risk and benefit to justify a unique Australian level of regulatory rigour. The Australian community may, in fact be prepared to accept a higher level of risk in return for the benefit of greater access to new treatments.

Greater rigour

It has been claimed in the past that the Australian evaluation process was of a higher quality than that of overseas countries. Noting that Australia had avoided 'calamities' associated with unsafe pharmaceuticals, a Public Service Board Review in 1987 attributed this in part to the 'very rigorous examination to which new drugs are submitted by the [then] Department of Health evaluation and the Australian Drug Evaluation Committee, and the excellence of the judgements made'. However, the review also noted that, in part, calamities were avoided due to delays in the Australian evaluation process which gave time for serious problems to emerge in markets overseas (PSB 1987, p. 42).

On the face of it, it is difficult to see why Australia, with regulatory resources a fraction of those available in the US, should provide greater protection for Australian consumers than the Food and Drug Administration (FDA) provides to American consumers.

There was little evidence presented to this Inquiry that the TGA is more effective than major overseas regulatory agencies in preventing drugs with an unacceptable level of risk reaching the market.

Sovereignty

Some participants suggested that it is important that Australia retains the power to decide which drugs are approved for marketing in Australia. A number of arguments have been put forward in support of this position.

First, the TGA stated that public safety is a consideration:

We believe there is still a role for sovereignty in the drug approval process ...

... we believe that it's in the interests of public safety that we make use of overseas reports and still have an approval process for Australia (transcript, p. 839).

Second, it was argued that the community expects a local drug evaluation capability. For example, the Consumers' Health Forum (CHF) agreed with the Draft Report finding that the capability to undertake drug evaluations locally through the TGA should be retained (sub. 120, para. 2.2.3).

Third, a drug evaluation capability is seen as a necessary part of the industry's infrastructure. Having a local capability allows rapid evaluation of Australian developed products. Participants particularly commented on the importance of an internationally respected regulatory authority for Australia's export prospects. For example, CSI suggested:

One of the aspects of the Australian operating environment from CSL's viewpoint, is the high regard with which Australian drug evaluation and general marketing approval decisions are held 'in Europe, North America and Asia. This enhances the ability of Australian registered products to be marketed in these regions (sub. 39, p. 8).

Eli Lilly argued that in the international context:

The maintenance of an effective drug evaluation and approvals capability will become increasingly important for Australia. It will affect Australia's ability to play a significant role in the provision of improved and cost effective health care in the Asia Pacific region. Accordingly [Eli Lilly] would be concerned if mutual recognition of drug approvals resulted in any, downgrading of Australia's capabilities in this area (sub. 142, p. 18).

Similarly, Pfizer encouraged the TGA to seek to become a lead regulator in the Asia Pacific region and believed this would particularly help in promoting Australia as an export source (sub. 133, p. 17).

The Commission considers it important that Australian Governments maintain the ability to respond to the community interest, for example by prohibiting the sale of particular drugs for social or ethical reasons, regardless of the drugs' scientific merits. However, retention of this sovereign power does not in itself justify a full independent drug evaluation capability.

The Commission considers that a local drug evaluation capability is part of the infrastructure expected by both drug companies and consumers. As long as the TGA continues to provide a competent and cost effective service to industry and consumers, the capability to undertake drug evaluations locally should be retained.

FINDING

The Commission finds that the capability to undertake drug evaluations locally through the Therapeutic Good Administration should be retained.

14.3.3 Integration with overseas arrangements

Given that local evaluation is retained, the challenge is to improve the TGA's responsiveness to trends in international pharmaceutical regulation, and more closely integrate Australian regulatory processes into the international system.

Most drugs for which local marketing approval is sought have either been assessed earlier or are undergoing evaluation in one or more developed countries with procedures and standards similar to those in Australia.

Scope for integrating Australian regulatory processes with those adopted internationally has been pointed to in several previous reviews such as the IAC (1986a), Public Service Board (PSB 1987), the Business Regulation Review Unit (BRRU 1989) and Baume (1991).

The broad policy alternatives to achieve integration are either to harmonise with the regulatory standards of comparable overseas countries, or to recognise the regulatory decisions of countries with comparable regulatory policies and processes. Box 14.1 outlines the features of harmonisation and mutual recognition policies.

Harmonisation

In implementing the Baume recommendations, Australia has pursued harmonisation of international standards. In addition, it has adopted European Union (EU) data requirements for registration applications.. As a matter of policy, Australia no longer develops its own standards for therapeutic goods, except for uniquely Australian products, in response to unique Australian conditions or for a demonstrated public health need.

The TGA undertakes a number of activities aimed at international harmonisation of regulatory controls and the development of international standards to allow the use of information developed overseas. For example, it is

involved with the International Conference on Harmonisation (ICH) (sub. 16, p. 23).

Box 14.1: Harmonisation and mutual recognition

- Harmonisation and mutual recognition both have the effect of eliminating regulatory barriers to trade. Regulatory co-operation may take the following forms:
- harmonisation between jurisdictions' regulations-a formal or informal process whereby the regulations of two or more jurisdictions become more alike;
- harmonisation to international standards-a formal or informal process where the regulations of a group of countries become more aligned with international standards;
- movement towards uniform regulations between a number of jurisdictions;
- unilateral recognition of regulations-where one jurisdiction unilaterally accepts goods which comply with the regulations of another jurisdiction;
- mutual recognition of regulations-where two or more jurisdictions agree to accept goods which comply with the regulations of any one of them;
- mutual or unilateral recognition of. conformance assessment-for example the acceptance of foreign compliance testing of Australia's regulations in relation to goods imported by Australia, and *vice versa*; and
- mutual or unilateral recognition of international standards.

Participants such as Glaxo Wellcome noted this progress:

The harmonisation of Australian drug registration requirements with European requirements has substantially reduced the need for time consuming and unnecessary additional activity in compiling a registration package for the Australian authorities (sub. 143, p. 2).

Other participants identified scope for further harmonisation. For example, the APMA noted 'it is important that these achievements should not be undermined by excessively stringent application of British Pharmacopoeia monographs' (sub. 3 1, p. 23).

The PMAA stated that the appropriate standard should be 'that which is most applicable to Australian conditions' (sub. 120, p. 4).

Sigma had difficulties with Australian insistence on British Pharmacopoeia (BP) standards in some circumstances and US Pharmacopoeia (USP) standards in others:

... a product in which Sigma Pharmaceuticals is interested is manufactured by the overseas suppliers to USP standards and marketed in the US and other countries for some time. TGA are insisting on the BP standard which includes tests not in the USP, and represents a tighter standard. This results 'm the product as produced not always being acceptable in Australia although acceptable by the FDA, in turn resulting 'm disruption to supply and additional costs for no demonstrable value.

Conversely, another product is in the position where the USP standard is demanded although it is marketed throughout Europe to the [European Pharmacopoeia] standard. In this case [although] the USP standard is tighter, the commercial consequences are identical to the previous example (sub. 19, p. 10).

The TGA argued that BP monographs are explicitly adopted under the Act and therefore must be administered as part of the law. The Act also allows for exemptions to be made and the TGA noted that such exemptions were often granted, particularly for imported products where the country of origin uses the USP (transcript, pp. 846-847).

The Commission considers that, in some cases the TGA appears to harmonise with the overseas standard regarded as stricter, or tighter, without taking the costs to companies or consumers into account. This is not necessarily the most efficient approach, as it may impose the greater costs of meeting the highest standard chosen, with little return to consumers in terms of significantly reduced risk. The TGA should continue to pursue international harmonisation of Australian data requirements and standards, with the emphasis on simplifying compliance by suppliers and adopting standards that provide a level of protection for consumers comparable to that provided to overseas consumers, but not necessarily the strictest standards applied overseas.

FINDING

The Commission finds that there are benefits for Australia in participating in international harmonisation of standards and data requirements as a means of strengthening links with overseas regulators.

Exchanging information and evaluation reports

The Australian drug evaluation process could be further integrated into the international system through increased Cupertino with the regulatory agencies of comparable developed countries by exchanging information and evaluation reports.

The TGA has in place a memorandum of understanding with Sweden and an agreement with Canada to access overseas evaluations, with the permission of sponsor companies. They may also participate in a combined evaluation process, with each regulator undertaking part of the evaluation, and sharing the resulting reports. In both cases the TGA still undertakes its own assessment based on the evaluation.

The TGA is endeavouring to use its membership of the Pharmaceutical Evaluation Reporting scheme to obtain evaluation reports from other member countries and provide Australian reports when requested (sub. 16, p. 23). However, the DHSH noted that 'there is still considerable progress to be made in securing the Cupertino of counterpart agencies in releasing reports' (sub. 153, p. 23). Of greatest concern has been the FDA, where possible compromise of commercial confidentiality as a result of the Australian *Freedom of Information Act* 1982 has been a 'major limiting factor'. It is seeking amendments to the legislation to give the FDA and other bodies greater assurance that commercial confidentiality will not be compromised (sub. 153, p. 23).

In addition, the creation of the European Medicines Evaluation Agency (EMA) has restricted access to European reports (only an EMA summary will be available). The DHSH stated that TGA will be exploring the possibility of a special relationship with EMA to overcome this' (sub. 153, p. 23).

However, direct use of overseas evaluation reports represents a small proportion of total evaluation work undertaken by the TGA. Consequently, the TGA's evaluation process remains uncoupled from the major world pharmaceutical evaluation programs conducted in Europe and the US.

For one reason or another we have not asked applicant companies what is the availability of supporting material. Some companies have supplied it in the past but that's relatively rare ... What we are going to develop and we are working on at the present time is a protocol in the application where the company can say to us, The following reports are available in external agencies and we give you permission to make access to them.' That will help the regulatory process (transcript, p. 841), .

Some pharmaceutical companies have criticised the way the TGA uses overseas evaluations. Schering-Plough and Pfizer noted the theoretical Cupertino of regulatory approval 'in very specific areas' but observed that the TGA had taken longer than overseas regulators to make evaluations, and had reached different decisions to overseas regulators based on the same evaluation reports.

Schering-Plough said:

We have experimented with that system and have actually come out behind Sweden and Canada in the regulatory process. In time we have also come out with a different registration conclusion to Sweden and Canada on the same drug (roundtable, p. 44).

Upjohn had a similar experience:

In a Joint evaluation process specifically agreed to by the company internationally, the Australian authorities have come out with the opposite conclusion to the Swedish authorities on exactly the same technical report (roundtable. p. 44).

However, the TGA responded that these examples illustrated why it is important that Australia conduct its own evaluations. It believes that its decisions in these cases were correct, and the overseas regulators were wrong:

The TGA's view [is] that the idea of having a uniform worldwide-at least in developed countries-attitude to approval of drugs is just too simplistic (transcript, p. 849).

The Commission considers that closer integration will allow the TGA to take advantage of the work of other regulatory agencies to improve its own efficiency. In particular, increased use of overseas evaluation reports could be a positive development, so long as the TGA uses these reports to avoid repeating evaluations already undertaken by overseas agencies, rather than as a means of placing unnecessary further demands on companies.

FINDING

The Commission finds that potential exists for Australia to pursue further agreements to exchange evaluations, particularly with the European Medicines Evaluation Authority and the US Food and Drug Administration.

Mutual recognition

The TGA stated that integration into the world regulatory system should stop short of automatic recognition of overseas approvals:

...related to mutual recognition, I would like to emphasise that we don't believe that it's appropriate to go down the approval path at this stage but look at the question of encouraging and making better use of overseas evaluation reports which can further streamline the evaluation process that has been identified within the department (transcript, p. 847).

However, other participants provided conditional support for the concept of mutual recognition of evaluation decisions. The DSHS supported mutual recognition arrangements 'providing they are based on standards which will afford appropriate protection to Australian consumers and to the international

reputation of the Australian pharmaceutical industry’ (sub. 153, p. 23). It stated that:

The Commonwealth is about to enter into a Mutual Recognition Agreement [MRA] with the European Union across a number of sectors including pharmaceuticals and medical devices. In the area of pharmaceuticals, the MRA will include recognition of GMP inspections of manufacturers and laboratory test results. In the case of medical devices the Agreement includes recognition of registration approvals (sub. 153, p. 24).

The CHF stressed that:

CHF acceptance of any moves toward mutual recognition ... would be dependent on ensuring that the recognised standards provided an appropriate level of consumer protection (sub. 139, p. 3).

The Commission considers that recognition of overseas evaluations has the following benefits:

- reduction in agency staff requirements and external expert consultancies;
- freeing up of scarce labour resources, such as toxicologists, for other activities (for example, research and development (R&D));
- faster processing of items unique to Australia (for example, Australian developments, new indication of existing drugs, processing of product information);
- new and/or advances in therapy are introduced into Australia earlier with added patient benefits and potential reductions to total health care costs; and
- increased market period before patent expiry resulting in a more viable industry.

If a group of disparate countries such as those in the EU can agree to a formula for mutual recognition, it is difficult to establish a case for Australian ‘uniqueness’. In the longer term the option of mutual recognition of evaluation decisions should be pursued.

Ultimate Australian sovereignty could still be retained by providing for exemptions from mutual recognition on public policy grounds, and by Australia maintaining an independent capacity to conduct evaluations where required by unique Australian conditions or where requested by suppliers.

The potential exists for the TGA to move to mutual recognition of overseas evaluations, by granting marketing approval in Australia if a drug has been approved for marketing by any one of a list of designated regulators and has not subsequently been precluded for clinical reasons by any of them. While not suggesting a definitive list of regulators, the Commission would envisage New

Zealand, the US, the UK, Canada, Sweden, Norway and the EMEA as appropriate.

FINDING

The Commission finds that potential exists for Australia, while reserving the option of conducting its own evaluations, to place greater weight on overseas evaluation decisions by regulators with comparable standards and known expertise, on a case by case basis.

The TGA as 'lead regulator'

Under mutual recognition arrangements it could be the case that most products are approved for the Australian market by the TGA accepting overseas evaluations. On the other hand, if the Australian approvals system is competitive, it could potentially become a 'lead regulator' for particular types of evaluations, or for the local geographic region.

For example, in the EU, broad mutual recognition arrangements between member states are leading to competition among regulatory agencies for evaluation business (see Box 14.2).

Box 14.2: European Union registration procedures

From 1995 onwards, three registration procedures for medicinal products have been available in the EU.

These consist of two EU procedures and existing national procedures.

A centralised procedure, leading to a single marketing authorisation, valid throughout the EU. Applications are submitted directly to the European Medicines Evaluation Agency (EMA), which contracts out the assessments to member states' regulatory authorities.

A decentralised procedure that is based upon the principle of mutual recognition of national authorisations. The procedure permits the extension of a marketing authorisation granted by one member state to one or more of the other member states. Should a national authorisation not be recognised by other member states, the dispute is submitted to EMA arbitration.

National procedures remain available to companies during a transition period until 1998, after which they may be used solely for nationally marketed products.

Source: EMA 1995, p. 2

The Commission notes that arrangements for mutual recognition of Australian evaluations may be difficult to negotiate.

The TGA considered overseas agencies may not accept TGA decisions:

I can't necessarily see other agencies being willing to accept Australian decisions in a mutual recognition agreement (transcript, p. 84 1).

Moreover, the APMA argued that if the TGA was not competitive in a climate of mutual recognition, Australia would be unable to maintain its expertise in pharmaceutical evaluation (sub. 119, p. 14).

If mutual recognition is adopted, over time the type and extent of evaluation work done in Australia will reflect the efficiency of the regulatory services provided. Recent improvements in the performance of the TGA suggest to the Commission that, provided it faces the right incentives and has the institutional flexibility to respond to market needs, it has prospects of succeeding in the face of competition.

Nevertheless, the Commission considers there is scope for further integrating Australia's drug evaluation regulatory regime with international evaluation activities, and potential for the TGA to compete as a lead regulator for particular types of evaluations or for the local geographic region.

FINDING

The Commission finds that there is potential for the Therapeutic Goods Administration to become a 'lead regulator' for particular types of evaluations or for the Asia Pacific region, provided its operations are more closely integrated with those of the world's major regulatory agencies.

Recommendation 14.2

The Commission recommends that Australia, through the Therapeutic Goods Administration:

- continues to pursue harmonisation of standards and data requirements;
- pursues further agreements to exchange evaluation reports and to undertake joint evaluations;
- while reserving the option of conducting its own evaluations, on a case by case basis places greater weight on overseas approvals by regulators with comparable standards and known expertise in a particular area; and
- in the longer term, pursues mutual recognition of drug approvals with countries with comparable regulatory standards while maintaining an independent capacity to conduct evaluations where required by unique Australian conditions or where requested by suppliers.

Trans-Tasman regulatory co-operation

In view of the importance of the New Zealand market to Australian suppliers, participants have raised the particular issue of trans-Tasman harmonisation and mutual recognition.

For example, the PMAA noted that its members have an extensive and growing trade with New Zealand, and:

Consistent with [Closer Economic Relationship] principles, we wish to see this trade grow and develop further. PMAA is more than willing to cooperate with the Australian and NZ authorities in seeking real progress in harmonisation of standards, the achievement of uniform regulations or a Mutual Recognition Agreement (sub. 71, p - 49).

The TGA has made some progress on developing co-operative arrangements with the New Zealand regulator, although these have been limited to negotiating harmonisation and mutual recognition of product standards, manufacturing standards, conformance assessment requirements and packaging and labelling requirements.

Mutual recognition of registration approvals is not yet contemplated. The TGA stated that the eventual goal should be 'mutual evaluation':

We will share evaluations and we will recognise New Zealand and New Zealand will recognise us. Alternatively we may have one regulatory authority as the outcome of these things, so that it will be an automatic regulation for Australia and New Zealand (transcript, p, 888).

The Council of Australian Governments (COAG) and the New Zealand Government are about to, enter into a Trans-Tasman Mutual Recognition Agreement to cover most traded goods, including pharmaceuticals. It is based on New Zealand becoming a party to the Australian mutual recognition arrangements. These provide for free trade in Australia of most products, notwithstanding differences in individual State regulatory requirements.

The agreement is titled 'mutual recognition'. However, for pharmaceuticals, it contemplates harmonisation of regulatory standards rather than mutual recognition of each country's evaluation decisions.

There appear to be three impediments to trans-Tasman mutual recognition of pharmaceuticals:

- differences between Australian and New Zealand legislation over pharmaceuticals-current New Zealand legislation does not cover medical devices, vitamins, herbal medicines, homeopathic medicines, traditional medicines and so on.,

-
- different standards-New Zealand uses both the USP and the BP as well as Australian standards, while Australia is more closely aligned with the BP with limited references to the USP; and
 - the use of overseas evaluation reports-New Zealand accepts overseas evaluation reports from a range of countries, while Australia is currently limited to sharing evaluation reports with Sweden and Canada.

Because of the wide variations between Australian and New Zealand technical requirements and drug evaluation procedures, therapeutic goods are to be given a temporary exemption from the Trans-Tasman. Mutual Recognition Agreement.

Under the terms of the temporary exemption, the parties will pursue a 'co-operative program' which aims to achieve accelerated harmonisation of each country's requirements. The co-operative program aims to identify differences in regulatory requirements and address them through either mutual recognition, harmonisation or permanent exemption.

If the outcome of this co-operative program is a recommendation that pharmaceuticals be permanently exempted from the Trans-Tasman Mutual Recognition Agreement the Commission suggests that the COAG conducts an analysis of the costs and benefits of such an exemption before making a final decision. The analysis should be commissioned by the Australian Health Ministers' Conference and be made publicly available.

Trans-Tasman harmonisation of packaging and labelling

Independent of the Trans-Tasman Mutual Recognition Agreement trans-Tasman harmonisation of packaging and labelling for drugs and poisons has been agreed to be implemented over five years from 1 July 1995.

However, harmonisation of labelling will not be straightforward. Australian regulations specify exact words, while New Zealand requirements are more flexible and allow for words of similar meaning or acronyms. New Zealand also wants to accept US and UK labels.

Even if labelling issues can be settled, harmonisation will be of only limited benefit if scheduling (classification) issues cannot be agreed. Classification issues are under discussion.

14.3.4 Benchmarking of TGA performance

In commenting on improved TGA performance, most participants have used the poor performance of the TGA's predecessor as the basis for comparison.

However, until recently, the Australian regulator has not compared its performance to that of overseas agencies.

The APMA suggested that:

Further improvements in Australian drug evaluation procedures could be achieved by the adoption of administrative aspects of drug evaluation in other comparable countries (sub. 119, p. 14).

However, the TGA has recently become involved in limited international benchmarking, for example by taking part in a Canadian comparison of generic drug review and approval processes (CDMAHC 1995).³ The TGA stated:

We have recently... participated in a Canadian survey which took up the question of benchmarking and it compared a number of agencies across the world, including Australia ... Australia was invited to participate in that program and so we will be able to get a benchmarking index from the findings of that Canadian study (transcript, p. 841-842).

The DSHS noted plans for more active benchmarking in the future:

The TGA will be taking up with key counterpart organisations the feasibility of undertaking comparisons of productivity, average elapsed times and other indicators with key counterpart organisations to assist in identifying scope for further improvement (sub. 153, p. 22).

However, the DSHS also noted difficulties associated with benchmarking the performance of regulators:

[International benchmarking] is not easy because agencies differ markedly in their procedures in drug evaluation and keep different sets of performance indicators. ...For example, whereas Australia makes a final decision following evaluation of a submission, the United States makes an initial decision and identifies the further information required before a final decision can be made. ... Thus there are effectively two decision points in the US compared to one in Australia. Such differences cause difficulty in drawing comparisons between the different systems and the interpretation of averages (sub. 153, p. 22).

Despite these reservations, the DSHS went on to state:

... benchmarking, even if only approximate, can provide useful insights into superior means of performing a wide range of functions (sub. 153, p. 22).

The TGA was concerned that benchmarking of processes may not take account of important qualitative factors. It stated:

...in the [Pharmaceutical Inquiry Draft Report] ... one gets the feeling that the best evaluation ... can be read as being the quickest-and I don't believe that that is necessarily the case. I think evaluation still does need a rigorous process and the quickest is not necessarily the best (transcript, p. 84 1).

³ This study benchmarked the costs charged to industry and review times for the generic review process in Australia, UK, US and Canada.

While acknowledging the difficulties, the Commission notes that other regulatory authorities are beginning to make comparisons of performance.

As well as the Canadian study referred to above, the US General Accounting Office (GAO) recently undertook a comparison of US and UK drug review times. While the GAO noted that analysis was difficult because the workload, approval criteria and review procedures of the two agencies differ, the most recent data showed that approval times were longer in the UK than in the US (*Scrip*, 17 November 1995, p. 17). This unexpected result demonstrated the ability of benchmarking to disprove popularly held beliefs about relative performance.

The Commission notes that particular performance measures, such as evaluation times, may not be strictly comparable because of different bases of measurement. However, the TGA publishes detailed reports on a range of performance measures. Reporting would be enhanced by comparing the more important performance measures (such as new chemical entity assessment times) to comparable results achieved by overseas agencies. The UK's MCA, for example, is reporting new chemical entity evaluation times which appear to be much shorter than those achieved in Australia (MCA 1995, p. 24). International benchmark monitoring of this type should encourage continuous improvement in TGA performance.

The Commission also notes that there is potential for benchmarking to do more than compare process parameters such as the time taken for evaluations. It can also be a valuable tool for assessing the efficiency of the processes themselves, in terms of outcomes achieved. In the case of the TGA, this could mean benchmarking outcomes such as the impact of its processes on the health of the community, both through the delays in approval of products with public health benefits and the incidence of approval of products subsequently found to be detrimental.

While the TGA has reduced its evaluation times through better management of its resources, there appears to be scope for further improvements if it benchmarks its performance against overseas agency best practice.

FINDING

The Commission finds that potential exists for the Therapeutic Goods Administration to take greater initiative in benchmarking the more important performance measures and the outcomes of its regulatory processes with similar agencies.

14.3.5 TGA independence

The Baume Review did not address the institutional structure of the TGA in detail. Rather, it concluded:

I have not been prescriptive about the structure of the TGA as a whole or the [Drug Evaluation Branch] in particular, preferring to concentrate on the desirable outcomes and leave Senior Management the flexibility to devise a structure which will achieve those outcomes. I am not convinced that the TGA should become a Statutory Authority as recommended in previous reviews, and consider that there is sufficient scope for flexibility in the current 'Specialist Agency' structure of the TGA (Baume 1991, p. 18).

As presently structured, the TGA is a division of the DHFS. As such it is obliged to pursue its objectives within the broad policy framework of that Department and it is subject to the resource constraints imposed by the Department. However, its scientific and medical assessments are conducted independently of the Department.

Some participants questioned the need for change to the present structure of the TGA. Schering-Plough argued that while granting the TGA more independence may facilitate its efficiency and effectiveness, 'ultimately it is the culture within the TGA which matters' (sub. 146, p. 1).

The APMA stated that it was not aware of any evidence to suggest that the performance of the TGA has been restricted by being part of the Department and that:

Further changes in philosophy can be achieved which would bring the TGA closer to the 'efficiency and vigour' of the UK MCA. However, the achievement of such changes is not predicated by TGA's greater independence from government. Rather, it is further acceptance by the TGA of internationally harmonised regulatory procedures and data requirements that is required (sub. 119, p. 14).

The DSHS argued that, in general, elements of departments are made independent in order to avoid conflict of interest within the Department, or to provide freedom from normal departmental administrative constraints and to allow the unit to compete in the commercial market while ensuring competitive neutrality. It said that neither of these considerations applied to the operation of either the drug registration or scheduling functions. It also argued that clear disadvantages of independence would be loss of accountability, capture by the regulated industry and the need to duplicate services within the Department to service the responsible Minister (sub. 153, p. 21).

On the other hand, some participants favoured greater independence and flexibility.

Notwithstanding the DSHS response, the TGA itself supported a review of its structure and greater independence:

We have looked at [structure and independence] since the Baume report brought up the suggestion ... but did not make any particular recommendation.

... The department certainly has some models for statutory authorities-the National Food Authority, Australian Hearing Service, Australian Radiation Laboratory, Australian Institute of Health and Welfare, Health Insurance Commission-so there are a number of areas where those models have been set. I believe the department will take this up in an internal review (transcript, p. 878).

The TGA also noted that since 1991 it has been operating as a semi-autonomous business unit within the Department. In addition, it has recently established a commercial office which offers consultancies to industry in the area of good manufacturing practice and consultancies to agencies such as AustAid, the World Health Organisation (WHO) and the United Nations. The TGA believes this is an area of future expansion, and that the TGA needs 'a new type of identity as an authority of some sort and can take advantage of these changes with greater flexibility' (transcript, p. 880).

The Royal Australasian College of Physicians considered that institutional arrangements for the regulation of therapeutic goods in Australia have not provided the independence and flexibility available to some overseas regulators, and favoured exploration of alternative structures for the TGA (sub. 140, p. 2).

The CHF stated there may be some consumer support for greater independence if it incorporates appropriate consultative structures and safeguards against regulatory capture by the pharmaceutical industry. However, an agency less subject to government control and less accountable to the community as a whole was not acceptable to the CHF (sub. 139, p. 5).

The PMAA noted that it may be appropriate for the TGA to become a statutory authority if the TGA is to adopt responsibility for scheduling (see Chapter 15 for a discussion of streamlining registration and scheduling). Commonwealth/State and potentially New Zealand relationships are involved in these broader activities, and there is a need for open, objective and due processes (sub. 120, p. 10).

The PMAA also noted that in practice, officials of the TGA take operational decisions on behalf of the Secretary or the Minister. The P~ concluded that the independence of the TGA is therefore open to question:

...it would seem that, when Departmental officials exercise discretion's conferred on them by statute. Government policy is for them more of a relevant consideration than it might be for a statutory authority (sub. 120, p. 11).

Models for independence

UK Medicines Control Agency

The MCA has the reputation as one of the most efficient medicines regulators in Europe. While maintaining high regulatory standards, it has developed a commercial approach to the use of its resources and a strong customer orientation. Despite the highest fees for new chemical entity assessments in the EU, it has attracted a large share of EU business under the mutual recognition arrangements now in place. Box 14.3 provides details of the MCA's administrative structure and operations.

Box 14.3: UK Medicines Control Agency

The Medicines Control Agency (MCA) was formed as an Executive Agency in 1989 from the old Medicines Division of the Department of Health, and achieved (self-funding) Trading Fund status in 1993.

The Secretary of State for Health remains accountable to Parliament for the activities of the Agency but has delegated responsibility for day-to-day operation to its Chief Executive. The Chief Executive is answerable to the Secretary for the Agency's operation and performance. The Chief Executive operates under a framework document and on the basis of Corporate and Business Plans approved by the Secretary. Each year the Secretary sets performance targets for the Agency, but the Chief Executive enjoys managerial authority for the Agency and its operations.

The Secretary of State is advised by a Departmental Board for the MCA. The Board is made up of Departmental and outside members, with the latter forming a majority. The Board's terms of reference are to consider the following matters with the Chief Executive and provide independent advice on them to the Secretary of State: the Corporate Plan, the business strategy and objectives, key financial and performance targets and the annual report and accounts.

Source: MCA 1991, p. 7

National Food Authority

In Australia, there is a trend for regulators of product safety to be granted a greater degree of independence. The National Food Authority (NFA) was established by co-operative agreement between Commonwealth and State Governments as a Commonwealth statutory authority.

The NFA was established under the *National Food Authority Act 1991* as an independent expert body with the primary functions of developing, varying and

reviewing standards for food available in Australia. A pre-requisite to its establishment was a formal agreement (the National Food Standards Agreement 30 July 1991) by State and Territory Governments to adopt, without variation, standards developed by the NFA and approved by the National Food Standards Council (NFSC). This agreement was developed under the COAG process (see Box 14.4).

In 1995, the *National Food Authority Act* was amended to include New Zealand within its scope, creating the National Food Authority of Australia and New Zealand (NFAANZ). This demonstrates the flexibility of the approach.

Box 14.4: The National Food Authority model

The National Food Authority (NFA) is a statutory authority within the Health portfolio, set up under the *National Food Authority Act 1991*.

The Authority consists of a full time Chairperson, and four part time Members. One part time Member is from a State or Territory authority responsible for public health, and another from a background in consumer rights.

The Authority makes recommendations on matters relating to development of, or variations to, food standards to the National Food Standards Council (NFSC). The NFSC comprises the Commonwealth, State and Territory Health Ministers with New Zealand represented as an observer.^a Once approved by the NFSC, a variation to the Code is gazetted and adopted as law automatically by reference by the States and Territories in accord with the 1991 Commonwealth, State and Territory Agreement on the adoption of uniform food standards.

^a In 1995, the NFA was expanded to include New Zealand and became the NFAANZ.
Source: NFA 1994, p. 5

Whilst the primary role of the NFA is to make recommendations on matters relating to development of or variations to food standards, an analogy may be drawn to the role of the TGA in making recommendations about approving drugs for marketing in Australia, and its potential role in recommending appropriate schedules for drugs.

The PMAA considered that both the NFA and the National Registration Authority provide appropriate models for the needed reforms (sub. 7 1, p. 65).

The Commission's view

The Commission believes that the TGA's role, structure and degree of independence are important issues. Elsewhere in the world there appears to be a trend towards increased independence of therapeutic goods regulators to

facilitate better management. For example, legislation is presently before the US Congress to introduce a modern management structure to the FDA, and the UK has established the MCA as a self-funded, executive agency.

The Commission considers there are lessons for Australia in the MCA model. In particular, the MCA has a modern organisational structure, comprising a Board, and the management and financial autonomy to pursue its government determined mission. Accountability is enhanced through the independent oversight of the Board.

FINDINGS

The Commission finds that the institutional arrangements for the regulation of therapeutic goods in Australia do not provide the independence and flexibility available to:

- some overseas pharmaceutical regulatory agencies; or
- comparable national bodies responsible for the regulation of food and agricultural and veterinary chemicals.

There are degrees of independence available in the management of an administrative agency. They range from significant autonomy to corporatisation.

Increased autonomy would provide for:

- a degree of financial independence from departmental budget constraints;
- the operational independence required to be responsive to changing market demands; and
- improved accountability for results.

Independence obliges the Government to spell out the details of its expectations of the agency, including for the provision of public goods, thus establishing a benchmark for performance measurement.

Corporatisation of an independent agency provides the additional benefit of removing the organisation from the limitations of public service employment rules. For example, this would allow the agency to pay competitive market wages for scarce technical staff.

The Commission considers that there are significant benefits to be gained from granting the TGA greater independence. Separation of the TGA from the DHFS would allow the objectives of the organisation to be set by Government independently of those charged with pursuing those objectives. Clear outcomes must be specified and the organisation given sufficient resources to achieve those outcomes. This allows for greater accountability by both the Government in explicitly setting objectives and resourcing the regulatory agency, and for the agency in pursuing those objectives.

Moreover, a more independent TGA would be better placed to respond to international developments in pharmaceutical regulation and, should the Government agree, to take a role in selling regulatory services to countries in the region, if the TGA decided it was worthwhile to do so.

The Commission recognises that there are some disadvantages associated with providing regulatory agencies with greater independence. For national bodies there may be a loss of accountability to Parliament. There is also a risk of 'regulatory capture', where those subject to regulatory supervision succeed in dominating the regulatory process. This may be a particular danger where the regulator is industry funded.

To ensure that the TGA has the autonomy to implement an independent national drug regulatory policy the Commission considers that its organisational form should be changed to that of a Commonwealth statutory authority. It suggests that the Commonwealth and the States enter into a co-operative agreement to implement the proposal. States should be represented formally in the management structure of the new national organisation. The NFA provides an appropriate model. A statutory authority structure also allows future flexibility for developments such as the inclusion of New Zealand in Australian therapeutic product regulation, as has occurred in the case of food regulation.

Recommendation 14.3

The Commission recommends that the Therapeutic Goods Administration be established as a Commonwealth statutory authority.

An important issue for an independent TGA is its funding base. It is Government policy, for the TGA by 1996-97 to recover 50 per cent of its operating costs through annual licensing charges, inspection fees, evaluation fees and other charges.

The Commission considers that a fee-for-service approach can provide important incentives for regulators where fees are made conditional upon the efficient delivery of services. However, it is not appropriate that any 'public good' aspects of regulation be subsidised by those subject to regulation.⁴

The Commission acknowledges the difficulty in estimating the appropriate proportion of the TGA's budget to be raised from fees. Nonetheless it supports

⁴ Public goods may include research undertaken by the regulator, the provision of information and education about the risks of pharmaceutical use.

the explicit budget funding of any public good aspects of the TGA's functions, particularly if it is structured as an independent statutory authority.

14.3.6 Regulation of exports

Exporting by non-sponsors

Some participants, particularly wholesalers, raised concerns about restrictions placed on 'parallel exporting' by the *Therapeutic Goods Act* 1989.⁵ Section 20 of the Act stipulates that only a 'sponsor', in whose name goods are registered, may legally export the goods.

This means that although registered pharmaceuticals can be wholesaled in Australia independently of the sponsor, it is an offence to export registered pharmaceuticals independently of the sponsor. Those, including wholesalers, wishing to export pharmaceuticals must either become a sponsor of the goods in their own right or become an agent of the established sponsor.

The primary reason given for the restriction is to maintain the quality and safety of exported drugs. The TGA argued that:

... the regulatory controls in the Act are intended to foster high quality exports, as well as ensuring that when export is undertaken, there is a sponsor in Australia responsible for the quality, safety and efficacy of the product ...

... In addition, the requirement for exported products to be the legal responsibility of a particular sponsor, also provides a deterrent to drug counterfeiting of products which have been included in the [Australian Register of Therapeutic Goods] ARTG in good faith by the 'original' sponsor (sub. 16, p. 16).

Galeshka, a wholesaler, argued that the TGA can maintain the quality and safety of exported drugs without restricting exports by wholesalers:

... if a therapeutic good is already registered on the ARTG by the manufacturer then that product should be exempted from re-registration by any exporter. Once registered, its quality, safety and efficacy is beyond reproach and complies with international standards of quality. ... The Commonwealth of Australia is THE ONLY country in the world with this archaic and primitive piece of legislation (sub. 127, Attachment 2, p. 2).

The Scientific & Medical Industries Association of Western Australia has also argued that the quality of exported pharmaceuticals is assured by their registration by the original manufacturer, and that the Commonwealth can trace

⁵ Parallel exporting, and parallel trade more generally, refer to the practice of traders buying products in low pricing countries and selling them in higher priced countries-a form of arbitrage often taking advantage of differential pricing by the manufacturer of the product.

batches of pharmaceuticals through wholesalers' sales records (Galeshka correspondence 19 January 1995).

In addition to the safety and quality arguments for restricting exports, there are broader economic issues associated with parallel trade in medicines:

- whether parallel trade acts to correct a market distortion, or whether it is a side-effect of a distorted market; and
- whether restrictions on parallel exports contribute to lower pharmaceutical prices in Australia.

Manufacturers oppose parallel trade, and argue that it is a result of the distortions created by controls over prices. On the other hand, parallel traders consider they are placing competitive pressure on original producers by reducing price differentials.

Senior (1992) argued parallel trade reflects a distorted market:

If the ... national governments were to remove the frictions associated with parallel trade without freeing prices, every importer and wholesaler would source from low price countries] irrespective of the comparative advantage or commercial efficiency of those countries (Senior 1992, p 76).

In Europe, the Head of the Competition Directorate criticised the cross subsidies caused by restrictions on parallel trade:

We cannot accept the argument that parallel imports should be limited because companies are obliged to charge excessive prices in countries without strict price controls to compensate for low margins in the lower price member states. This would simply result 'in the higher price countries subsidising the cost of healthcare elsewhere in the Community, and is wholly unacceptable (*Scrip*, 8 December 1992, p. 4)

However, the European Commission also recognised that allowing free parallel trade while governments controlled prices could damage the European pharmaceutical industry. It encouraged governments to replace price controls by transparent rules in the belief that this will ultimately lead to pan-European pricing in a single market.

The Commission's view

The Commission considers that once a drug is registered for sale in Australia its safety and efficacy have been established. Requiring the drug to be registered in relation to the individual exporter does little to ensure the quality of the product exported. The industry based Australian Code of Good Wholesaling Practice for Therapeutic Goods for Human Use already sets out procedures for handling, storage and distribution of pharmaceutical products.

If parallel trade merely reflects government induced market distortions, this may justify restrictions to contain the distortion to a particular market. In the absence of controls there may be increased demand by wholesalers driven by prices artificially depressed by government, leading to an inefficient over-investment in drug production in Australia. If a comparative advantage or production efficiency exists in Australia, it is likely that manufacturers would themselves take advantage of the opportunity to export, or willingly enter into an agency arrangement with wholesalers.

In addition, restricting exports of pharmaceuticals by wholesalers may be viewed as a trade-off for the benefit of low PBS prices. Manufacturers may be more willing to accept these relatively low prices because they know that the prices are effectively 'quarantined' to Australia and that they can charge higher prices in other markets without the fear of being undercut by a wholesaler offering Australian prices overseas.

However, these economic arguments do not justify the involvement of the TGA in the regulation of trade in pharmaceuticals. If it is regarded as appropriate to restrict parallel exports of drugs for economic reasons this is better regulated directly through trade related mechanisms such as the Customs Act 1901 (which already deals with prohibited exports and imports). An explicit policy decision to restrict opportunities for export should be made, rather than a *de facto* restriction created by the inappropriate application of TGA requirements.

FINDINGS

The Commission finds that there is no justification for the restriction of exports by wholesalers on safety or quality grounds. However, restrictions may be justified if such trade reflects Government induced distortions in the market.

The Commission finds that it is inappropriate for the Therapeutic Goods Administration to be involved in the regulation of trade. Such regulation is more appropriately undertaken through trade related mechanisms such as the *Customs Act*.

Export only certification

Participants have criticised the TGA's administration of export controls, arguing that it has led to lost opportunities for Australian exporters.

Australia is a signatory to the WHO export certification scheme. This scheme was introduced in response to concerns that drugs for export are not always subject to the same controls as those for the home market and that some developing countries lack adequate facilities for drug evaluation. The scheme is also promoted as a mechanism for combating the illicit drug trade and falsely labelled counterfeit drugs.

Some participants argued that the TGA's insistence upon the use of the term 'export only' to describe products that do not meet Australia's packaging and labelling requirements restricted export opportunities.

The PMAA stated that the use of the term 'export only' has led to difficulties for Australian exporters:

... a view is taken in some countries ... that 'for export only' signifies a product of lower standard than that required for domestic sale (sub. 7 1, p. 5 0).

Moreover, companies argued that Australian 'export only' labelling requirements are out of step with practices adopted elsewhere in the world, and that this affected Australian exports. For example, RP Scherer stated:

[Japan, Germany, the Republic of Korea, Italy, UK and the US] (with the possible exception of Korea) are signatories to the WHO Export Certification Scheme yet all the governments of these countries produce alternatively worded export certificates for those countries which will not accept the Export Only certificates (sub. 29, p. 5).

The TGA argued that the real problem is lack of understanding by overseas regulators of the meaning and purpose of 'export only' labelling:

A number of countries in the Asia-Pacific region, in particular China and Malaysia, have formally advised the TGA that products which are not supplied within Australia would not be acceptable for import. The TGA has pointed out to countries in the region that the 'export only' listing arrangements in fact cover the key and critical elements of product approval for supply in Australia, but there has been little feedback as to the effect of these initiatives (sub. 16, p. 18).

The Commission found evidence of this lack of understanding in discussions with regulatory authorities in Singapore. The Commission was told that as a matter of policy Singapore would not accept any products labelled 'export only' because of the negative connotations implied by the label. Singapore relies on marketing approval in the country of origin and it does not have the resources to establish what export only certification means in each case.

However, in an address to the PMAA, the DSH recognised industry concerns about the language of export only certificates, and invited industry to present its ideas on how to address this problem. The Deputy Secretary stated:

... if it is adversely affecting the exports of such product, we need to look at ways around the problem. Any solution needs to ensure that we still tell the truth about the product and its standing in Australia but in language which does not lead to unfounded negative inferences (Lindenmayer 1995, p. 9).

In an effort to address the confusion surrounding this issue, the TGA has made it clear that it issues two certificates for exported products:

- the Export Only Listing Certificate for a product placed on the ARTG for supply solely outside Australia; and
- the Certificate of Pharmaceutical Product is issued under the WHO Certification Scheme on the quality of pharmaceutical products traded internationally.

The Export Only Listing Certificate is intended only as documentary evidence that the sponsor's goods meet Australian requirements for inclusion in the ARTG for export purposes, but is not intended to be used to support export initiatives (DHS sub. 153, p. 25).

The Certificate of Pharmaceutical Product is intended for use by companies to establish the status of products for export initiatives. The Certificate of Pharmaceutical Product is that recommended to be adopted internationally under the WHO export certification scheme. It does not contain the words 'export only' but does indicate whether or not a product is marketed in Australia.

The Commission considers there is some evidence that the administration of 'export only' labelling in the past has confused industry participants and impeded exports of Australian manufactured pharmaceuticals. However, it recognises that the TGA has acknowledged the problem and taken action to facilitate the administration of export controls by adopting the new simplified WHO Certificate of Pharmaceutical Product and promoting its use by exporters.

FINDING

The Commission finds that the Therapeutic Goods Administration has acknowledged industry concerns in regard to export only certificate arrangements and taken action to facilitate the administration of export controls through the adoption of the World Health Organisation Certificate of Pharmaceutical Product.

14.4 Conclusion

This Chapter has examined regulatory issues associated with the drug approval process. However, this is only one aspect of the regulation of pharmaceuticals. There are strong links between drug approval and drug scheduling processes. The relationship between approval and scheduling is discussed in Chapter 15, as well as the scheduling process itself, and scheduling related issues such as advertising.

15 REGULATORY ISSUES- SCHEDULING AND ADVERTISING

In Chapter 14 issues concerned with the regulation of the drug approval process were examined. This Chapter takes up the major issues identified by participants in relation to the scheduling system.

These issues are of particular relevance to the over the counter sector. They include the relationship between self-medication and scheduling, the scheduling process and criteria applied and the advertising of pharmaceuticals.

15.1 Self-medication

Consumers make an important and often overlooked contribution to their own health care. As the Consumers' Health Forum (CHF) noted:

This industry uses the term 'self-medication'. The reality is most of us self-medicate all the time, even if we have got a prescription medicine. ... It has got to be seen in that context: that we are managing our own health (roundtable, p. 15 8).

Participants noted an increasing trend toward self-medication in Australia. Parke Davis commented that 'there is little doubt society has changed over the last few decades and is evolving toward 'self determination'; 'the right to know'; and 'the right to make decisions which affect oneself' (sub. 121, p. 2).

In a joint submission, prepared in 1996 for the incoming Government, the member bodies of the Australian pharmaceutical and pharmacy industry associations noted that 'governments, recognising social trends and consumer pressure, have acted to give consumers ready access to safe and cost effective remedies'. The Joint Submission went on to predict:

Escalating health care costs and growing consumer interest in self care will inevitably lead to the further development of responsible self-medication strategies. In order to realise the potential benefits in terms of health cost containment and better community health outcomes, joint action is recommended involving government, industry, the health professions and consumers (Joint Manufacturers/Distributors/Pharmacy 1996, pp. 21-22).

Reckitt & Coleman called for relaxation of regulations restricting self-medication:

I fervently believe that self-medication is something that can be of great benefit to our community if done responsibly. ... Let us not allow what I consider to be out of

date regulations ... wrapped up around this scheduling process to stop a move which will lead to better health in our community (roundtable, p. 147).

However, analysis of the efficiency of present Australian arrangements is constrained by the lack of detailed studies of the economics of self-medication.

One of the few such studies was commissioned by the Non-Prescription Drug Manufacturers' Association of Canada (NDMAC). The report noted that despite the expanding role of self-medication in health care systems, there have been relatively few economic analyses of the over the counter (OTC) availability of medicines (NDMAC 1994, p. 18). It concluded:

... there has yet to be a thorough critique of the methods used to measure the economics of self-medication ... the literature relies heavily on measures that may not accurately reflect the risks and benefits of self-medication. We think that there needs to be a more systematic analysis of self-medication in Canada-one that accounts for the differences in outcomes from self-medication and formal medical care. This will require a forward looking model such that the results are useful as a prescriptive tool for policy analysis (NDMAC 1994, p. 37).

Given community and Government concerns with rising health care costs, the Commission considers that more research into the economics of self-medication in Australia should be undertaken.

15.1.1 Links between self-medication and scheduling

Appropriate use of drugs, including self-medication, is linked to the system of scheduling pharmaceutical products. This system establishes the rules for the prescribing and dispensing of pharmaceuticals and it indirectly determines how medicines can be advertised. Its present coverage extends beyond medicines to the control of all poison substances.

The scheduling decision is concerned with the risks and benefits of various levels of access to a drug, taking into account consumer response to availability, provision of advice and 'quality use' considerations.

Inquiry participants supported the concept of scheduling, but criticised many aspects of the current arrangements. For example, although the Proprietary Medicines Association of Australia (PMAA) supported scheduling for public health reasons, it commented:

... there is considerable scope to both rationalise and simplify that scheduling aspect in the hierarchy that exists at the moment (roundtable, p. 124).

The Medicines Evaluation Committee expressed confidence in the structure and principles of the Australian scheduling scheme, but accepted that some procedural aspects may need attention (sub. 160, p. 3).

Many participants, particularly those from the OTC sector, raised the following issues relating to the scheduling system:

- the legislative base underpinning current cooperative Commonwealth/State scheduling arrangements;
- the degree of national uniformity that has been achieved;
- scheduling medicines separately from other poisons;
- the process of allocating products to schedules-this has particular implications for scheduling guidelines and criteria, the roles of individual schedules and switching between schedules; and
- transparency and due process in decision making.

These issues are addressed in the following Sections.

15.2 General issues in scheduling

15.2.1 Legislative base

Although the drugs and poisons schedules of each State¹ are legislatively based, current arrangements for cooperation between the Commonwealth and the States are administrative in nature and have no legislative underpinning at the national level.

As noted in Chapter 3, the National Drugs and Poisons Schedule Committee (NDPSC) compiles the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) which is 'issued' or 'approved' by the Australian Health Ministers' Advisory Council (AHMAC). However, the PMAA pointed out that the Council, which comprises Commonwealth and State Health Department officials, is not established under statute, and the standard itself has no legal effect until it or its provisions, are adopted into State legislation (sub. 71,p. 5 7).

'Interim Guidelines for Applications for Scheduling of Drugs', prepared under the auspices of AHMAC, were issued by the NDPSC in March 1995.

Although it lacks a national legislative base, some aspects of the standard are imported into Commonwealth legislation and other instruments treat the standard as having some legal force. In particular, the Therapeutic Goods Regulations and standards made under the Therapeutic Goods Orders

¹ State refers to State or Territory.

extensively take up various provisions of the SUSDP, thereby importing them into Commonwealth law.

The importance of the scheduling standard has been observed by the PMAA:

... fundamental questions relating to drug scheduling, labelling point-of-sale controls, advertising and packaging are all, in the end, matters decided by reference to what goes into [the] SUSDP (sub. 71, p. 63).

The Victorian Government noted that because the NDPSC and its decision making processes are not formalised in legislation, the SUSDP could not be easily adopted by reference. Adoption of the standard in Victoria therefore has had to be more complicated and more resource and time intensive than desirable. However, Victoria considered that 'while the process requires formalising, the quality of decisions made is not in question' (sub. 182, p. 5).

AHMAC (sub. 152, p. 4), Tasmania (sub. 112, p. 9) and South Australia (sub. 189, p. 5) argued that the legal foundation for scheduling pharmaceuticals is in States' poisons legislation.

The South Australian Government defended the current arrangements:

[The NDPSC] has worked well and has achieved a high degree of uniformity in classification and regulation in Australia but each State ... has the right to vary the classification or to write a regulation to control any situation that exists solely within its jurisdiction.

... Although neither the NDPSC nor any of its predecessors were founded on a Commonwealth Act of Parliament it has functioned and continues to function well (sub. 189, p. 5).

The Commission considers that the lack of an adequate legislative base at the national level has made it difficult for the recommendations of the SUSDP to be adopted by reference. In addition, the lack of an adequate legislative base for scheduling at the national level has implications for the transparency and accountability of the decision making process. Issues relating to transparency are discussed further in Section 15.2.5.

FINDING

The Commission finds that current scheduling arrangements do not have an adequate legislative basis at the national level.

15.2.2 National uniformity

Governments have recognised that there are benefits from pursuing scheduling uniformity. The then Department of Community Services and Health, now the Department of Health and Family Services (DHFS), advised the Public

Accounts Committee in May 1988 that it initially intended to have Commonwealth legislation impose the decisions of the Drugs and Poisons Scheduling Committee. However, this plan was abandoned in favour of cooperative Commonwealth and State action, and the NDPSC was established.

However, complete national uniformity of scheduling has yet to be achieved. The PMAA stated '... uniformity is never absolute, nor is every State's timing in harmony with the others' (sub. 7 1, p. 10)

For example, there may be delays in the adoption of amendments to the SUSDP. Amendments are not uniformly adopted in all States with effect from the same day. In addition to timing differences, States may make amendments to the SUSDP before adopting it.

The PMAA stated that 'resultant differences between States are subtle but real'. The PMAA documents the differences in its publication *National Comparison of Poisons Lists*, which 'runs to some hundreds of pages' (PMAA sub. 71, p. 61).

However, AHMAC cautioned that:

mere comparison of the schedules on a jurisdiction-by-jurisdiction basis is of little value in any assessment of national uniformity ... The schedules often contain substances which are not *bona fide* pharmaceutical products and which are included therein for control and enforcement purposes. Furthermore, whilst the actual wording of some entries may vary from that of the SUSDP in some jurisdiction due to local legislative requirement or legal drafting practice, such variations have no practical significance if the meaning of the entry is common (sub. 99, Attachment A, p. 1).

Sigma noted that lack of scheduling uniformity 'imposes additional costs and inefficiencies' on industry (sub. 19, p. 9). For example:

- national companies have to schedule separate product runs for different jurisdictions;
- individual packages and labels may be required for products for different markets; and
- additional stocks of different formulations or different packages have to be held.

Lack of uniformity also affects consumers. The CHF stated that 'the current lack of uniformity in State ... adoption of the [SUSDP] results in inconsistencies in the scheduling of-and hence consumer access to-pharmaceuticals' (sub. 13 9, para. 2. 1. 1).

Scheduling differences can also result in price differences between States, because of the link between schedules and pharmacists' dispensing fees. For example, the National Asthma Campaign noted that:

Ventolin and similar drugs are not recordable and counselling is not required in New South Wales and Western Australia, but in the other States they are. So in New South Wales and Western Australia of course it's cheaper (transcript, p. 164).

Parke Davis-Wellcome provided the example of the drug Ponstan:

... that was schedule 3 in some States and schedule 2 in other States I had a woman who rang me up and said, 'I buy normally from Albury and I went to Wodonga and I paid \$9 instead of \$3' (roundtable, p. 164).

The Commission notes that an alternative to strict uniformity is the mutual recognition of scheduling decisions. Under mutual recognition arrangements, a drug could be sold in every State in any schedule category applying in any State.

However, the sale of therapeutic goods appears to be exempt under national mutual recognition arrangements. Section 11 of the *Mutual Recognition Act* 1992, lists State laws exempted from mutual recognition. These include laws relating to 'the manner of the sale of goods' or alternatively, laws relating to 'the transportation, storage or handling of goods' directed at 'matters affecting health and safety'.

In its Draft Report, the Commission found that 'lack of national uniformity in scheduling created unnecessary and avoidable costs, while providing few benefits for consumers'. In addition, the Commission was not convinced that the exemption of pharmaceuticals from national mutual recognition was warranted.

In the light of evidence received in response to the Draft Report, the Commission now considers that while there is evidence of some minor differences between State legislation and regulation implementing the SUSDP, by and large, the same substances tend to be in the same schedules throughout Australia. Hence, the Commission has concluded that the remaining differences in legislation have only a small practical effect on the operation of markets and on consumers' welfare.

Nevertheless, the Commission considers that, as long as differences remain, unnecessary costs are incurred by companies, consumers and Governments. There appears to be no good reason for all States not to adopt the national standard by reference.

FINDING

The Commission finds that there are likely to be benefits to the community if all States and Territories adopt the national standard by reference.

States have a number of powers, apart from poisons scheduling, to control access to drugs. Some participants noted that the exercise of these powers differs between States.

The Commission considers that differences related to the requirements imposed on pharmacists and distributors when dealing with particular products do not reflect a lack of national uniformity in the schedules themselves. As the Victorian Government stated:

... differences in availability, result not from differences in the schedules between the States but from some differences in the regulations that apply to the relevant schedules (sub. 182, p. 3).

15.2.3 Separation of drugs and poisons scheduling

The scheduling of drugs and poisons together, is an 'accident of history'. States began scheduling medicines as poisonous substances well before they introduced specific regulation of pharmaceuticals. When it was decided to control access to pharmaceutical products, the States generally adopted the scheduling processes already in place for poisons. National arrangements through the NDPSC and its predecessors continued this combined system.

Participants argued that it is inappropriate to continue to schedule therapeutic products as poisonous substances. For example, the PMAA stated that 'it is ... important that the scheduling system relate to medicines alone' (sub. 71, iii).

First the scheduling of drugs requires a risk/benefit trade-off quite different to that applying to poisons. It must balance the risk of abuse or misuse, with the significant benefits to public health that access to drugs can provide. Scheduling of poisons places a greater emphasis on the risk associated with a substance, as the benefits are of a different degree.

Second, separating out the scheduling of drugs would ensure that public health objectives are consistently met. It would also allow the benefits of appropriate use to be better evaluated. Moreover, all important stakeholder groups could participate in the process. One of the weaknesses of the current NDPSC process is that neither the Pharmacy Guild nor the Pharmaceutical Society are represented on the NDPSC, despite its large size.

Third, other participants argued that scheduling drugs and poisons together also disadvantages the non-therapeutic products. The same system is attempting to

control access to different types of products and is not meeting community expectations associated with specific classes of products. The National Registration Authority stated:

At present, the scheduling of non-pharmaceutical products follows an out-dated and confusing system that has its origins in human pharmaceuticals and not in the range of chemicals now available to the community, many of which require specific control over their availability and use (sub. 15 8, p. 5).

The Commission considers that the above arguments make a strong case for separate scheduling of drugs and poisons. It notes, however, that if pharmaceutical substances were scheduled separately to poisons, arrangements would have to be made for the scheduling of those other products. This is discussed in* Section 15.5.2.

FINDING

The Commission finds that the scheduling of drugs should be conducted separately from poisons.

15.2.4 Scheduling criteria

Although the classifications of the schedules specified in the SUSDP appear to represent a cascading set of increasingly restrictive access requirements corresponding to increasing levels of 'danger', 'hazard' or 'potential for abuse', substances are not scheduled on the basis of a universal scale of toxicity. Although toxicity is one of the factors considered in the scheduling decision, it is itself a complex of factors, and other criteria, such as the proposed use, potential for abuse, safety in use and the need for the substance are also taken into account (AHMAC 1994, p. ix).

This means that, in practice, some schedules contain a number of substances with widely varying characteristics. For example, the TGA stated in relation to schedule 3:

... it's a very wide and diverse range of substances. Some appear to be fairly innocuous, like some of the topical steroid creams. Others, like the asthma inhalers, can in fact be quite dangerous, and you have got things like quinine injection and calcium leucovorin injection and folic acid injection. These were never intended to be advertised and supplied to the public. They're virtually always used in a hospital setting. They're in S3 because they're not toxic enough to be in S4 (transcript, p. 866).

The wide variations in the characteristics of substances included within schedules have led participants to demand objective criteria (and transparent processes) to provide certainty and consistency in decision making.

Interim Guidelines for Applications for Scheduling of Drugs, issued last year, did little to expand on the brief definitions of the criteria underlying scheduling contained in the SUSDP. Nor did they provide much guidance in relation to the NDPSC's decision making process.

In a move to clarify the scheduling process AHMAC is developing, with the assistance of industry and consumer representatives, a further set of guidelines:

... on administrative aspects, including communication with and making applications to NDPSC, scheduling and rescheduling of drugs and poisons, appeal procedures, confidentiality and public consultations ... (sub. 152, p. 3).

A draft of the new guidelines, provided to the Commission by AHMAC, appears to emphasise the margin of safety in schedule 3 products:

Schedule 3 poisons are substances and preparations:

- for therapeutic use (ie. drugs);
- with low toxicity;
- which are substantially safe in use (or misuse) but require some professional advice or counselling from a person with appropriate expertise (at pharmacist level); and
- which are for relatively minor ailments or symptoms amenable to rapid resolution, which do not require medical diagnosis or management (sub. 99, P. 12).

The proposed guidelines appear to adopt different interpretations of the schedule definitions to those in the SUSDP, where the emphasis appears to be on the risk inherent in such products.

For example, the SUSDP defines schedule 3 products as:

Poisons for therapeutic use that are dangerous or are so liable to abuse as to warrant their availability to the public being restricted to supply by pharmacists or medical, dental or veterinary practitioners (AHMAC 1994, p. vii).

The PMAA argued that the draft guidelines were:

... an attempt to not only redefine but to, in fact, under the heading of 'Classification', establish a specific system of identifying those factors which may need to be taken into consideration in [scheduling] decision-making (transcript, p. 964).

The PMAA called for a review of the schedules and the criteria for each. to be undertaken against agreed objective scheduling criteria (sub. 120, p. 8). The CHF supported a review of the scheduling process 'aimed at establishing a nationally uniform, transparent and accountable system provided that there was appropriate consumer participation in the process' (sub. 139, p. 3).

The Victorian Government recognised that:

... there is a paucity of data which demonstrate the value or otherwise of the current scheduling arrangements. It would be helpful if research into the benefits and costs was encouraged so that decisions could be made on the basis of firm evidence (sub. 182, p. 8).

The Australian Pharmaceutical Advisory Council (APAC) noted that it has been concerned for some time with the scheduling process, and supported the urgent need for criteria on principles relating to scheduling to be publicly known (sub. 137, p. 2).

The Commission considers that the apparent difference between the Guidelines and the SUSDP reflect varying opinions within the industry about the role and nature of the various schedules. This difference has implications for self-medication issues dependent on scheduling, such as the roles of individual schedules, rescheduling and links between schedules and advertising. These issues are discussed below in Sections 15.3 and 15.4.

FINDING

The Commission finds that, for effective scheduling, criteria need to be specified that are clear to all parties, measurable, capable of being applied objectively and that adequately reflect the degree of risk associated with a therapeutic substance.

15.2.5 Lack of transparency

Unlike the Therapeutic Goods Regulations and the Therapeutic Goods Orders, the SUSDP is neither subject to parliamentary scrutiny nor administrative appeal processes. Participants argued this leads to a lack of transparency and accountability.

The PMAA suggested the AHMAC process occurs

... without observance of any of the usual modern requirements for procedural fairness or due process ... there is no legal instrument, Commonwealth or State, which defines the criteria for scheduling decisions. ... In any event, final decisions on much that affects the OTC industry are taken in secret by AHMAC and industry has no access to an appeals process (sub. 71, pp. 62-63).

The Pharmaceutical Society of Australia (PSA) stated that the lack of open and accountable processes has led to a lack of confidence in the outcomes of the scheduling process:

... to be honest we don't have faith in the committee and its deliberations at the present time and we would love to see a scheduling process whereby correct criteria and processes were followed. We would have faith in that. ... It's just that

at the present time we don't see it functioning in the best interests of patients and consumers (transcript p. 1028).

AHMAC argued that transfer of the scheduling function from the National Health and Medical Research Council to AHMAC in 1993 provided the opportunity for introducing more transparent decision making. AHMAC broadened NDPSC's Terms of Reference and expanded its membership to include industry and consumer representatives. The NDPSC now has formalised procedures for public consultation and AHMAC has endorsed and begun implementing the findings of an independent review of the NDPSC. AHMAC is also developing operational guidelines to increase the transparency and efficiency of NDPSC decision making. AHMAC intends to take the Council of Australian Governments (COAG) principles for standard setting and regulatory action into account (sub. 99, pp. 18-19).

The NDPSC has attempted to improve the flow of information to and from the Committee:

... they are improving access to information about matters before the Committee. Direct correspondence with representatives of identifiable interests besides Gazettal is achieving this. Industry and consumer members are encouraged to seek advice and opinion from their constituencies (sub. 99, p. 19).

The Commission notes recent initiatives by AHMAC to improve the NDPSC administrative arrangements and its proposals for further reform. However, the Commission considers that, despite these developments, the lack of an adequate legislative base for scheduling at the national level has ongoing implications for the transparency and accountability of the decision making process. Scheduling decisions are made at the national level by consensus of the NDPSC, but are implemented at State level. Overall responsibility and accountability for scheduling decisions is unclear, and some systemic 'checks and balances' meant to provide for scrutiny of regulatory decision making are avoided.

FINDING

The Commission finds that the National Drugs and Poisons Scheduling Committee does not have adequate administrative arrangements for transparent and accountable decision making.

15.3 Specific scheduling issues

As well as the general scheduling issues addressed above, several specific issues relating to scheduling were raised by participants. These included the role of the pharmacist, the roles of schedules 2 and 3 and processes for rescheduling.

15.3.1 Role of the pharmacist

The PMAA characterised scheduling as 'a system regulating public access to medicines in an ascending order of controls', and regarded the need for professional advice as the most important factor. It stated:

These controls should relate, not so much to controls on access, as to the degree of professional assistance or advice appropriate to achieve quality use of medicines so as to allow best therapeutic outcomes for the consumer. ... [T]he professional role of the community pharmacist is to provide a service to consumers in making informed choices about self-medication. The development of the [Consumer Product Information] processes ... the opening up to advertising of S3 and the growth of the community pharmacy concept work for the positive reinforcement of this role (sub. 120, p. 7).

There is little information available on the effectiveness of pharmacist counselling. A recent study by the UK Consumers' Association found that many UK pharmacists were 'selling people the wrong medicines or failing to offer the right advice'. A senior editor stated:

We have criticised pharmacists time and again for failing to protect consumers from the dangers of over the counter drugs. Unfortunately the service is still not up to scratch, despite pharmacists promoting their advisory role (*The Times*. 4 January 1996).

The lack of research on the effectiveness of Australian pharmacists makes it difficult to assess whether or not a similar situation exists in Australia. The role of the pharmacist is, particularly unclear in the sale of schedule 2 products, which may be sold without any contact with a pharmacist. However, the Pharmacy Guild argued that 'non-apparent safeguards are inherent in the present public health system', and that:

The standards of pharmacy practice are regulated and controlled by Pharmacy Boards in each State and should a pharmacist act in an unprofessional manner in the supply of medication, such as neglecting to ensure the pharmacist's supervision, there are serious penalties available to these public health authorities (sub. 126, p. 7).

A recent research report into community attitudes towards pharmacy undertaken on behalf of the Pharmacy Guild throws some light on perceptions of pharmacy. The report concluded that:

- community attitudes towards, and the image of, pharmacy is extremely favourable;
- participants in the study generally perceived the local pharmacy to be a source of professional advice on a range of health matters;
- participants trusted the pharmacist's thorough knowledge of products. And

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- the pharmacist's role is simultaneously a qualified drug dispenser, a source of free advice, a middle man, a second opinion to the doctor, a retailer, a business man and, above all, a health professional (Elliott & Shanahan 1994, pp. 15, 17).

The Commission notes the widespread belief that access to pharmacists' advice should be an important consideration in scheduling. However, the Commission considers that further research into the extent and effectiveness of pharmacist counselling should be undertaken.

FINDING

The Commission finds that there is insufficient research or monitoring of the counselling role of Australian pharmacists in relation to schedule 2 and schedule 3 drugs,

15.3.2 Roles of schedules 2 and 3

Despite a lack of information on the economics of self-medication, several participants proposed changes to the way different products should be made available (scheduling) and the processes for changing this (rescheduling-see Section 15.3.3).

There was general agreement that certain substances should only be available on prescription (schedule 4) but that others are suitable for general sale (unscheduled). The main area of contention relates to the need for the intermediate schedules of 'pharmacist only' (schedule 3) and 'pharmacy only' (schedule 2).

The role and importance of these intermediate classes have been examined in two recent studies.

In 1995 the US General Accounting Office (GAO) released a report into drug distribution in ten countries and the EU, and the practice of pharmacy, focusing on pharmacist counselling of patients on the use of non-prescription drugs. The study concluded that 'no systematic evidence supports the superiority of one drug distribution system over another'. The GAO found there were no major benefits to be gained from establishing a 'pharmacist-controlled' class of non-prescription drugs in the US (GAO 1995, Chapter 0:4. 1).

In contrast, the Canadian Drug Advisory Committee (CDAC) released a report in May 1995 recommending a model for drug scheduling in Canada which closely resembles the schedules adopted in Australia (CDAC 1995).

In relation to these two studies, the PMAA commented that 'it is notable that with two countries with so many cultural similarities, entirely different conclusions were reached' (sub. 120, p. 8).

In the Draft Report the Commission called for views on the likely effects of discontinuing schedule 2 or schedule 3 listing. While an intermediate category between prescription only and general sale status was generally supported, some participants questioned the need for two intermediate classes.

The PMAA stated that there was no consensus among its members in relation to the roles of schedule 2 and schedule 3, and that 'many question whether the S2-S3 dichotomy ought to be retained' (sub. 71, p. 23).

Pfizer found the current scheduling arrangements too restrictive, and in the case of schedule 2 products, a barrier to open and fair competition. It recommended the retention of schedule 3 and schedule 4, and the deletion of schedule 2 (sub. 133, p. 17).

Faulding held the view that an intermediate class was justified, but that schedules 2 and 3 'could readily combine elements of both schedules into one system' (sub. 129, p. 8).

However, most participants supported the present schedule structure. For example, APAC supported the intermediate pharmacy schedules as a transition between open selling and prescription only medicines, as being in the public interest (sub. 104, p. 2).

The Pharmacy Guild of Australia supported the current system as it provides 'a flexibility that would not be available if either schedule 2 or schedule 3 were eliminated' (sub. 53, p. 19). It stated:

The present system works extremely well in Australia providing ready availability of medications to the community while at the same time seeking to ensure that consumers use medications appropriately (sub. 126, p.5).

A majority of the members of the Medicines Evaluation Committee noted that the existence of two intermediate classifications should not be surprising as different substances or classes of substances demand different degrees of control. The Committee 'was not attracted to the proposition of having a single pharmacy-only schedule' (sub. 160, p. 2).

Although Schering-Plough originally proposed that schedule 3 and schedule 2 be combined into a single OTC category, in responding to the Draft Report it stated that it believed this would be too great a change at this time, particularly given the wide variety of OTC medications (sub. 128, p. 7).

The CHF urged caution, suggesting that any changes to schedule 2 and S3 scheduling would only be appropriate after an overall review of scheduling, and concurrently with more rigorous post-market surveillance (sub. 139, p. 3).

Many participants were concerned that, without two intermediary schedules, fewer products would be available for self-medication. The Department of Human Services and Health (now the Department of Health and Family Services) noted that 'while the S3 category is not particularly large, it provides a means of removing some of the higher level restrictions applying to S4':

In general, decisions to switch from S4 to S3 reflect a judgement that it would be unduly risky to assign S2 status as some level of consumer protection is needed for that product above that attached to S2 status. It is likely, therefore, that if S3 status were removed, many S4 products would not be downscheduled or would not be downscheduled as early as they would with the continuation of an S3 classification option. [DHS] therefore favours the continuation of the existing range of scheduling options (sub. 153, p. 22).

The Tasmanian Department of Community and Health Services argued that schedule 3 should be retained, as otherwise a drug that should not be taken without professional advice would have to be classed schedule 4 (sub. 112, p. 8). The Victorian Government agreed 'the likely effect of discontinuing schedule 2 or schedule 3 listing is that substances will become more restricted (as is the case in the US) and as a result will become less accessible to the public' (sub. 182, p. 4).

The Commission's view

The Commission notes that Australia's system of poisons scheduling is of long standing, and was the original means of regulating medicines. Its structure and processes are familiar to those in the industry.

Support for intermediate schedules between prescription only and open sale rests on the argument that because pharmacists can be involved in consumers' selection and use of non-prescription drugs, such schedules increase the range of drugs available for self medication and reduce drug misuse. Health care costs are reduced if there are fewer visits to doctors for conditions that could be self diagnosed and treated under the supervision of a pharmacist.

Consequently.. the counselling role of the pharmacist is the most important characteristic of schedule 2 and schedule 3. If the pharmacist provides the required level of advice, retention of the intermediate schedules can be justified.

FINDING

The Commission finds that the counselling role of the pharmacist is the dominant consideration in relation to schedules 2 and 3. If such counselling can be shown to contribute to the quality use of medicines and improved health outcomes, then the current scheduling categories are justified.

Recommendation 15.1

The Commission recommends that both schedule 2 'pharmacy only' and schedule 3 'pharmacist only' be retained, pending further research into the role of pharmacist counselling in ensuring improved health outcomes and the monitoring of the extent of such counselling.

15.3.3 Rescheduling

Products can be rescheduled (or 'switched') from one schedule to a less restrictive schedule if they are shown over time to meet the criteria for the less restrictive schedule.

Rescheduling from prescription to OTC (usually schedule 4 to schedule 3) is driven by fiscal pressure, consumer demand, availability of safe and effective prescription drugs which are 'ripe' for switching, and lobbying by the pharmaceutical companies.

Rescheduling may provide companies with:

- greater control over price;
- access to a larger market; and
- in the case of schedule 2, access to product advertising.

Some Governments encourage rescheduling as a means of reducing national health budgets, as prescription products are often subsidised while OTC products are not.

Participants' views

The PMAA noted cost savings and efficiency benefits from greater access to OTC products through rescheduling:

From the viewpoints of costs (both private and public) and of efficiency, it would be consistent with public policy objectives to reduce health-care costs, if people had the widest possible access to OTC products and if as many such products as possible were available. Provided public health and safety are not at risk, 'switching down' to OTC status of some prescription products makes economic sense (sub. 71, p. ii).

SmithKline Beecham would like to see the definition of products suitable for OTC listing expanded:

It is the objective of [SmithKline Beecham's] Consumer Healthcare division to extend the definition (as understood by Government and healthcare professionals) of responsible self-medication to include the maintenance and control of chronic conditions in addition to its historic definition of symptomatic relief of self-limiting ailments (sub. 13, p. 33).

In contrast, the Pharmacy Guild expressed concern at the 'growing trend toward de-scheduling and downgrading of drugs' from pharmacy only to open sale:

... which may initially result in a lower direct cost but lead to higher social and community costs in the longer term (sub. 53, p. 5).

However, the Guild did suggest there could be greater flexibility in rescheduling drugs from prescription to schedule 3 status. It argued that several drugs currently listed as schedule 4 drugs could be switched to schedule 3 to increase consumer access while at the same time maintaining the provision of professional supervision and advice in the pharmacy (sub. 126, p. 4).

Sigma had concerns about the trend toward rescheduling:

Such a move will result in many patients self-medicating inappropriately thereby delaying proper professional attention. There is also a move to completely deregulate long standing staple medications previously the subject of professional advice. If left uncontrolled this could substantially add to overall health costs (sub. 19, p. 7).

Recent trends in rescheduling

In recent years a number of major drugs, previously available on prescription only, have been made available from pharmacists (see Table 15. 1).

Table 15.1: Major drugs now available over the counter

<i>Description</i>	<i>Drugs^a</i>
Non-sedating anti-histamines	Teldane, Claratyne, Hismanal
Non-steroid anti-inflammatory drugs	Nurofen, Actipufen, Act-3
Anti-fungal creams (topical, oral and/or vaginal)	Daktarin, Gyno-daktarin, Canesten, Lotremin
Haemorrhoid ointment	Proctosedyl
Anti-fungal shampoo for dandruff	Nzoral
H2-receptors for treatment of peptic ulcer	Tagamet, Zantac, Pepcidine, Amfamox
Asthma relieving spray	Ventolin

a Drugs are scheduled by chemical name but are here identified by brand name
Sources: *Courier-Mail* 5 February 1996, p. 27; *BRW* 12 February 1996, p. 76

However, the PMAA regarded decisions to move drugs from schedule 4 to less restrictive schedules as relatively slow in Australia:

PMAA considers that it is time Australia moved closer to world practice and released further products for OTC sale. Overseas experience shows that this is sound in terms of social and economic policy, as well as being a safe path to follow (sub. 71, p. ii).

Table 15.2 illustrates how a number of medicines available as OTCs in other parts of the world are restricted in Australia. Australia appears to be closest to Canada, with slightly less restrictive requirements for some products (Topical Benzoyl Peroxide and Naproxen). Many substances appear to be less restricted in the UK and New Zealand. The PMAA noted that, in addition, more restrictive conditions, such as pack size and/or strength and/or route of administration, are also placed on schedule entries in Australia (sub. 71, p. 19).

Rescheduling criteria

The Australian NDPSC *Interim Guidelines for Applications for Scheduling of Drugs* list a number of 'criteria' to be met and 'factors' to be taken into account when re-scheduling is considered. However, the criteria are expressed as absolute, and there is no indication of the relative weightings given to the various 'factors'.

For example, the guidelines require at least two years of local clinical use and post marketing experience before consideration can be given to the re-scheduling of a prescription drug to OTC, or the rescheduling of a drug from schedule 3 to schedule 2. Exceptions to this requirement will only be considered when 'a strong public health need for the drug to become available without prescription, within that two year period, can be clearly demonstrated and where safety concerns are addressed adequately' (NDMAC 1994, p. 2).

SmithKline Beecham stated that this two year waiting period is very restrictive and causes unnecessary delays especially when the drug has been available overseas for many years with evidence of safe and effective use (sub. 13, p. 33).

Schering-Plough provided the example of its application to reschedule Claratyne tablets. Despite extensive safety data and OTC availability overseas since 1988, the NDPSC enforced the requirement for two years local marketing on prescription (sub. 128, p. 6).

In addition, in Australia, the onus is on companies to argue the case for switching. In contrast, in both the UK and New Zealand Government initiated programs of review of the schedule status of 'prescription only' medicines have been undertaken.

Table 15.2: Availability of certain medicines, Australia and selected comparable countries

<i>Substance</i>	<i>Therapeutic Category/common use</i>	<i>Australia</i>	<i>Canada</i>	<i>UK</i>	<i>NZ</i>
Acyclovir Topical	Anti viral-herpes simplex	S4	S4	S2	S3
Amphotericin Buccal	Antibiotic, anti-fungal-mouth conditions	S4	S4	S4	S3
Benzoyl Peroxide Topical 5% or less 10%	pimples, acne	S2 S3	S2 S4	S2 S2	GSL S3
Clindamycin Topical	Antibiotic-acne	S4	S4	S4	S3
Hydrocortisone Topical 0.5% 1.0%	Anti inflammatory, anti itch-range of skin conditions	S3 S4	S2 S4	S2 S2	S2 S3
Ibuprofen Oral	Anti inflammatory	S2	S2	S2 GSL (Packs 18 tabs)	S2
Ketoprofen Oral Topical	Anti inflammatory	S4 S4	S4 S4	S4 S2	S3 S2
Minoxidil Topical	Baldness	S4	S4	S2	S3
Naproxen Oral	Anti inflammatory	S2	S4	S4	S3
Nicotine Patch Gum	Smoking cessation	S4 S3	S4 S3	S2 S2	S3 S3
Piroxicam Topical	Anti inflammatory	S4	S4	S2	S2
Silver Sulphadiazine Topical	Antibiotic-wounds/burns	S4	S4	S4	S2
Triamoinalene Buccal	Anti inflammatory-mouth conditions	S4	S4	S2	S3

Notes: Equivalent Australian symbols have been used: S4-prescription only; S3-pharmacist only; S2-pharmacy only; GSL-general sale (for example, supermarkets).

Source: PMAA sub. 71, p. 20

The NDMAC developed a framework for identifying the costs and benefits of switching from prescription to OTC (see Table 15.3).

Table 15.3: Costs and benefits of switching from prescription to OTC

<i>Perspective of analysis</i>	<i>Costs</i>	<i>Benefits</i>
Government	administrative costs of switching ongoing prescriptions	reduced visits to physicians drug subsidy savings reduction in other health care costs
Consumer	increase in adverse effects masking of symptoms leading to increased morbidity out of pocket OTC expenses	reduction in physicians visits reduced drug costs (if OTC cheaper than prescription) increased autonomy
Health care provider	loss of fee for service income	more effective resource allocation
Pharmacist	increased time educating consumers	increased OTC sales
OTC industry	regulatory costs costs of marketing	increased OTC sales

Source: NDMAC 1994, pp. 41-43

The Commission's view

The Commission considers that there may be scope for efficiency and health gains through measures to reduce marketing restraints on those drugs with acceptable safety and familiarity levels.

However, the Commission considers that in deciding scheduling and switching questions the regulatory authority should adopt a more explicit cost benefit approach. Costs and benefits should be defined broadly, along the lines proposed in the NDMAC study (the Guideline 'factors' already encompass many of these broad costs and benefits). Such an approach would be consistent with the application of COAG principles.

Application of these principles requires the clear specification of the criteria used to schedule drugs and their consistent application. Drugs that meet the requirements of a schedule should be placed on that schedule, not on a more restrictive schedule as a conservative transitional measure.

In particular, the Commission considers that the rigid application of the 'two year rule' has caused unnecessary costs to Government, community and industry, and decreased consumers' opportunities for appropriate self-medication. The wider implications of delays in rescheduling do not appear to have been taken into account in the blanket imposition of the rule.

For example, in the Schering-Plough case of Claratyne, approximately 712 000 prescriptions were dispensed between their launch in April 1992 up to the rescheduling to schedule 3 in December 1994 (correspondence 3 April 1996). If each prescription required an appointment with a general practitioner at the standard schedule fee of \$24, this amounts to a total cost of over \$17 million. A large proportion of these visits may have been avoided if Claratyne had been available as an OTC.

FINDING

The Commission finds that the requirement for two years Australian marketing before rescheduling will be considered is applied too rigidly without due regard to evidence of overseas use and economic costs and benefits.

15.4 Labelling and advertising

Consumers need information and advice on which to base their self-medication decisions. Labelling and advertising are two of the major sources of information on diseases and their treatments.

15.4.1 Labelling

Many Commonwealth and State regulations control a label's content. These arrangements have been criticised on several grounds:

- their complexity and lack of uniformity; and
- a tendency, to be overly prescriptive.

The issue of 'corporate packaging' has been raised in the course of this Inquiry. The Pharmaceutical Society of Australia noted that:

... during the last 12 months at least five major pharmaceutical manufacturers have g adopted a corporate style of packaging. ... This has resulted in each company's individual products being almost identical in appearance (PSA 1995, p. 5).

The Commission's draft report into Packaging and Labelling found that such problems would be better addressed if regulation stated its objectives in terms of performance outcomes. The Commission draws attention to that Inquiry's recommendation in relation to packaging and labelling requirements (see Box 15. 1).

Box 15.1 Industry Commission Packaging and Labelling Inquiry recommendation

Packaging and labelling regulation (including primary legislation) should be drafted in terms of general objectives or outcomes which producers are required to satisfy, rather than in terms of specific prescriptive standards.

In addition, regulatory authorities should have the capacity to make regulations which deem specific prescriptive standards to comply with the general objectives.

Source: IC 1995b, p. 95

15.4.2 General advertising issues

As discussed in Chapter 3, advertising is extensively regulated. The form and nature of the regulation is dependent upon several factors including a drug's schedule, the intended audience and the advertising medium. Advertising to health professionals is subject to less stringent control than advertising to consumers. The general issue in relation to advertising of pharmaceuticals to consumers is finding the appropriate balance between providing information and inappropriately stimulating demand.

The DSHS agreed that a balance was necessary:

The issue of advertising is a difficult one. It raises the problem of a clash between the general principle of freedom of expression and the obligation upon governments to protect people from injurious consequences of unrestricted expression of view (Lindenmayer 1995, p. 10).

On the other hand, the PMAA summarised the position of many companies as seeking a balance between information and promotion within advertising rather than addressing the question by banning advertising altogether (roundtable, pp. 182-183).

Arguments against advertising

Some participants opposed advertising of pharmaceuticals. They expressed concern that drugs were not 'ordinary items of commerce' and that advertising would impair the quality use of medicines. Several arguments were raised.

First, advertising may lead to inappropriate demand for some drugs. For example, the Pharmacy Guild argued:

Marketing of ordinary items of commerce is characterised by price and promotion vigorous advertising of price differentials, or by advertising quality or exclusivity. The aim of such activity is to maximise sales and profits.

The Guild believes advertising or promotion intended to increase consumption of potent therapeutic substances is totally inappropriate and irresponsible (sub. 53, p. 2 1).

Second, advertising may not adequately inform consumers. The DSHH stated:

Although it may convey information, its ultimate purpose is to make the public want a product rather than be comprehensively and accurately informed about it.

... Product advertising is not a reliable way to educate consumers. Education will be better achieved by consumer product information (sub. 153, p. 25).

Third, advertising favours the use of particular drugs, not necessarily the most appropriate treatments. The Medical Lobby for Appropriate Marketing (MALAM) argued that 'advertising leads not only to high consumption levels but also favours the use of particular drugs, those which are the most advertised' (sub. 135, p. 2).

Fourth, consumers were concerned about the persuasive power of advertising. The CHF argued that although consumers want access to information, they are wary of being influenced by advertising:

The consumer position about advertising varies. There is no doubt that we want the information ... but we want that in a context of making a choice about using a medicine and how to use it (roundtable, p. 186).

Finally, participants were concerned about the potential effect on the relationship between health professionals and consumers. AHMAC stated:

Advertising can shift the balance in the relationship between a patient and their professional carer. Modern advertising techniques can be so persuasive that they can displace professional advice in favour of an opinion engendered by advertising (sub. 99, p. 16).

The Society of Hospital Pharmacists of Australia stated that brand specific advertising would increase pressure on health professionals and 'undermine the professional process of selection of appropriate over the counter preparations by pharmacists' (sub. 155, p. 2).

Arguments in favour of advertising

On the other hand, some participants suggested that advertising can contribute to the quality use of medicines.

AMRAD argued that 'the advantages to the consumer of pharmacist only OTC products for self diagnosed conditions can only be realised for the Government and industry if the advantages can be communicated to the consumer' (sub. 165, p. 7).

Some participants criticised the conservative approach to advertising adopted by the regulators. The Advertising Federation of Australia stated that arguments

against advertising reflect a paternalistic view held by some medical practitioners towards their patients. It suggested that patients want to be better informed and to take responsibility for their health (sub. 107, p. 8).

Marion Merrell Dow stated:

The failure of the authorities to allow advertising of S3 products or products implies more of a mistrust of the public than it does a mistrust of the companies. I would suggest that [it implies] very strong 'People cannot look after themselves, we have to look after them' (roundtable, p. 188).

The Coalition for Healthcare Communication in the US recently proposed a broad overhaul of Food and Drug Administration (FDA) regulation of pharmaceutical marketing and advertising, and stated that the FDA's argument that 'advertising claims could jeopardise the public health':

...believes an underlying bias which views American industry as exploitative and short sighted and American physicians as credulous or lacking in professional judgement (Scrip, 22 September 22 1995, p. 15).

Impact of advertising on demand for medicines

There is little data about the act of advertising on consumer demand for pharmaceuticals, and its broader impact on health outcomes. Consequently, it is difficult to establish whether advertising increases overall demand for pharmaceutical products, or encourages existing consumers to switch between products.

Boots compared per capita consumption of schedule 2 analgesics and advertising expenditure from 1989 to 1995. It noted that significant advertising activity took place during that period, such as the launch of Setamol and Nyoprin 1989, the launch of Tylenol in 1990 and the introduction of Panadol gel caps in 1992. In 1994 advertising expenditure actually dropped by \$5 million. However, despite these activities, consumption remained at 'around three packs per annum per head, regardless of what advertising was occurring'. Boots commented:

I don't think there is any logic in the proposition that people will [consume] more analgesics simply because they are advertised (transcript, p. 1116).

Boots also discussed the act of advertising on its product Nurofen, an analgesic containing ibuprofen. Ibuprofen was rescheduled from schedule 3 to schedule 2 on 22 December 1995. This meant that for the first time, it was permitted to advertise this product to consumers.

Boots noted that prior to the introduction of advertising, Nurofen's market share was 6.4 per cent. Its share at March 1996 was 14.8 per cent while a number of the smaller brands lost share. A recent survey of 13 pharmacies showed that, in

January 1996, compared with December 1995, 390 additional Nurofen packs were sold and 177 less Panadol and Panadeine packs (the market leaders) were sold. Boots concluded that the impact of its advertising was to induce consumers to switch from other analgesics to Nurofen rather than to create new demand:

I think it's reasonable to assume that although Nurofen is doing extremely well, it is not expanding the market hugely (transcript, p. 1118).

A second issue is whether any increased demand reflects some sort of 'excess consumption' with potentially harmful health outcomes, or whether it represents appropriate self-medication by better informed consumers. The Commission has not received evidence of significant research into this issue. Some companies offered anecdotal reports.

For example, Schering-Plough referred to case histories of advertising in New Zealand of products which it is not allowed to advertise in Australia. It believed that the lack of reported adverse events in New Zealand indicated that advertising had not led to adverse health outcomes:

Though the adverse event reporting system is not perfect and though the monitoring system is not perfect we have to believe that the absence of any deleterious consequence over these years must be indicative of something (roundtable, p. 189).

The Commission's view

The Commission considers that notwithstanding continuing controversy, there has been little formal research undertaken into the impact of advertising pharmaceutical products on the quality use of medicines.

FINDING

The Commission finds that there is insufficient information about the impact of advertising of pharmaceutical products, particularly brand advertising of over the counter products, to adequately assess the health outcomes of such advertising.

15.4.3 Self-regulation

As well as State and Commonwealth Government restrictions on advertising, the pharmaceutical industry and advertising media self-regulate advertising. It is argued that, if Government advertising restrictions were relaxed, these self-regulatory mechanisms could be extended to provide a measure of consumer protection. For example, the PMAA argued that maintaining high standards was in the industry's own interests:

We understand that representations to the public must be responsible and even cautious. No margin for dissimulation can be permitted. Indeed it is not in tile industry's interest, any more than the consumer's, for any standards other than the highest to be observed (sub. 71, p. 3 2).

Advertising to consumers

The Therapeutic Goods Advertising Code of the Media Council of Australia applies to the content of advertisements submitted for publication or broadcast by its members and is applied in conjunction with the Advertising Code of Ethics. The object of the code is to ensure responsible advertising of OTC products to the general public. This code does not cover advertising to health care professionals.

Under the Code, all advertisements are subject to prior clearance before publication or broadcast. The *Broadcasting Services Act 1992* requires advertisements proposed for broadcast on commercial radio or television to be cleared by the PMAA (acting as a delegate of the Health Secretary) before submission to the designated clearance body.²

As well as acting as the delegate of the Health Secretary for clearance of advertisements for medicines in the broadcast media, the PMAA administers a voluntary Code of Practice Regarding Advertising and Promotion of Non-prescription Medicines. Acceptance and observance of the code are binding conditions of membership of the PMAA. The PMAA Code extends beyond the Media Council code to cover all forms of promotional activity (for example, point of sale promotions) and includes promotion to health professionals. However, unlike the Media Council Code, it does not require pre-vetting, but rather, responds to complaints.

In 1994-95, a total of 13 complaints were received. They were concerned with the advertising practices of PMAA members and non-members, and covered promotional practices aimed at disputed product claims. Some were referred to the TGA as potential breaches of the Therapeutic Goods Act, while others were resolved satisfactorily by companies agreeing to abide by PMAA determinations.

² The designated media clearance bodies are the Federation of Australian Commercial Television Stations, The Federation of Australian Radio Broadcasters Limited, Australian Publisher's Bureau, The Outdoor Advertising Association of Australia Incorporated and the Australian Cinema Advertising Council. The review body is the Therapeutic Goods Advertising Code Council and the appeal body is the Advertising Standards Council.

in its role as pre-clearance delegate, the PMAA has not had any approvals challenged through the Advertising Standards Council. One advertiser appealed PMAA's refusal to approve an advertisement, and the appeal was dismissed. The delegation to the PMAA was reviewed in July 1995. This review concluded that 'it appears the delegation continues to operate in a satisfactory manner' (TGA correspondence 20 July 1995).

Advertising to professionals

The APMA administers a voluntary code of conduct in relation to the promotion of prescription products to health professionals. Acceptance and observance of the code is a condition of membership of the APMA.

In 1994-95 the APMA Code of Conduct Subcommittee received nine complaints from Government bodies, 18 from members of the APMA and six from external parties.

Of the 33 complaints considered by the subcommittee, 13 were found to not be in breach of the Code, and 20 were found to be in breach. The Code of Conduct Appeal Subcommittee heard four appeals, of which one was dismissed, one upheld, and two partially upheld.

There have been two external reviews of this code. The first was the 1992 Health Action International evaluation of Codes of Conduct against the World Health Organisation (WHO) ethical criteria for medicinal drug promotion. The APMA code scored the highest rating in an international comparison of a number of countries' Codes of Conduct. The second review, undertaken by the Trade Practices Commission in 1992, gave positive acknowledgement to the scope, operation and administration of APMA's Code of Conduct (sub. 31, p. 21).

The Trade Practices Commission has authorised the Codes of Practice for the promotion of drugs developed by the APMA and PMAA (AHMAC, sub. 99, p. 16).

Arguments against self-regulation

Despite the small number of complaints about promotional activities, the effectiveness of self-regulation was questioned by some participants. The Victorian Government stated that 'further research is required into ... the self-regulation performance of the industry' (sub. 182, p. 4).

The CHF stated that, if advertising to consumers of schedule 3 products were allowed, it would not support self-regulation alone. The CHF argued for the establishment of effective co-regulation through a combination of self-regulation, which incorporates consumer involvement and public reporting to

make it transparent and accountable, and underpinning regulation, based on the relevant sections of the Industry Code of Conduct (sub. 139, p. 5).

The Commission's view

The Commission considers that while it may be possible to legislate satisfactorily for the testing, manufacture and control of medical products, appropriate standards of marketing conduct are more difficult to define. For this reason, self-regulation of promotional activities through industry codes of conduct can provide more appropriate controls than Government regulation. Where greater control than that provided by voluntary codes is regarded as necessary, mechanisms such as the delegation of the Health Secretary's pre-clearance power to the PMAA provide for flexible co-regulation between Government and industry.

FINDING

The Commission finds that current arrangements for the self-regulation of the promotion of pharmaceutical products appear to be working well in most cases.

15.4.4 Advertising of schedule 3 products

At present products containing schedule 3 substances cannot be advertised to consumers by brand name, although some 'indirect' or 'generic' advertising to consumers is allowed.

As discussed above, there are two opposing views of the impact of advertising of schedule 3 products. One sees advertising primarily as a source of information about the availability of products, while the other fears advertising will create 'irrational' demand, leading to increased cost and potentially adverse health consequences.

Many participants were wary of relaxing existing restrictions on advertising of schedule 3 products to consumers. For example, current CHF policy is to oppose such advertising (sub. 139, p. 5). MALAM argued that there was no evidence that schedule 3 products were under-utilised, and that advertising would lead to overuse (sub. 135, p. 2).

The Society of Hospital Pharmacists strongly opposed the deregulation of advertising of drugs, and argued that 'drug companies cannot be relied upon to act responsibly in regard to advertising because of their primary desire to create demand and increase sales' (Society of Hospital Pharmacists correspondence 23 February 1996).

In addition, it was argued that advertising of S3 products may have an adverse effect on the pharmacist/consumer relationship. The DSHS stated:

... the advertising of S3 products could make it difficult for the pharmacists to undertake their functions responsibly and increase the chances of mis-medication (sub. 153, p. 25).

The Pharmacy Guild recommended that 'any move to increase consumer information concerning such products should be educational in nature' (sub. 53, p. 3).

However, other participants recommended that greater advertising to consumers be permitted. For example, the PMAA characterised the issue as a matter of consumer's rights:

Only with a full and free interchange of information will the consumer's rights be fully advanced. As things stand, people have very little information about the range of OTC products which is available (sub. 71, p. 32).

Parke Davis also argued that advertising restrictions prevent consumers from knowing about schedule 3 products. It contrasted these restrictions with a 'society...moving toward self-determination and the right to know' (sub. 121, p 8).

The current situation

Revision of advertising controls to permit the advertising of schedule 3 drugs to the public has been considered recently in the House of Representatives Standing Committee on Community Affairs Report (1992a) and a Trade Practices Commission Report (1992). Both these bodies recommended that the prohibition on the advertising of schedule 3 products to the public be maintained.

The DSHS also supported current restrictions, but agreed they should be subject to review:

[there is] a persuasive case for continuation of restrictions on the advertising of certain products. That, however, does not suggest that all of the existing array of products which cannot be currently advertised should continue to be excluded - nor that the current form of advertising controls should remain precisely as they are (Lindenmayer 1995, p. 11).

Indirect advertising

Recently, APAC has supported indirect advertising of some schedule 3 product groups in accordance with the PMAA code on a case by case basis (sub. 137, p. 3). The Advertising Federation of Australia provided several examples of such programs supported by health bodies (see Box 15.2).

Box 15.2: Public information campaigns

The Advertising Federation of Australia provided the following examples of public information campaigns supported by health bodies:

- the Ciba-Geigy campaign to quit smoking-endorsed by the St Vincent's Hospital addiction unit;
- the allergy campaign by Marion Merrell Dow-endorsed by the Road Traffic Authority;
- the Wellcome campaign for herpes awareness-endorsed by the Sexual Health Clinic; and
- the Glaxo/A&H campaign 'Could it be asthma'-endorsed by the Royal Australian College of General Practitioners and the Thoracic Society.

Source: The Advertising Federation of Australia sub. 107, p. 2

Although often sponsored by companies, these public information campaigns do not mention a particular product or brand, but refer the consumer to their doctor or pharmacist for information and treatment, if warranted.

Brand advertising

It is argued that indirect advertising of schedule 3 products may be so indirect as to not adequately inform consumers about the product. For example, the Asthma Foundation observed that brand names are often the 'language of the market', and if they cannot be used, it is difficult to convey a meaningful message:

We have to talk about reliever and preventer medication. It always bothers us enormously, do people really know what we're talking about? But we of course are not allowed to name the drugs (roundtable, p. 152).

Marion Merrell Dow and Schering-Plough (roundtable, p. 180) gave the example of generic advertising for non-sedating antihistamines:

... not only couldn't we mention the brand, we couldn't mention the drug, we couldn't mention the therapeutic category ... many people thought it was an ad for tyres because it was somebody in a car (Marion Merrell Dow roundtable, p. 179).

In addition, there may be only a limited incentive for companies to advertise generically if there is a danger that competitors in the same therapeutic class may be able to 'free ride' on their advertising, because it is not brand specific.

The Commission's view

As a general principle, the Commission considers governments should avoid placing restrictions on peoples' access to information, particularly information of a generic nature such as the existence of a new treatment for a disease state or the development of a new class of therapeutic products. Indeed, information bans are one area where clear justification of regulation and close monitoring of its results are particularly important.

The Commission considers that, on balance, the APAC case by case approach to indirect advertising represents an appropriate compromise between providing information and fears of creating 'irrational' demand. As the present schedule 3 contains drugs with a wide range of safety concerns, there is no strong rationale for the retention of close links between the schedule and a blanket restriction on advertising to consumers. It is clear that some schedule 3 products should not be advertised, but the indirect advertising to the public of other schedule 3 products is likely to have public health benefits.

The Commission notes that substantial self-regulatory controls of advertising exist and trade practices legislation provides additional protection for consumers and aggrieved competitors.

FINDING

The Commission finds that for schedule 3 products, the current case by case approach to allowing indirect advertising is likely to lead to better informed consumers and improved health outcomes.

Previous decisions not to allow brand advertising of schedule 3 products largely rested on the argument that it was not possible to make a blanket recommendation on advertising for the entire schedule. For example, in relation to the Jenkins Report, the TGA stated:

In 1992 the ... Jenkins report ... came to the decision that because [schedule 3] was such a diverse range of products one couldn't make any blanket recommendation about advertising them, and in fact their position was that, because it was not possible to distinguish among them because of the range, that the wisest move was to maintain the prohibition (transcript, p. 866).

However, once the direct link between the schedule and advertising restriction has been broken, as has now occurred with indirect advertising, the question of allowing appropriate brand advertising for some schedule 3 products arises.

It should be possible to assess on a case by case basis not only whether a particular schedule 3 product is suitable for indirect advertising, but also whether it may be allowed to advertise by brand name. Such decisions should

be based on an assessment of the likely effect on health outcomes of such advertising.

The Commission acknowledges that there is as yet little information available on the health outcomes associated with any increased demand caused by advertising, particularly brand advertising. The evidence presented to the Inquiry is unclear on whether the ban on the brand advertising of schedule 3 drugs to the public has generated benefits by preventing promotions which might have brought about excessive consumption levels.

Companies that wish to relax current restrictions on brand advertising of pharmaceutical products should take the lead in further research into the impact of advertising of pharmaceutical products on health outcomes. Such research could include studies of the impact of advertising in those overseas countries where it is permitted.

If, in the future, brand advertising of schedule 3 products is allowed, it should be subject to appropriate restrictions.

FINDING

The Commission finds that, in some circumstances, there are limits to the usefulness of indirect advertising of schedule 3 products and public health benefits may be lost because consumers lack adequate information on which to make self-medication decisions. In such circumstances brand advertising may be justified.

Recommendation 15.2

The Commission recommends that, where it can be demonstrated that brand advertising of particular schedule 3 'pharmacist only' products will lead to improved health outcomes, such advertising should be permitted on a case by case basis, subject to appropriate industry self-regulation.

15.4.5 Advertising of schedule 4 products

In its Draft Report, the Commission called for views on the need for restrictions on advertising to consumers of schedule 4 products, and under what conditions, if any, such advertising should be allowed.

The great majority of participants rejected advertising schedule 4 products to consumers except in the limited circumstances where current restrictions on advertising of prescription products do not allow sufficient information to reach consumers in public health campaigns.

For example, The Royal Australasian College of Physicians supported the restriction on advertising to consumers of schedule 4 drugs, although there 'should possibly be a mechanism for exemptions to be given, for example for advertising the availability of vaccines' (sub. 140, p. 2). CSI, supported the advertising of selected schedule 4 products such as vaccines for public health programs:

This would be in the community interest given the inadequate level of vaccine uptake which currently exists in Australia (sub. 118, p. 13).

MALAM noted that the ethical criteria on drug promotion adopted by the WHO in 1988 state that advertisements to the general public 'should not generally be permitted for prescription drugs or to promote drugs for certain serious conditions that can be treated only by qualified health practitioners'. However, the criteria allow for exemptions on public health grounds (sub. 135, p. 3).

Some participants took a broader view of the potential for advertising of schedule 4 products. The APMA considered that 'a less patronising view of consumers should be adopted in relation to the Government restrictions on the advertising of prescription products' although it recognised that 'such advertising must enhance, rather than detract from the doctor-patient relationship' (sub. 119, p. 16).

The Advertising Federation of Australia argued that direct to consumer advertising of medicines, including prescription drugs, can address high risk groups and urge them to seek appropriate treatment by a doctor. It identified several major underdiagnosed/undertreated or preventable diseases in Australia, including: cardiovascular disease; hypertension; high cholesterol; diabetes; cancer; and HIV/Aids. The Federation concluded that there is a public need for information on symptoms, prevention and treatment, and that cost savings to the community can be obtained with early medical treatment (sub. 107, p. 4).

The TGA and the National Coordinating Committee on Therapeutic Goods recently proposed a two year trial period allowing advertising to the public of the availability of prescription medicines for certain medical conditions in the interests of public health. The APMA noted that this did not extend to all areas or to the advertising of all prescription products. The APMA is currently involved in discussion with the TGA on the advertising to the general public of the availability of a broader group of pharmaceutical medications under the auspices of the APMA's Code of Conduct (sub. 119, p. 16).

The Commission's view

Once again the Commission notes the lack of research into the impact of advertising of prescription pharmaceuticals on health outcomes. However, it

considers that if such research were undertaken, and these studies showed that advertising of particular classes of schedule 4 products will lead to improved health outcomes that indirect advertising should be permitted. Such permission should be granted on a case by case basis.

However, the Commission considers that direct advertising of prescription products to consumers is not as important as for schedule 3 products. Under current regulations companies may advertise prescription products directly to health professionals who act as 'gate keepers' to these products. In addition, company representatives (detailers) may promote drugs directly to health professionals.

FINDING

The Commission finds that, where appropriate marketing and health outcome studies show advertising of particular classes of schedule 4 products will lead to improved health outcomes, that indirect advertising on a case by case basis, subject to appropriate industry self-regulation, may contribute to improved health outcomes.

15.5 Streamlining drug approval and scheduling

Many of the more fundamental concerns about current scheduling arrangements could be addressed by streamlining drug approval and scheduling arrangements.

15.5.1 Combining drug approval and scheduling

Drug evaluation and scheduling are closely related, but separate, processes for the control of access to drugs. Many Inquiry participants commented on the scope for their integration. For example, the PMAA observed:

The fact that, in Australia, there are two sources of Authority for the classification ('scheduling') of medicines creates unnecessary complications and overlaps:

- The scheduling system relates to 'substances' and the registration system to 'products'.
- Scheduling derives its authority from State legislation; registration from the Commonwealth.
- Scheduling relates to 'poisons' which are not confined to medicines; registration relates to therapeutic goods alone (sub. 71, p. 12).

In its response to the Draft Report the PMAA stressed that:

The dichotomy of control between TGA (in relation to product registration/listing) and SUSDP and the States (in relation to substances scheduling) remains the most important issue for the OTC industry (sub. 120, p. 3).

The proposal to integrate scheduling within registration processes is a fundamental condition precedent to the removal of regulatory impediments now affecting the OTC industry (sub. 120, p. 5).

Schering-Plough regarded this as a fundamental issue:

The fundamental question is why should scheduling and evaluation be conducted separately by two different bodies? Why can't they be conducted by one body at the same point in time in the pursuit of efficient regulation and timely regulation? (roundtable, p. 143).

APAC considered that 'it is not ... necessary to continue the separation of State and Commonwealth legislation (sub. 137, p. 5). The TGA proposed to a 1993 DSHS review that the scheduling of drugs be separated from that of other substances and that the TGA assume responsibility for the administration of the drug scheduling system (TGA, sub. 16, p. 3).

In 1994, the APMA, the PMAA and the PSA submitted a *Proposal for Medicines Scheduling*. In brief they suggested:

- Separation of decision-making process for therapeutic goods from all other poisons.
- A Medicines Scheduling Committee with Commonwealth/State, New Zealand, industry and consumer representatives.
- Due process for consideration of applications, hearing of appeals, etc (sub. 71, p. 64).

However, not all participants agreed that integrating registration and scheduling was appropriate. State Governments in particular opposed the proposal, and argued that the States should retain control of scheduling.

The Victorian Government agreed that there is scope for streamlining of scheduling and registration, but it is our view that these activities should not be combined. Decisions with regard to scheduling of a substance need to be made prior to applications for registration of products containing the substance (sub. 182, p. 4).

The Tasmanian Department of Community and Health Services argued that the registration of products was fundamentally different to the control of substances through scheduling, and that scheduling, 'must be owned by those who implement the controls ... The States ... carry that responsibility' (sub. 112, p. 4). It saw:

... difficulties in combining registration of products to any great extent with the regulation of drug distribution. There may be difficulties in reconciling in one system the two objectives of:

-
- the safety, quality and efficacy of products (tangible, based on physical sciences); and
 - the distribution of drugs in a way that prevents accidental or intentional misuse (behavioural) (sub. 112, p. 5).

Similarly, the Pharmacy Board of Victoria stated 'there is scope to reform the process of scheduling, but does not support the view that the TGA should be expected to combine product registration and scheduling procedures'. It felt the TGA lacked the necessary expertise to undertake scheduling (sub. 114, p. 5).

AHMAC argued that the NDPSC has made significant progress in streamlining the scheduling process and has begun changes to eliminate overlap between the scheduling and registration processes. It stated that:

Following an independent review ... in 1994, AHMAC agreed that the scheduling process would be streamlined and its procedures codified in operational guidelines. These are being developed with the assistance of industry and consumer representatives. The guidelines on administrative aspects, including communication with and making applications to NDPSC, scheduling and rescheduling of drugs and poisons, appeal procedures, confidentiality and public consultations will be available for public comment shortly. They will take the COAG principles into account (sub. 152, p. 3).

The Pharmacy Guild acknowledged that the streamlining of the registration and scheduling process would hasten the availability of new products for consumers and reduce the time lag for companies between the production and sales of these products. However, it argued that the present system of having two separate bodies provides checks and balances in regulating the availability of products for consumers (sub. 126, p. 3). The Society of Hospital Pharmacists of Australia expressed similar views (sub. 155, p. 2).

The Commission's view

The Commission considers that pre-market evaluation of pharmaceuticals is closely linked to scheduling. It notes that other countries, such as the UK and New Zealand, have adopted a streamlined approach.

The persistence of current arrangements seems to have more to do with the retention of traditional divisions of Commonwealth and State powers than the efficient regulation of pharmaceuticals.

The Commission considers there are sound reasons for unifying the registration and scheduling processes. In particular:

- as scheduling and registration decisions are essentially about the management of risk, consistent decision criteria would reduce the costs of delay, lack of uniformity and errors; and

-
- drugs are different to other poisons and require careful consideration of risk/benefit trade-offs, including the risks associated with undue restriction of availability.

Moreover, in a unified system duplication is avoided and product sponsors would be able to make a single application for registration and scheduling.

FINDING

The Commission finds that there is considerable scope for streamlining the scheduling and registration of therapeutic goods and for unifying these processes in a single administrative unit.

15.5.2 Options for reform

Draft Report options

In the Draft Report the Commission proposed three options for the reform of scheduling and registration institutional arrangements.

The first option maintained current separation of scheduling and registration, but proposed a new national body with responsibility for scheduling. The quasi-national nature of existing scheduling arrangements (NDPSC/AHMAC) could be recognised formally by creating a National Scheduling Authority, with a structure and role similar to that of other national bodies established cooperatively in recent years.

The second option combined registration and scheduling. The Commission identified alternative ways of doing this:

- a) the Commonwealth and States could implement a cooperative national drug evaluation and scheduling process through the TGA; or
- b) the States could give up their direct role in scheduling, and allow the Commonwealth, through the TGA, to run a combined scheduling and registration process.

A final more fundamental 'option', not directly related to scheduling, was reform of the TGA with or without scheduling responsibilities as an independent regulatory agency. This 'option' is discussed in Chapter 14.

Participants' views

Industry participants who responded to these options generally favoured the combination of registration and scheduling in the TGA. However, as noted earlier, other participants, most notably the pharmacy sector and the States, supported the current separation of scheduling and registration.

The Pharmacy Guild supported the first option, proposing a new national body to give formal recognition to the existing scheduling arrangements (sub. 126, p. 4).

The PMAA favoured the second option, combining registration and scheduling in the TGA through Commonwealth and State Government cooperation:

The Commonwealth and States should implement a cooperative national, uniform (including New Zealand) drug evaluation and scheduling process through the TGA, for example by extending the [National Food Authority of Australia and New Zealand] model to scheduling as well as all TGA's present functions (sub. 120, p. 10).

The APMA also supported the second option, but considered that in order to fully implement national uniformity of scheduling and registration, the States should give up their direct role in scheduling. However, the States would still participate in the development of scheduling objectives and criteria to be adopted by the TGA (sub. 119, p. 13).

The DSHS recommended a system with:

... a single agency such as the TGA undertaking all of the scheduling and registration procedures up to and including marketing approval with local retail inspection and enforcement functions resting with the States. The TGA would continue with its current conformance and compliance roles in relation to general product marketing (sub. 153, p. 20).

The Commission's view

The Commission considers that the most appropriate way of unifying the processes of scheduling and drug approval is for the Commonwealth and States to implement a cooperative national drug evaluation and scheduling process through the TGA (option 2(a)).

As discussed in Chapter 13, the Commission considers that the TGA should become an independent statutory authority. Expanding the TGA's responsibilities to include scheduling, and the need to coordinate State and Commonwealth interests accentuates the need for an independent TGA.

In order to achieve this, a number of practical steps must be taken. These are discussed below.

Necessary steps to combine registration and scheduling

To take on the responsibility for scheduling, the TGA would need to acquire expertise in pharmacy practice and drug use in the community. The Pharmacy Guild argued that TGA officials are experienced administrators equipped to

make registration decisions but not to make decisions about scheduling (sub. 126, p. 4).

Another essential prerequisite to unification will be to separate therapeutic substances from the SUSDP. The sale of non-medicinal poisons remaining on the standard would then be regulated as at present or in conjunction with the national arrangements applying to the particular product group.

The groups of substances currently scheduled in the SUSDP are therapeutic goods, agricultural and veterinary chemicals and industrial chemicals. National arrangements already exist for each of these groups (see Table 15.4). AHMAC noted that the recommendations contained in the SUSDP advise these authorities, as well as State authorities, 'of the restrictions necessary for safe and effective use of drugs and poisons in Australia. This advice includes the context in which substances are to be available and used plus standards for packaging and labelling to facilitate their safe use' (sub. 99, p. 6).

Table 15.4: National arrangements for regulated products

<i>Category</i>	<i>Regulator</i>
Therapeutic goods	Therapeutic Goods Administration
Agricultural and veterinary chemicals	National Registration Authority
Industry chemicals	National Industrial Chemicals Notification and Assessment Scheme
Food additive chemicals ^a	National Food Authority of Australia and New Zealand

a Food additives have been traditionally exempted from scheduling

The National Registration Authority argued that it had been hindered in its activities by the operation of the scheduling process for agricultural and veterinary chemical products outside the National Registration Scheme. It proposed:

... that the existing scheduling system be dramatically overhauled and replaced by a 'scheduling system' that is more in keeping with the legislative requirements and community expectations associated with specific classes of chemicals ... The end result would be a comprehensive regulatory coverage of those chemical classes within existing regulatory structures (sub. 158, p. 5).

Similarly, Worksafe Australia argued that 'the issues of national uniformity and legislative adequacy have arisen for industrial chemicals in ways that are similar to those described in the draft report on the pharmaceutical industry':

... considerable efficiencies could be gained by amending the *Therapeutic Goods Act* 1989 to enable the Therapeutic Goods Administration to control both the

labelling and scheduling of therapeutic substances. Similarly, legislative amendments could enable industrial chemicals to be scheduled under the *Industrial Chemicals (Notification and Assessment) Act 1989* and agricultural and veterinary chemicals to be scheduled under the *Agricultural and Veterinary Chemicals Act 1994* (sub. 208, p. 1).

Where a substance is likely to come under more than one of these authorities (for example a drug with both human and veterinary uses) the Commission considers that it would be appropriate for the TGA to adopt a 'lead regulator' role and facilitate a coordinated approach to its regulation.

Placing responsibility for scheduling decisions on a Commonwealth body does not mean there is no role for the States. This approach would rely on State agencies to enforce scheduling arrangements. State Governments have established administrative mechanisms for the regulation of retail pharmacy and related local drug supply activities. These could continue to operate as the inspectorial arms of a national system.

Moreover, State control over access to medicines in particular circumstances could still be maintained through regulation of the practice of pharmacy and the operation of pharmacies and distributors.

The Commission notes that a rationalisation of roles and responsibilities to streamline regulation and scheduling has been rejected by Health Ministers in the past. However, the Commission considers that a cooperative approach between Governments would offer significant benefits to the industry and consumers and should be pursued.

Recommendation 15.3

The Commission recommends that the scheduling of therapeutic goods become the responsibility of the Commonwealth Government under the Therapeutic Goods Administration.

16 INTELLECTUAL PROPERTY ISSUES

Adequate protection of intellectual property is of fundamental importance for research based industries. Given the high risks and costs involved, pharmaceutical companies rely on a period of patent protection for successful products to secure an adequate return on their total investment in research and development.

This Chapter analyses a number of issues relating to the protection of pharmaceutical intellectual property.

16.1 Protection of intellectual property

Intellectual property rights are of particular importance to the pharmaceutical industry. The Commission's report on Research and Development (R&D) noted:

Intellectual property rights work better for some goods than others. ... In Australia, the sector 'chemicals and drugs' attracts a quantity of patents greatly out of scale with its research effort (IC 1995b, p. 182).

The Government has made specific allowances for pharmaceutical patents in recent times (for more discussion see Chapter 3). In 1987, the Government extended the general 16 year patent period for pharmaceuticals by four years. At the same time it introduced a two year springboarding provision. Springboarding was removed in July 1995 when a standard 20 year patent term for all products was introduced to implement Australia's obligations under the Trade Related Intellectual Property Agreement (TRIPs) as part of the Uruguay round of the General Agreement on Tariffs and Trade (GATT). In 1993 the Government announced its intention to introduce a 15 year effective patent life for pharmaceuticals, although this has yet to be implemented.

Respondents to a 1995 survey by the Australian Pharmaceutical Manufacturers Association (APMA) regarded intellectual property protection in Australia as both a positive and negative factor influencing business development (APMA 1995a). The APMA noted that this partly reflected the heterogeneous nature of the survey sample, which included both research based and generic manufacturers, but also commented that various factors influenced company perceptions.

Positive factors included:

- the extended patent term of 20 years introduced as part of the Government's Pharmaceutical Industry Development Program (now subsumed in the general 20 year patent term under TRIPs); and
- the relative strength of Australia's intellectual property regime and its enforcement compared to other countries in our region.

Negative factors included:

- Australia was seen as lagging behind leading Organisation for Economic Co-operation and Development (OECD) countries in relation to intellectual property protection, particularly in relation to patent term restoration; and
- the question of confidentiality of proprietary data.

The Government promise of an effective 15 year patent term was seen as both positive and negative. Some respondents viewed the prospect of patent term restoration as positive, but others felt that, until it was actually in place, it only contributed to industry uncertainty (APMA 1995a, p. 23).

It is in this context that a number of pharmaceutical patent issues remain to be settled. Participants stressed the need to view intellectual property issues as elements of a 'package' of property rights protection. However, participants have identified the need to address particular elements of this package:

- the appropriate intellectual property protection for pharmaceutical products in Australia;
- whether original patent terms should be restored to compensate for delays in mandatory drug evaluation;
- whether Australia should allow generic 'springboarding';
- appropriate transitional arrangements if changes are made; and
- the appropriate use of confidential information by regulatory authorities.

16.2 Appropriate level of intellectual property protection

A threshold issue is determining the appropriate level of intellectual property protection in Australia. One point of view argues against the extension of intellectual property rights by countries, such as Australia, that are net importers of intellectual property. In such cases, it is argued, most of the benefits of intellectual property rights flow to foreign patent holders. For example, in Australia over 98 per cent of payments to patent holders go to foreign holders.

Australia's position may be contrasted with the situation in the US. It is in the interests of the US to extend intellectual property rights unilaterally, because it is a net exporter of intellectual property.

The Prices Surveillance Authority has observed:

Monopolies granted as a result of intellectual property rights may unnecessarily diminish competition in the Australian market. ... Enhanced intellectual property rights can only adversely affect our terms of trade. It is therefore by no means certain that Australia should always seek to align itself with the first world countries ... which clearly have a vested interest in strengthening intellectual property rights on a global basis (Prices Surveillance Authority 1993 in BIE 1994, p. 47).

The Bureau of Industry Economics (BIE) reached a similar conclusion:

... it does not appear to be in the broad national interest to alter the system in any way that contravenes international conventions and agreements and thus may invoke trade or political retaliations. On the other hand, neither is it in Australia's national interest to pursue the protection of patent rights beyond accepted international norms (BIE 1994, p. 50).

This argument suggests that Australia should extend its intellectual property rights only as part of international negotiations which lead to their global adoption. In such a context, Australia may be able to trade off extended intellectual property protection for other benefits such as trade liberalisation.

However, another point of view argues that, rather than just meeting its strict international obligations, Australia should provide an equivalent level of protection for pharmaceutical patents to that provided by comparable nations. It is argued that the level of intellectual property protection is an important contributing factor to companies' perceptions about Australia's attractiveness as an investment location. For example, the Australian Council of Trade Unions stated that 'to be internationally competitive Australian patent terms for pharmaceuticals need to be ... comparable to other developed countries' (sub. 55, p. 2).

Companies such as AMRAD were concerned that Australia is at risk of 'falling behind' other developed countries with pharmaceutical industries:

Australia is at risk of falling behind other developed countries with indigenous pharmaceutical industries where initiatives have already been established to ensure that local intellectual property protection is maximised to the benefit of that country's internal and export activities (sub. 24, p. 18).

The Commission considers that Australia is bound to abide by its international obligations in the area of intellectual property protection. The Commission's Report on R&D (IC 1995b) examined the potential for maximising the use of

knowledge generated in the rest of the world by revoking intellectual property rights in Australia. It concluded that:

... while theoretically possible under some assumptions, the dangers to Australia's standing in the world (including with respect to GATT obligations) and the likelihood of retaliation obviously make such a policy undesirable (IC 1995b, p. 186).

The Commission's R&D Report also accepted the BIE conclusion that, even if it seemed desirable for Australia to offer protection for different periods from those elsewhere, in most circumstances it would be undesirable to get out of step with those in the rest of the world (BIE 1994).

16.3 Effective patent term and patent term restoration

Manufacturers and developers of patented drugs argued that one area where Australia is out of step with the level of protection provided by comparable nations is in relation to patent term restoration for pharmaceutical products. Both the European Union (EU) and the US have introduced forms of patent term restoration (see Box 16.1).

Patent term restoration refers to extending the patent term to 'restore' time lost in gaining marketing approval. Patent holders argue that, where a product must go through pre-marketing approval, the period during which they can exploit their statutory monopoly (the 'effective patent life') is reduced. The reduced patent life is too short to allow a satisfactory return on their investment in R&D.

For example, the Institute of Drug Technology argued:

... the current patent life for pharmaceutical products is insufficient to enable innovator companies to obtain a satisfactory return for the considerable investment made in the development of new pharmaceutical agents (sub. 30, p. 3).

However, extended patent terms involve a trade-off. A longer statutory monopoly period for patent holders may mean higher prices for drug purchasers and diminished opportunities for generic manufacturers.

As well as delaying the entry of Australian generic manufacturers to the local market, patent restoration may also reduce their potential to export. If other countries have a shorter patent period, generic customers will source their requirements from a country with shorter patent protection. In addition, foreign generic suppliers may be in a stronger position to sell in Australia once the Australian patent expires, as they will already be in production.

Alphapharm stressed that ‘in relation to generics, patent law changes, if mishandled, could wipe out overnight all Australian based generic research, development and manufacturing’ (sub. 14, p. 1).

Box 16.1: Patent term restoration overseas

European Union

In June 1992 the European Communities adopted a regulation to create ‘Supplementary Protection Certificates’ for medicines. The regulation provides that pharmaceutical patents can be extended for a maximum period of five years, to give up to 15 years of exclusivity from the date of first marketing in the European Union (EU).

The extension applies for one patent per chemical entity (that is, for only one use).

No springboarding of generic products is allowed (that is, no development, registration activities, manufacture or stockpiling can occur until the patent expires).

Different transitional arrangements were made in different member states, with retrospectivity ranging from five to eleven years.

United States

In the US, the *Drug Price Competition and Patent Term Restoration Act* became law in 1984. The Act provides for an extension to a drug patent’s term equal to the period of regulatory review (to a maximum five years), to a maximum effective patent period of 14 years from marketing approval.

An applicant for extension is required to pursue the marketing approval process with due diligence and can only claim one half the time used to conduct clinical trials after the date the patent is issued.

Only one patent per drug can be extended.

Generic activities solely for uses related to the development and submission of information to the Food and Drug Authority can take place at any time.

A period of two and a half years retrospectivity was imposed.

The current position

The then Department of Industry, Science and Technology (now the Department of Industry Science and Tourism) (DIST), noted that it is important to strike the right balance between the interests of producers of new drugs and those producing generic versions of drugs.

DIST stated:

From the consumers' point of view, a balance that encourages both research and production of new drugs and the availability of lower priced generic drugs is important. This balance is also important in the context of retaining competitive pressures which keep PBS prices low (DIST 1995c, p. 4).

In February 1993, the then Prime Minister announced an intention to introduce extended patent protection for pharmaceuticals and stated that:

... Government would provide 15 year effective patent life for pharmaceuticals in line with US and European standards (Keating 1993).

To advance this commitment a DIST Discussion Paper was released in October 1995. This paper outlined options for achieving 15 years of effective patent life (DIST 1995c).

The Government's preferred approach is described in Box 16.2.

Box 16.2: Government's approach to 15 year effective patent life

The Government is committed to providing 15 year effective life patent protection for pharmaceuticals in line with US and European standards. This means extending the term of a patent to up to 25 years depending on when the new drug was authorised for marketing in Australia. In detail, this equates to extending the term of the patent by a period that does not exceed five years but would otherwise be equal to the period between the date of the patent (defined in s. 65 of the *Patents Act* 1990) and the day on which registration of the new drug in the Australian Register of Therapeutic goods commenced (as set out in s. 25(5) of the *Therapeutic Goods Act* 1989), reduced by five years.

For example, a patent for a drug registered in the fifth year of the patent would not get an extended term. Registration in the eighth year of the patent, on the other hand, could result in an extended term of three years, whereas registration after ten years would give a five year extension.

An extension would only be available in relation to a single patent covering the drug itself—not in relation to new uses for, or new methods of producing, the drug.

Source: DIST 1995c, p. 3

Participants disagreed on whether the European or US approach was more appropriate for Australia.

In its Draft Report, the Commission stated that it may be more appropriate to align Australian patent law with the US ‘given that country’s importance as a developer and exporter of pharmaceuticals’.

Merck, Sharp & Dohme argued that the Australian market is very different to that in the US:

The Australian pharmaceutical market is characterised by extensive price regulation. ... US products do not experience a similar impact. The US market has no such Government intervention; the US industry does not experience delay through the reimbursement process; there is also no legislation which mandates generic substitution in the US (sub. 122, p. 8).

Many participants argued that because of extensive Government regulation of the pharmaceutical market, Australia is closer in character to the EU. For example, the APMA considered that the European system ‘is more relevant to Australian circumstances’ (APMA 1994b, p. 1).

The Commission’s view

The Government’s proposed 15 year effective patent life for pharmaceutical products, running from the date of Australian marketing approval, has a number of features in common with the EU approach (see Table 16.1).

First, both offer a maximum five year extension with a maximum 15 year effective patent life.

Table 16.1: Comparative periods of patent term extension

<i>Period between grant of patent and marketing approval</i>	<i>US</i>	<i>EU</i>	<i>DIST proposal</i>
0 to 5 years	0	0	0
6 years	0	1	1
7 years	up to 1 year of regulatory delay	2	2
8 years	up to 2 years of regulatory delay	3	3
9 years	up to 3 years of regulatory delay	4	4
10 years	up to 4 years of regulatory delay	5	5
10 to 20 years	up to 5 years of regulatory delay	5	5

Second, both adopt an ‘averaging’ approach to the period of the extension. That is, all pharmaceutical patent holders are entitled to the same five year extension; an arbitrary period chosen to compensate for the ‘average’ delay to pharmaceutical products.

Third, both go further than compensating patent holders for the time lost in regulatory delay. The period of the extension in the EU and proposed for Australia is not directly linked to the period of regulatory delay, but rather, is linked to the entire delay between the grant of patent and marketing approval. This includes time taken in R&D before marketing approval was sought. DIST stated that this was its intent when designing the proposal:

... mention is made of the pre-marketing regulatory delay as the rationale for an extension of term ... Whilst that was the case for the previous extension of patent term provisions, the current proposals derive from the long development time as well as the pre-marketing regulatory delay (sub. 154, pp. 5–6).

The Commission notes that the EU model provides for 15 years effective patent life from the date of first approval anywhere in the EU. Therefore, a patented product will enjoy 15 years of protection only in the country of first approval, and a lesser period of protection in other EU countries. However, in practice this feature has not been significant, as companies generally lodged marketing applications in most markets virtually simultaneously. The importance of this feature has also been diminished by moves toward mutual recognition of marketing approval decisions in the EU.

The proposed Australian scheme would provide 15 years protection from the date of marketing approval in Australia, regardless of when the drug was approved overseas. This may affect incentives to submit a drug promptly for approval in Australia, although the existence of the 15 year maximum effective patent life and maximum five year extension act to penalise delays in marketing in Australia.

In conclusion, the Commission notes that it is Government policy to introduce a 15 year effective patent term for pharmaceuticals. This approach to patent term restoration is more in line with the EU and as such is more generous than the US approach.

Adequate patent protection is a critical factor for success in the pharmaceutical industry and so has an important influence on company perceptions of Australia as an investment location.

The Government's 1993 announcement of its intention to introduce a 15 year effective patent life for pharmaceuticals recognised the importance of this issue to the industry. As indicated by the APMA survey (1995a), failure to implement the proposal is causing concern and uncertainty to the industry.

FINDINGS

The Commission finds that the Government's commitment to a 15 year effective patent life for pharmaceuticals is more in line with the European Union approach and as such goes further than compensating patent holders for the time lost in regulatory delay.

The Commission finds that the delay in implementing this commitment is causing concern and uncertainty.

16.4 Generic springboarding

The timing of the first marketing of generic products also needs to be considered in comparing effective patent life periods. Where springboarding exists, companies are permitted to commence developing generic products ahead of patent expiry. Drug evaluation authorities may also commence processing of marketing applications for generic drugs in time to allow their launch immediately after patent expiry.

Potentially, springboarding may cover a range of activities including importing, conducting bioequivalency studies (including clinical trials) regulatory approval, manufacturing and stockpiling of the product. When springboarding was allowed in Australia all activities except 'sale, offering for sale or distribution for a purpose other than marketing approval' were permitted.¹

The generic and patented sectors of the industry had conflicting views on springboarding. Manufacturers of patented drugs generally regarded springboarding as an unwarranted intrusion into effective patent life. For example, the APMA stated:

Although APMA recognises that several of its members do consider that some 'springboarding' should be allowed, as this has been permitted in the past under the previous patent extension arrangements, APMA's view is that there should be no 'springboarding' (sub. 119, p. 15).

Generic manufacturers favour springboarding primarily because it allows them to enter the market as soon as the patent expires. Faulding argued that, in the absence of springboarding, regulatory and other delays could occur in bringing generic products into the Australian market. This would further increase the effective patent period:

Without springboarding provisions, patent holders can enjoy a 20 year term plus any 'effective term extension' if provided plus a *gratis* additional two to five years protection against domestic generic developers (sub. 46, p. 8).

¹ Under arrangements in place between 1987 and 1995, if a pharmaceutical patent had extended from 16 to 20 years, springboarding was allowed during the last two years of the extension.

Companies such as the Institute of Drug Technology (sub. 156, p. 2) and Alphapharm (sub. 14, p. 1) were also concerned about the competitive consequences if Australia does not allow springboarding when it is permitted in other countries. Faulding described the consequences of not allowing springboarding:

This not only provides an additional unwarranted extension of term but encourages offshore generic development since offshore companies are not restricted, by patent term in Australia, from commencing development and registration activities (sub. 85, p. 8).

Alphapharm noted the effect of the lack of springboarding provisions in Europe on the European generic industry:

The generic industry response has been to prepare applications offshore, manufacture and stockpile offshore and import into Europe once the patent expires (sub. 14, Attachment 1, p. 2).

The current position

The Government has not yet identified a preferred option for springboarding. Four options for springboarding identified in the DIST options paper are summarised in Box 16.3.

Box 16.3: DIST options for springboarding

1. No springboarding.
2. Springboarding only during the extended term.
3. Springboarding during the extended term and the patent term proper, from the time of receiving an extension.
4. Springboarding during the extended term and the patent term proper, from the time of getting marketing approval.

Source: DIST 1995c, p. i

DIST noted that participants in its roundtable discussions generally agreed that:

The 20 year GATT patent term should be preserved but that innovator companies should not be given a *de facto* extension to the patent. There was widespread recognition that generic manufacturers should be granted some concession (DIST 1995d, p. 3).

The Commission's view

As discussed above, it is not possible to design a system that aligns with both the EU and US approaches. The Commission has found that the Government's approach for introducing patent term restoration appears to be closer to the EU approach than the US model. However, the EU approach does not include springboarding.

There is merit in the argument that springboarding should provide parity between the market position of domestic producers of generics and generic importers. If overseas countries allow potential competitors to develop and begin manufacturing of generic products before the patent for those product expires in Australia, this will have a significant impact on Australian generic manufacturers.

As the Government's preferred approach for patent term restoration is closer to the EU model, and as both provide a level of protection which may exceed that required to compensate for regulatory delay, there may be scope for Australia to adopt a period of springboarding to provide an overall package of protection somewhere between the EU and US approaches.

The Commission notes that allowing springboarding during the 20 year minimum patent term required under the TRIPs agreement may be in breach of the agreement. This would mean that DIST options three and four (see Box 16.3) are not practicable.

Allowing a period of springboarding during the period of an extended patent appears to strike an appropriate balance between the interests of patent holders and manufacturers of generic products.

FINDING

The Commission finds that the Government's foreshadowed approach to providing 15 years of effective patent life provides scope to allow generic springboarding.

16.5 Transitional arrangements

If the Government introduces some form of extended patent term for pharmaceutical products, a further issue arises as to the nature of the most appropriate transitional arrangements—to which patents should the new system apply? This could range from patents granted only on applications filed after the new scheme commenced, to existing patents whose extended term under the new scheme would end after the scheme commenced.

APMA argued that a degree of retrospectivity is necessary to correct erosion of patents for products already marketed, to ensure equitable treatment for all pharmaceutical patents and to prevent anomalies. APMA proposed a period of retrospectivity of 8 years (APMA 1994b, p. 3).

The current position

DIST proposed that patents in force when the new scheme starts or granted after that time be eligible for 15 years of effective patent life under the new scheme (DIST 1995c, p. 5).

A number of participants at the DIST roundtable discussions argued that:

... the new scheme should apply to all patents alive in 1993 when the commitment to the extended term was first made. At the very least, they argued, if the scheme was not put in place until 1996–97 it should apply to patents currently alive (DIST 1995d, p. 3).

Various periods of retrospectivity were imposed when patent term restoration was introduced in the US (two and a half years) and the EU (from five to eleven years in different countries) (see Box 16. 1).

Transitional arrangements adopted in Australia in the past have tended to apply extensions to all patents in existence at the time of the amendment.

The four year administrative extension legislated in 1987 was available for patents granted on or after 2 June 1986 or for new drugs whose 16 year standard term expired after 2 June 1986. That is, all patents still running when the amendment took effect, or which had expired between 2 June 1986 and the amendment's taking effect, were entitled to the extension.

The introduction of standard 20 year terms for all patents legislated in 1995 applied to all patents granted on or after 1 July 1995 or whose 16th anniversary falls on or after that date. That is, all patents still running when the amendment took effect were entitled to the extension.

The Commission's view

The Commission considers that extending pharmaceutical patents will provide an additional incentive to invest in developing new products because the period of protection has been lengthened. However, extending existing patents provides a windfall gain to the holders of existing patents, who had already made the decision to develop their patented product under the old system.

Retrospectivity also creates problems for the generic industry. Patent extensions of expiring or expired patents would affect the activities of generic manufacturers, which may have invested in the development of generic versions of products expected to lose patent protection.

The Commission notes arguments by companies that it is revenue earned on existing products that finances current R&D and so existing patents should be extended if the intention is to encourage greater investment in R&D. However, the decision to invest in R&D is based on the expected return on that investment.

The Commission considers that it may be appropriate to allow extensions to patents granted after the Government announced its intention to provide for 15

year effective patent life, as it can be argued that investment in R&D made after this announcement was encouraged by the anticipation of extended patent terms.

However, it is difficult to establish exactly when the Government made such a commitment. The March 1992 *Statement on the Pharmaceutical Industry* by the then Minister for Industry, Technology and Commerce stated that:

The Government is concerned that effective patent life in Australia is not reduced by delays in the drug approval process. ... the Government will monitor and respond to any moves by other countries to extend the patent life for pharmaceuticals (Button 1992, p. 6).

This statement falls short of an actual commitment. Similarly, in 1993, the Health Minister offered support for patent term restoration in return for industry support for generic substitution. However, polarised industry opinion prevented acceptance of that proposition and generic substitution was introduced without any Government commitment on patent term restoration.

The first Government commitment to extend patent terms for pharmaceuticals was in the February 1993 policy speech by the then Prime Minister. This would appear to provide a suitable reference date for patent extension.

A March 1995 Joint Statement by the then Minister for Industry, Science and Technology and the Assistant Treasurer confirmed this commitment (Cook & Gear 1995).

16.6 Confidential information

A relatively recent issue arising in pharmaceutical intellectual property in Australia relates to the confidentiality of information provided to government regulators. Manufacturers of originator brand products object to regulatory authorities sharing test data and the use of brand name product data to support applications for registration by generic versions of the same product.

It has been argued that Australian regulators should provide greater protection to confidential information for three reasons:

- ‘fairness’ grounds;
- public health reasons; and
- international obligations under TRIPs.

The US Pharmaceutical Research and Manufacturers Association (PhRMA) argued that protection of test data is important from the standpoint of ‘fairness’:

Disclosing this data ... denies the compiler of the data the value for its efforts and grants an economic advantage to a later applicants for marketing approval, enabling them to avoid the cost of developing test data for their own products (sub. 147, p. 3).

For example, Bristol-Myers Squibb Company (US) was concerned with the use of company information in the Australian approval of a generic version of Taxol (paclitaxel). Generic paclitaxel was approved in Australia shortly after the approval of Taxol, on the basis of data originally provided to Bristol-Myers Squibb on an 'exclusive use' basis by the National Cancer Institute. Bristol-Myers Squibb argued that the use of the National Cancer Institute data to approve the generic product was in breach of confidence (sub. 148, p. 2).

PhRMA also argued that lack of data protection could have public health implications:

Countries that allow such unfair advantage to later applicants discourage developers of new, and often more effective, pharmaceuticals from seeking to introduce their new products in the country's market. So ... such protection is ... wise from a public and health policy standpoint (sub. 147, p. 3).

US companies and organisations have expressed particular concern about Australia's approach to data exclusivity. The American Chamber of Commerce in Australia (sub. 194), the Australia—US Business Council (sub. 190), PhRMA (sub. 147) and the US Trade Representative's Office (sub. 136) argued that providing a period of data exclusivity is an obligation under TRIPs and strongly urged the Australian Government to protect the test data submitted by one applicant against its direct or indirect use by later applicants for a set period of time.

Parties to the TRIPs agreement are required to protect 'trade secrets and know-how' which have commercial value from 'breach of confidence and other acts contrary to honest commercial practices'. Test data submitted to governments in order to obtain marketing approval for pharmaceutical or agricultural chemicals must be protected against 'unfair commercial use'.

The actual period of data exclusivity contemplated is unclear. For example, TRIPs is silent on this issue. In the US, three periods of exclusivity are possible, ranging from 180 days for 'the successful challenger of a pioneer drug's patent based exclusivity', three years for new approvals for drugs previously approved based on new clinical trials and five years for new approvals of drugs not previously approved (section 505(j) of the Federal *Food Drug and Cosmetics Act* 1938). In addition, the *Orphan Drugs Act* 1983 confers seven years exclusivity on particular drugs with small market size.

In 1994 New Zealand adopted a five year period of data exclusivity, based on consideration of the equivalent provision in the North American Free Trade Agreement and the history of the TRIPs negotiations (Ministry of Commerce, New Zealand, 1994, p. 2).

The arguments against providing data exclusivity generally relate to promoting the public interest in having efficient and transparent regulatory processes. It is inefficient for regulators to demand that the suppliers of generics repeat tests undertaken in support of original applications. Moreover, if data are not protected regulators can share information, encouraging more efficient regulatory processes internationally. In addition, if the data on which decisions are made are publicly available, regulators can be made more accountable for their decisions.

There is also an argument that all data should be available for public health purposes. However, current US arrangements allow for the use of confidential data in such circumstances. Similarly, TRIPs only forbids the ‘unfair *commercial* use’ of confidential information. It does not prevent the release of confidential data for reasons of public health.

In addition, if the period of protection for confidential information goes beyond the patent term, this can have the effect of excluding competitors from the market for a period longer than the patent term. It can, therefore, act as a *de facto* extension of patent term for those pharmaceuticals with an effective patent term of less than five years.

The current position

DIST noted that no formal provision is made for data exclusivity in relation to drugs in Australia:

In a number of countries, notably the US and Europe, there are limitations on the use by other persons of data submitted as part of the marketing approval processes. ... No such limitation applies in Australia (sub. 56, p. 37).

The TGA stated that it has had discussions on data exclusivity with the Department of Foreign Affairs and Trade and has requested the Attorney General’s Department to provide advice on its legal obligations in relation to confidential information:

... we want to examine first of all exactly what the position is with other comparable regulatory authorities ...

We’re not quite sure what the situation is. We’re very much at this stage in a sort of fact-finding mode (transcript, p. 894).

In a related area of regulation, the National Registration Authority stated that a limited form of data exclusivity has been negotiated between the National Farmers' Federation and Government for data lodged in formal reviews initiated by the Authority:

The period of exclusivity is [two to seven] years depending on the type of data. There is no ... protection for new products. This limited form of [Proprietary Rights to Registration Data] PRRD was considered essential if the review of old chemicals was to be successful in bringing forward the maximum amount of information from around the world (sub. 158, p. 5).

The Commission's view

Protection of commercially sensitive data supplied in confidence is understandably a major concern to international business. Although there are some reasons for not providing data exclusivity, it is in Australia's interest to ensure that it meets its international obligations in relation to data protection.

Of particular concern is the potential for companies to withhold new drugs from the Australian market if commercial confidentiality cannot be assured. Given the importance of proprietary data to pharmaceutical companies and the possible impact on public health it is important that Australia's obligations under TRIPs be clarified as a matter of urgency.

FINDING

The Commission finds that there is potential for the availability of some important new drugs to be jeopardised in the event that Australia's current practice relating to the protection of confidential information does not meet its international obligations.

17 IMPLEMENTING CHANGE

This final Chapter summarises the Commission's broad conclusions and sets out its proposals for reform against a background of the views received from Inquiry participants about the future of the industry. A program of phased implementation of the Commission's package of reforms is suggested. The impact of the Commission's proposals on sections of the industry and on the wider economy are assessed.

17.1 The Commission's approach

In this Inquiry the Commission was asked to examine the performance, prospects and economic contribution of the human use pharmaceutical industry in Australia and to make recommendations to improve the industry's efficiency and remove impediments to its growth. Its coverage has been of the manufacture and distribution of, and research into, prescription and over the counter (OTC) drugs. A major part of the Commission's task has been to evaluate the impact of the present Government policy environment on the industry and, in particular, to examine the effectiveness and efficiency of the Factor f scheme.

During the Inquiry, the Commission received submissions from many companies in the industry, the major industry associations, research institutions, Government agencies, consumer and health groups and individuals. Roundtable meetings with industry and consumer representatives were held. The Commission had discussions with executives of local and overseas companies and Government officials. Following the release of the Draft Report, public hearings were held in Sydney, Canberra and Melbourne. Consultancies were undertaken by the Bureau of Industry Economics (BIE) and the Centre of Policy Studies, Monash University (COPS) to assist with the evaluation of the effectiveness and efficiency of the Factor f scheme and the economy wide contribution of the industry.

The picture of the industry which emerged from this consultation and analysis was complex, but encouraging. Both the prescription and OTC sectors are adapting to the changes imposed by worldwide rationalisation in manufacturing and research. The industry has broadened the range of its domestic capabilities and linkages, both between companies and with research institutions. The

strong growth in exports demonstrates that new types of opportunities are being taken up.

Notwithstanding past difficulties in managing the competing health and industry objectives inherent in the subsidised supply of pharmaceuticals, there are some positive signs that the responsiveness of Governments to removing costly and unnecessary regulatory impediments has increased. The improved performance of the Therapeutic Goods Administration (TGA) drug evaluation activities is notable in this regard.

The Commission has looked behind these broad trends to isolate remaining impediments to development and to comment, in particular, on whether the community is receiving value for the financial support currently provided to the industry through the Factor f scheme.

17.2 Perceptions of policy coherence and stability

The main message Inquiry participants have given the Commission is that there is a strong link between the ongoing development of the industry in Australia and the coherence and stability of Government policy as perceived by decision makers, particularly the managers of multinational companies.

In a rapidly changing world companies in all industries face uncertainty in their business environments and success depends on the ability to adapt to change. However, for research based pharmaceutical companies, high research and development (R&D) costs, long lead times in new product development and Governments' extensive involvement in markets make uncertainty a more significant issue. As a result of rapid internationalisation of pharmaceutical markets and domestic cost pressures, the Australian industry is facing extensive change in its markets and in its production and research activities.

Australia is seen by industry decision makers as a favourable location on both economic and political considerations. However, a number of factors under the control of Governments have reduced the attractiveness of the operating environment by increasing uncertainty. In broad terms, investment in the industry is claimed to be lower than it would otherwise be due to perceptions of:

- inconsistency of the Commonwealth Government's policy stance towards the industry—for example, PBS cost containment practices, failure to address satisfactorily the tension between health and industry policy and problems in administration of the Factor f scheme;
- unresponsiveness of PBS policy—particularly to developments in health policy in Australia and elsewhere in the world; and

- uncoordinated administration—particularly of closely related and interacting pricing, tax and intellectual property rules and drug evaluation and scheduling policies.

The Commission has assessed these claims to isolate the major impediments to the future development of the industry and to comment on whether the community is receiving value for money from the financial support currently provided through the Factor f scheme.

17.3 A vision for the industry

The pace of change in the international industry, increasing pressures on the Australian health system and instability in the policy environment make the future of the sector uncertain. This uncertainty is increased by the extensive presence of multinational companies in the industry. The domestic activities of these companies can change quickly in response to international market forces and changes to Government regulation. Because the time horizon of pharmaceutical investments is relatively long, uncertainty may be costly. Some participants considered a vision for the industry's future and the development of plans to pursue this vision as ways of reducing the cost of uncertainty.

17.3.1 The industry's view of its future

The then Department of Industry, Science and Technology (now the Department of Industry, Science and Tourism) (DIST) convened a conference in December 1995 to address the future of the industry. It was agreed at that conference that the question of developing a vision for the sector should be pursued by a smaller group of industry representatives and Government officials.

A number of participants from companies, industry associations, research bodies and Commonwealth Departments made comments to the Inquiry on the future of the sector. As is to be expected, the views expressed reflected the perspectives of those making them, although a number of common themes emerged.

Some companies presented their vision for the industry in broad and simple terms. For example, Glaxo Wellcome said:

I believe that we share a vision that is shared with most other companies in the industry ... that we would see a desire to capture the talents and skills that are available in Australia. As a country, it has amongst the best in the world in terms of medical research expertise and basic science. In a global industry and in a competitive world which is getting smaller in that context, maintaining that

competitive edge is very important. My understanding is that there's a great desire to not only maintain and build on that, to be the clever country ... but also to capture the commercial benefits of it ... That is very much our vision of the future (transcript, pp. 1275–1276).

AMRAD expressed a similar, straightforward view:

To me the vision and outcomes are very simply described: a significant industry sector contributing positively to the economic well being of Australia. The vision to me is no more complex than that (transcript, p. 1240).

In contrast, Bristol-Myers Squibb presented a comprehensive view of the sector's potential which emphasises the contribution multinational enterprises can make to broadening skills and delivering better health outcomes if impediments are removed and attitudes change (see Box 17.1).

Box 17.1: Bristol-Myers Squibb's vision for the pharmaceutical industry

In the future:

- the industry should be accepted as a full and equal partner in the health care debate;
- the cost of the PBS should be seen within the full spectrum of health costs and not in an isolated and independent cost centre;
- the registration and PBS processes should be modified in such a way that they reduce the loss of intellectual property protection;
- the industry should broaden its contribution to improve health care outcomes through more creative use of the very considerable worldwide knowledge and skill base residing within the industry;
- with financial and resource support of the industry, Australia should become the pre-eminent R&D centre for the Pacific rim and the skill and training base for the Asian region;
- there are very significant opportunities for additional investment in R&D across a broader base; and
- Australia should also become the manufacturing base for the Pacific rim and a niche supplier to the rest of the world.

Source: transcript, pp. 814–815

For other companies and research bodies, the focus was on filling gaps and integrating the capabilities of the sector. The Institute of Drug Technology, a local actives manufacturer, said:

My own personal vision for the industry is to see the industry rather more unified in the sense that we can bring all of these things together. As I say, at the moment the opportunity to supply active raw materials is one that we recognise is a commercial opportunity for Australia. I say that because if we think about what happens with multinational pharmaceutical companies in Australia, the active raw materials are brought in, formulated and sold, so there's a large export component of bringing active raw materials in.

... the reason I feel that there is a broader opportunity here than just ourselves is to do with the vision that I was trying to expound earlier on, and that is that Australia doesn't do this at all. It only does it in a small way. If we're really going to create an Australian pharmaceutical industry then we ought to be doing this. We ought to be doing this in a significant way, in a way that is bigger than we're currently doing it, in a way that we have a vision to do (transcript, pp. 1090, 1099).

A pharmaceutical discussion group, comprising CSL, Glaxo Wellcome, Eli Lilly and Merck, Sharp & Dohme expressed a view of the industry's key features important in the future:

Although it is difficult to be prescriptive with regards to the future of the pharmaceutical industry in Australia, there are a number of key features worth highlighting to ensure companies have the ability to prosper in any improved environment. The features include:

- focus on innovation, product development and exports;
- skills and infrastructure capability to match opportunities that arise in Australia, the region or globally;
- industrial depth and flexibility in both development and manufacturing;
- numerous linkages between medical science and industry;
- indigenous companies and subsidiaries of multi-national companies participating in growth together;
- a regional focus particularly for manufacturing and the supply of medical information support; and
- significant involvement in coordinated care and better health programs (sub. 198, p. 1).

Professor Peter Andrews, Director of the Centre of Drug Design and Development at the University of Queensland, put numbers to his view of the future level of the R&D activities of the industry:

... but to me at least I think there's no doubt that we have the capacity to develop a substantial pharmaceutical industry in this country. The benchmark that I used in the DIST meeting in developing a future scenario was that we should be able to ultimately—and I used the year 2010—reach the point where our industry supplied 5 per cent of the world's pharmaceutical products. At present we supply about 1 [per cent]. That would mean that we would have to have over the

next 14 or 15 years—we would have to double twice, once every seven years. We have done more than double in the last seven. So we would have to maintain something like or a little less than the current rate of growth that has been achieved since the Button plan was implemented (transcript, p. 1131).

Government agencies saw the industry's future as being in its own hands. Their views stressed the particular interests of Government and the potential role it can play in future planning. DIST stated:

In terms of a blueprint for the future of the industry, we would think that while it's not the Department's role, or the Commission's role, to make detailed suggestions or set targets ... about where the industry should be. ... we think that the Government needs to look at long term what it is likely to get out of a pharmaceutical industry in Australia ... and it also is an issue of the timing (transcript, p. 779).

These views were echoed by the then Department of Human Services and Health (now the Department of Health and Family Services):

Again I think there is a need in parts of the industry to have a much clearer vision ... of where the industry should be. There does seem to be an attitude at times that the Government should set the policy. I think there is an expectation that the industry can participate in that and to do that they basically have to be able to think about the issues and be able to contribute to that process (transcript, p. 765).

Finally, the complexities involved in developing a collective vision and the importance of differentiating the roles and responsibilities of Government and industry were summed up by CSL:

I think the APMA [Australian Pharmaceutical Manufacturers Association] has embraced the notion that it's important to try and present a vision for the industry because it does help Government. So I think really it's the APMA with DIST, in particular ... that over the next few months will come up with a vision. I think it's going to be a vision that's ... going to be broad and it's going to provide a lot of opportunities for participants to be involved. I don't think there's one simple solution for our industry (transcript, p. 1189).

17.3.2 The Commission's view of planning the industry's future

Some participants expected the Commission to set out a vision for the future of the industry and devise an industry development plan to achieve that vision or to propose targets for future levels of particular industry activities, such as R&D.

The Commission considers any such planning initiatives should be undertaken by companies in the industry rather than by a Government body. A large amount of information is required for such complex tasks, which is generally

inaccessible to Government. However, the Commission has played a facilitating role by examining and reporting on the views put to the Inquiry.

Further, the Commission acknowledges the importance of Government in setting an appropriate policy environment to allow the industry to fulfil its potential. The Report makes a number of recommendations which identify and remove regulatory and institutional impediments. Other recommendations aim to provide the industry with future Government policies which are as coherent and stable as possible.

17.4 A whole of Government approach to reform

There was strong agreement on the importance of consistency over time and the integration of the major Government policies affecting the industry. Participants expressed a range of concerns.

The APMA argued that if international decision makers are to see Australia as having the potential to provide an ongoing research and manufacturing base, an appropriately supportive, consistent long term policy environment must be demonstrated. This requires all Government Departments—including Health, Industry, Finance, Treasury and Prime Minister and Cabinet—to support the policy of achieving and maintaining a viable pharmaceutical industry (sub. 119, p. 20, 22).

At the public hearings, it provided examples of failure of policy coordination:

... there needs to be collaboration ... between [the Pharmaceutical Benefits Pricing Authority] PBPA and the Taxation Department so the Taxation Department has appreciation of how pharmaceutical benefit prices are set, how the margins are determined by PBPA, how they use cost comparisons, therapeutic group reviews as mechanisms for setting prices, within that environment, which causes a great deal of difficulty for industry, it's not acceptable to have the [Australian Taxation Office] ATO then say, 'Well, we're going to ignore that as a factor and we will look at some other mechanism by which we will determine what is an appropriate price and what tax is therefore payable' (transcript, p. 599).

Drawing on its recent experience of closing its New Zealand manufacturing facilities, Pfizer emphasised clarity and stability in policy:

... consequently any investment which can be quite sizeable that we may be wanting to make has to recognise the lead times ... and therefore we look for obviously well-established, clearly delineated and also clearly understood policies that may impact both in the market performance of a particular pharmaceutical business, and also what encouragements and what inducements there may be from a long-term Government policy perspective that clearly shows

us that this is a region or this is an area where we feel very comfortable (transcript, pp. 498–499).

Bristol-Myers Squibb was concerned that ‘within the same Government, policy changes at the whim of an individual Minister—from one to the other’ (transcript, p. 813).

Concerns about policy stability extended into the research sector. Professor Peter Andrews said:

... that means that the pharmaceutical industry has got to see the future as being relatively assured, relatively unchanged at least in terms of the things that are there and obviously changes like those to the transfer pricing type regimes, policies on pricing compounds, policies on incentives like Factor f, 150 per cent, syndication etc, all of those things need to be stable, provide a stable environment if the industry is going to be encouraged to come to Australia at the level that I’m talking about. I believe that’s a key point (transcript, p. 1132).

17.4.1 Current arrangements for policy coordination and development

Governments have adopted coordinating policies, supported by institutional and administrative arrangements, to try to bring together the disparate elements of pharmaceuticals policy. These arrangements attempt to provide consistency of approach and to ensure that the health and industry aspects of Government policy are taken into account in decisions related to the subsidised supply of pharmaceuticals. They also allow for consultation with and between the many groups in the community with an interest in the provision of pharmaceutical based health care. The more important coordinating policies are:

- the National Medicinal Drug Policy (NMDP); and
- the Pharmaceutical Industry Development Program (PIDP).

As discussed in earlier Chapters there is evidence that these arrangements have yet to achieve the level of coordination sought by Governments at the time of their adoption.

The NMDP is overseen by the Australian Pharmaceutical Advisory Council (APAC), an advisory body comprising representatives of a large number of industry, consumer and health professional interest groups. Although it has considerable potential to influence policy development, it has no direct role in policy coordination. To date, the focus of this body has been on promoting the appropriate use of medicines. While it has done some useful work on specific issues important to the industry, such as facilitating the introduction of consumer product information, it has paid little attention to integrating into

health policy development the fourth arm of the NMDP—the maintenance of a viable pharmaceutical industry.

The PIDP, when announced in 1987, established the Pharmaceutical Benefits Pricing Authority (PBPA) as an independent body with the purpose of taking into account the level of an individual company's Australian pharmaceutical activity when setting or making recommendations on price. By confining its interest in activity to the Factor f scheme, the PBPA has been selective in its administration of this function. For instance, the PBPA takes no account in pricing of the activity of companies outside the scheme. Although initially integrated, the PBPA's Secretariat is split across two Government Departments with different and potentially conflicting objectives.

There have been other attempts by Government to progress industry aspects of pharmaceutical policy development. For example, the Industry/Government Consultative Forum was created in response to a recommendation in the BIE's review of Phase I of the Factor f scheme. It appears to have had little impact on fundamental issues and its future is under review.

Moreover, coordination of some overlapping Commonwealth and State Government pharmaceutical policies has not worked well. In particular, the Commission encountered a high level of dissatisfaction with national scheduling arrangements. Although under development for a number of years, these arrangements have yet to gain the confidence of the industry and community groups affected by them.

Effective arrangements for integrating and coordinating policy and its administration are fundamental for successful pharmaceutical policy reform yet difficult to achieve. In developing its proposals the Commission has given particular attention to the institutions and processes required for coordination.

17.5 The Commission's reform proposals

In considering proposals for reform the Commission has paid attention to those Government policies identified by participants as having the greatest impact on costs and opportunities. These fall into three broad groups—PBS policy and administration, the Factor f scheme and the general regulatory environment.

17.5.1 PBS policy and administration

In establishing the NMDP and its supporting administrative arrangements, the Government has taken the important step of acknowledging the need for an

integrated and efficient approach to the supply of subsidised pharmaceuticals to the community and the development of the industry. But, as discussed above, more needs to be done to realise in practice the objectives of that policy. In particular, the interacting operations of the Pharmaceutical Benefits Advisory Committee (PBAC) and PBPA are not working as well as they might and, despite recent improvements in communications with the industry, there remains dissatisfaction with the transparency of some aspects of these operations.

The administrative processes leading to PBS listing involve a number of distinct and interacting stages and complex decision making. Before effective reform proposals can be made, these processes need to be studied in much greater depth than this Inquiry has been able to do. Nevertheless, from an analysis of the issues raised, the Commission has concluded that there is scope for improvement in the efficiency, transparency and accountability of PBS listing and pricing processes. In particular, over reliance on the use of cost effectiveness analysis may be significantly distorting PBS prices, particularly for innovative products, and limiting access to some drugs for applications which could have value to consumers.

To address these concerns with the listing process the Commission has proposed that the functions of the PBAC and PBPA be rationalised and that a process review be undertaken urgently to identify ways of improving all aspects of pharmaceutical listing.

It has suggested that the pricing authority be made independent of the health and industry portfolios and be given full responsibility for price negotiation, including the evaluation of cost effectiveness analyses provided by companies.

While the proposed process review should cover all administrative aspects of listing, the Commission has suggested that because of emerging pressures on the PBS, it is desirable that it be extended to address the PBS in a wider health policy context or, preferably, a separate policy review should be undertaken.

In the meantime, the Commission has recommended that companies should have the option of delaying cost effectiveness analysis for two years after initial listing to allow for the collection of costing data based on actual pharmaceutical use.

17.5.2 The Factor f scheme

The Commission considers the present Factor f scheme to be an adjunct to, rather than a replacement for, more fundamental reforms. It has a particular purpose—the restoration of efficient economic activity lost as a result of PBS price suppression. It should not promote industry development for its own sake.

In examining the case for compensating for activity lost as a result of PBS price suppression, the Commission has studied the effectiveness and efficiency of the present Factor f scheme and its administration. The scheme's effectiveness is its success in restoring efficient activity lost to Australia from inappropriate price suppression. Its efficiency is the extent to which the reallocation of resources brought about by the scheme has resulted in net benefits to the community.

After extensive analysis, the Commission has concluded that the effectiveness of the scheme has been reduced through overcompensation of some companies, particularly those continuing from Phase I to Phase II, and undercompensation of eligible companies denied entry to Phase II.

The Commission has concluded also that these distorting features, together with a high payment rate, are likely to have prevented the scheme from providing benefits to the community which exceed the scheme's costs.

Additionally, its administration has been complex and not transparent and the link to its original purpose of compensating for PBS price suppression does not appear to be strong. The sudden imposition of the Phase II funding cap increased uncertainty in the industry about the Government's commitment to implementing an integrated pharmaceuticals policy. The Commission has concluded that the scheme has suffered from severe administrative problems and these have contributed to uncertainty about the operating environment, particularly for companies excluded from Phase II.

Given this experience with the present scheme and the inadequacy of any financial intervention in addressing all of the problems the PBS creates for the industry, the Commission has not recommended that a Factor f type scheme be introduced after 1999. The Commission has noted that the current Factor f scheme has been no more than a 'band aid'. Another scheme may act as an impediment to further reform and would only tackle part of the problems facing the industry. A much better way of dealing with these problems is to reform the PBS itself.

Fundamental reform of PBS processes should, at a minimum, involve the establishment of a truly independent pricing authority, better use of cost effectiveness analysis and proper weightings for all pricing factors.

However, if the Government decides that such reform is either not currently a priority or likely to take considerable time to implement, it could choose to introduce a modified Factor f type scheme as an interim measure. The Commission has considered alternative scheme designs. The scheme which has

the best chance of providing value for money is one which has as few decision-distorting characteristics as possible and is easy to administer.

The scheme designed by the Commission would be open to all companies supplying patented and innovative products listed on, or indirectly affected by, the PBS and undertaking eligible activity. Eligible activity would include R&D and value added production activity. Payments would be made for all increased activity above an administrative threshold and applied as either notional or actual price increases at companies' discretion. The scheme's rules and payment rates, which would be low and the same for all activities, would be announced at the start and not varied during its life. Participating companies would not be required to make activity proposals to Government for prior approval. Rather, to receive payment at the end of each period they would have to provide evidence of eligible activity undertaken during the period.

17.5.3 The general regulatory environment

The pharmaceutical industry is influenced by general Government and industry specific policies. Because this broader regulatory environment is fragmented change is needed on a number of different fronts.

Improvement in the performance of the TGA has been widely acknowledged, but there is scope for further gains. For example, the timeliness and quality of drug evaluation can be expected to increase if the TGA monitors its performance against international best practice benchmarks. More closely integrating the activities of the TGA with those of major overseas drug regulators will provide a stimulus to further improvement. Integration can be achieved progressively by increased harmonisation of standards and data requirements, exchange of evaluation reports and selective use of overseas agency evaluation decisions. Mutual recognition of evaluations with comparable countries should be a longer term objective.

The Commission has concluded that, to achieve a truly national and efficient system for the regulation of therapeutic goods, some further reforms are required. In particular, current Commonwealth/State cooperative arrangements for the scheduling of drugs need to be put into legislation. There is scope for better integration of drug evaluation and scheduling processes and the Commission has recommended these functions be combined. To provide the autonomy and flexibility appropriate for its national role, the Commission has recommended the TGA be reconstituted as a Commonwealth statutory authority and that it be given responsibility for scheduling.

The Commission has examined the current commitment to the introduction of a 15 year effective patent term for pharmaceuticals and considers that the delay in implementation is causing uncertainty and concern in the industry. It also concluded that there is scope to introduce a period of generic springboarding.

Finally, closer attention needs to be paid by the ATO to improving the clarity of its position on transfer pricing and wholesale sales tax arrangements.

17.6 Implementing reform

The need to improve Australia's pharmaceutical policy environment has already been recognised by the Commonwealth Government. The Federal Coalition Industry Policy stated that the Government will:

Provide a commitment to the pharmaceutical manufacturing industry for a broadly based program of assistance to offset the impact of the Pharmaceutical Benefits Scheme when the existing Factor f program expires in 1999 (Moore 1996).

17.6.1 A package of reform

The extent of specialised Government intervention in the pharmaceutical industry and the close interaction of its health and industry policy elements make coordinated implementation of reform a desirable approach. The Commission's major proposals could be drawn together into a reform package.

Adoption of a reform package will send a positive signal to the industry. The likely impact of this should not be underestimated. Industry participants have pointed out that a public commitment to removing impediments and improved policy coordination will go a considerable way towards reversing the present negative perceptions of the policy environment. Adoption of all elements of the package will facilitate coordination of reform within the Commonwealth Government and across Commonwealth and State Governments.¹

Timing is also important. In particular, if appropriate PBS listing and pricing are to be achieved, the recommended PBS process review should start without delay and be completed quickly.

¹ States refers to States and Territories.

17.6.2 Lessons from past reform programs

There are some lessons to be drawn from the implementation of past pharmaceutical reform programs.

It is worth recalling that the PIDP was adopted not only to deal with the distortion of low PBS prices but also to allow other policy problems to be addressed. The Government announced the Factor f scheme in 1987 as part of a wider program of measures:

...designed to create an environment which would encourage a significant increase in R&D performance by the industry, together with increased investment, production and export performance, and strengthened employment opportunities (Button & Blewett 1987a).

The three most important elements of the Government's decision were to:

- replace the Pharmaceutical Benefits Pricing Bureau with an independent Authority;
- require the Authority to take into account the level of the individual company's pharmaceutical activity when setting or making recommendations on price; and
- provide for extensions to patent life on pharmaceuticals for human use.

Failure to implement these measures as intended has been an underlying cause of many of the problems identified during the Inquiry.

This is not to say that there has been no worthwhile reform in the pharmaceutical policy environment. Indeed, the Baume Review of the TGA and the Government's insistence on the quick implementation of all its recommendations has been acknowledged widely as a model of a successful reform program in the health portfolio.

The Commission considers that these lessons of the past should be borne in mind in the implementation of this Inquiry's recommendations. Specifically, if a Factor f approach is adopted as an interim measure, this should not be allowed to impede fundamental reform of the PBS.

The Commission suggests that suitable arrangements are made to implement all its recommendations together. To do this, the responsible body must have the authority and Government support required to take a whole of Government approach. It will need to be able to initiate change to existing institutional arrangements and to conduct relevant Commonwealth/State negotiations.

17.6.3 Phasing of the implementation of the reform package

The Commission anticipates that the Commonwealth Government, as soon as it consults with the States, would announce details of the major elements of its decisions on the Commission's recommendations. An early announcement of the content and phasing of the reform package will give companies and agencies time to plan their response to future conditions in the industry, easing the cost of adjustment.

Some of the recommended reforms should be able to start without delay, while others will require further examination, negotiations between Governments and consultation with the industry and consumers.

The Commission proposes that the reform program proceeds in two stages. The emphasis in the first stage is on getting reform started and laying the foundations for the implementation of later change. The major organisational changes proposed should be implemented and the PBS process review completed (see Box 17.2).

In addition, the Commission's recommendations to overcome problems with cost effectiveness analysis and the current Factor f scheme should be commenced as soon as possible. These interim arrangements would allow companies to delay the implementation of cost effectiveness analysis for two years after the listing of a drug. They would also allow for Factor f payments to be applied as actual, rather than notional, price increases.

Box 17.2: Implementation stage 1: six months

- Announce decisions regarding future approach (PBS process and policy reviews, intellectual property, scheduling and independent TGA).

PBS reform

- Undertake Baume style review of PBS processes.
- Establish PBS policy review.
- Commence collection of international pricing, volume and market share data.

General regulatory reform

- Establish independent TGA and introduce regular international benchmarking.
- Commence negotiation on combined scheduling and registration arrangements with the States.
- Implementation of intellectual property policy.

Interim arrangements

- Modify Factor f Phase II to allow payments to be based on actual prices.
- Introduce an option to delay cost effectiveness analysis for two years.

In stage two, the detailed recommendations of the PBS process review could be implemented and the policy review finished. Given sufficient resources and commitment, this phase could take a further 12 to 18 months. If this is achieved, the policy environment of the industry will be significantly changed before the end of Phase II of the Factor f scheme in 1999 (see Box 17.3).

Box 17.3: Implementation stage 2: twelve to eighteen months*PBS reform*

- Implement PBS process reforms, including modified cost effectiveness analysis.
- Establish independent pricing authority and implement new pricing guidelines.
- Continue PBS policy review.

General regulatory reform

- Absorb scheduling into independent TGA.

The Commission recognises that this reform program is ambitious. Its success depends on a willingness by Government to address some fundamental issues relating to the PBS processes and the PBS itself. It also requires significant organisational, managerial and political adjustments to be made. However, given sufficient resources and commitment and started without delay, it could be completed substantially before the expiry in 1999 of current industry development arrangements.

The Government may decide to introduce a scheme to replace Factor f Phase II. Payments could commence only after completion of Phase II. The scheme would be reviewed in 2003.

17.7 Impact of reform proposals

Under its legislative charter the Commission is required, among other things, to have regard to the desire of the Commonwealth Government to facilitate adjustment to structural changes in the economy and to ease social and economic hardships arising from those changes. Also, it must report on the

social and environmental consequences of any recommendations it makes. In addition, the terms of reference of this Inquiry specify that the Commission have regard to the health objectives of Government and the effect of these objectives on the pharmaceutical industry.

As discussed above, the Commission's proposals involve addressing the underlying impediments to the development of the industry principally by reviewing the future role of the PBS and its administration. The proposals in total can be expected to have broad economic and social effects and particular consequences for industry, regulatory bodies, consumers and taxpayers.

The work undertaken to assess these effects and the Commission's judgments of their impact on individual groups are described below.

17.7.1 Economy wide effects

COPS was commissioned to simulate and study the economy wide effects of the present Factor f scheme and any replacement schemes proposed, using the MONASH model of the economy. The results of this work are reported in Chapters 2 and 11 and Appendix L. The major conclusion is that Phase II of the Factor f scheme has minor economy wide implications due to the relatively small size of the pharmaceutical industry.

The Factor f replacement scheme, which the Government may adopt as an interim measure, has been designed to be of no greater magnitude and less distorting than Phase II. Hence, it is reasonable to conclude that its economy wide effects will also be minor.

The BIE study of the efficiency of the Factor f scheme has been conducted from a broad perspective. Its results and the Commission's more comprehensive analysis of the efficiency of the scheme are reported in Chapter 11.

It should be borne in mind that the Factor f scheme is only one of a range of policies influencing the industry's performance. For this reason, and because of methodological and data constraints, the COPS and BIE studies provide, at best, a broad indication of the impact of Government intervention on the industry.

17.7.2 Impact of proposals on companies, institutions and consumers

The impact of the Commission's proposals will be determined by the extent to which the recommended reforms are taken up by Governments and the responses by pharmaceutical market participants.

The Commission draws the attention of particular groups to those proposals most likely to affect them.

Pharmaceutical companies

All companies bringing new drugs to market can expect to benefit from reforms emerging from the reviews of the PBS and the unifying of drug evaluation and scheduling. Better use of cost effectiveness analysis and more flexible price negotiations will allow products to be listed on the PBS with prices and applications closer to those applying elsewhere in the developed world.

The APMA has speculated on the likely outcome if proposals similar to those recommended by the Commission are adopted (see Box 17.4).

Box 17.4: APMA best case scenario for the prescription sector

Assumes that if the policy environment provides:

- prices for products that provide an appropriate return on investment, especially for new chemical entities, in return for value adding, R&D, export and medical/health infrastructure activity by companies;
- prompt availability of these newly approved products through the PBS or other Government subsidised schemes on the basis of their marketing approval;
- protection of intellectual property through appropriate patent extension and data exclusivity arrangements;
- continuing support for basic research and new product R&D;
- continuing improvement in the harmonisation and streamlining of drug evaluation and scheduling arrangements and international recognition of Australia's standards of manufacture and drug evaluation;
- broadened Government perspectives on the role of pharmaceuticals in health care and recognising the benefits flowing from the pharmaceutical industry to science and technology development in Australia; and
- a consistent, supportive environment for industry in general.

This could lead to:

- more than a doubling in pharmaceutical exports from the predicted \$800 million in 1995–96 to over \$1.6 billion in 2005–06; and
- a doubling in industry's R&D expenditure from the predicted \$227 million in 1995–96 to \$450 million in 2005–06.

Source: sub. 199, Attachment A, p. 2

The Commission's proposals for intellectual property protection attempt to balance the competing interests of companies holding patents and generic suppliers. It is expected that generic producers will continue to maintain a significant presence in the market.

The OTC sector will be advantaged by scheduling reform, including the recommended relaxation of present restrictions on the advertising of some schedule 3 products.

Research institutions

As prices for new products move closer to other countries, companies will generate additional revenue in Australia. This may be expected to stimulate investment in competitive R&D.

Health professionals

Health professionals may be affected directly by the Commission's proposals for the reform of scheduling and drug evaluation. Pharmacists should note the Commission's recommendation concerning the advertising of schedule 3 products.

Consumers

Consumers may benefit directly from proposed reforms to scheduling, drug evaluation and the PBS by gaining earlier access to new pharmaceutical products. In addition, having better information about medicines through advertising will allow them to take a greater role in the management of their own health.

Those consumers wishing to gain access to drugs currently not subsidised could be given the opportunity to do so if they are prepared to make a copayment to cover the difference between the cost effective price for that prescription and its market price. This would require a change to the PBS itself.

State Governments

The Commission's proposals will affect current State regulatory arrangements for drugs and poisons scheduling.

17.8 Conclusion

In examining the performance and prospects of the prescription and OTC sectors of the pharmaceutical industry, this Inquiry has covered a lot of ground.

In its analysis, the Commission has taken account of the industry's complex and changing environment. It is apparent that significant further change is imminent, particularly in the way the Government buys and funds drugs on the PBS. With this in mind, the Commission has formulated its major recommendations to stimulate policy change and to accommodate it within the proposed reform program. By addressing underlying impediments the recommendations are consistent with the Commonwealth Government's overall approach to microeconomic reform.

Pharmaceutical research, manufacturing and supply is an important Australian industry. The challenge for Governments is to introduce and sustain integrated policies which, while directed at improving the performance of the industry, also enhance the health and wellbeing of all Australians.