INDUSTRY
COMMISSION

THE PHARMACEUTICAL INDUSTRY

VOLUME 2: APPENDICES

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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.

VOLUME 2—APPENDICES

A INQUIRY PROCEDURES

This Appendix outlines the Inquiry process and the organisations and individuals that participated in the Inquiry.

A.1 Introduction

On 21 June 1995, the Industry Commission received the terms of reference for the Inquiry. The reference directed the Commission to report on ways of improving the overall economic performance of the Australian human use pharmaceutical industry, encompassing the prescription drug and the over the counter sectors, and its contribution to the Australian economy. The original time frame for the Inquiry was nine months. However, following requests from the Australian Pharmaceutical Manufacturers Association and the Proprietary Medicines Association of Australia, the Assistant Treasurer granted an extension of six weeks to the final reporting date. The Final Report was submitted to the Commonwealth Government on 6 May 1996**.**

The Commission placed a notice of the Inquiry in the national press inviting individuals and organisations with an interest in the pharmaceutical industry to make written submissions. To assist in preparing a submission, an Issues Paper was released outlining the scope of the Inquiry.

Prior to the release of the Draft Report, on 23 November 1995, a total of 96 submissions were received by the Commission. A further 112 submissions were received in response to the Draft Report. A list of submissions is provided in Section A.2.

During the course of the Inquiry, the Commission held discussions with individuals, organisations and Government Departments in Australia and overseas to gain background information and to assist in setting an agenda for the Inquiry. Those visited by the Commission are listed in Section A.3.

Due to Inquiry time constraints, the Commissioners convened a number of roundtable discussions rather than public hearings prior to the completion of the Draft Report. These discussions enabled the Commissioners to exchange views with small groups of key industry members on major issues. Roundtable participants are listed in Section A.4.

Public hearings were held in Sydney, Canberra and Melbourne during February 1996 to give participants an opportunity to comment on the Draft Report. There was considerable input from participants with 33 participants appearing over nine days (see Section A.5).

To assist the Inquiry, the Commission engaged the services of the following consultants:

Bureau of Industry Economics—to report on the effectiveness and efficiency of the Factor f scheme by using an updated version of the analytical approach developed in its 1991 Review (BIE 1991); and

Centre of Policy Studies, Monash University—to provide a model to capture the economy wide impacts of the Factor f scheme to date, and to forecast impacts of any proposed scheme changes.

Additional information and data were also requested from many organisations at various times during the Inquiry. The Commission is grateful for the cooperation it received from participants.

A.2 Submissions received

Participant	*Submission No.*
Abbott Australasia	48, 109
Advertising Federation of Australia	107
AIDS Council of New South Wales	196
Alcohol and Other Drugs Council of Australia	37
Alphapharm	14
American Chamber of Commerce in Australia	194
AMRAD Corporation	24, 117, 165, 177, 187
Andrews, Prof Peter	51
Association of Australian Medical Research Institutes	18, 157
Association of Pharmacy Registering Authorities	161
Astra Pharmaceuticals	20, 141, 205
Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists	6, 103
Australia—US Business Council	190
Australian Academy of Science	60
Australian Chamber of Manufactures	59
Australian Council of Trade Unions	55

A.3 Visits

Australian Capital Territory

Attorney General's Department
Australia Intellectual Property Organisation
Australian Medical Association
Australian National Audit Office
Australian Pharmaceutical Advisory Council
Australian Taxation Office
Bureau of Industry Economics
Commonwealth Department of Finance
Commonwealth Department of Foreign Affairs and Trade
Commonwealth Department of Human Services and Health (now Commonwealth Department of Health and Family Services)

Commonwealth Department of Industry, Science and Technology (now Commonwealth Department of Industry, Science and Tourism)
Consumers' Health Forum of Australia
Health Insurance Commission
National Drugs and Poisons Scheduling Committee
Pharmaceutical Benefits Advisory Committee
Pharmaceutical Benefits Advisory Committee, Economic Sub-Committee
Pharmaceutical Benefits Pricing Authority
Pharmaceutical Health And Rational use of Medicines Committee
Pharmacy Guild
Proprietary Medicines Association of Australia
Therapeutic Goods Administration

New South Wales

Alphapharm
Astra Pharmaceuticals
Australian Pharmaceutical Manufacturers Association
Australian Taxation Office
Baume, Prof Peter
Bayer Australia
Blackmores
Ciba-Geigy Australia
Eli Lilly Australia
Garvan Institute of Medical Research
Merck, Sharp & Dohme (Australia)
Parke Davis
Pfizer
Reckitt & Coleman
Roche Products
Schering-Plough
University of Sydney, Clinical Trials Centre

Victoria

AMRAD Corporation
Biota Holdings
Bristol-Myers Squibb Australia
CSL
Department of Industry, Science and Technology (now Commonwealth Department of Industry, Science and Tourism)

Glaxo Wellcome Australia
ICI Pharmaceuticals
Sigma Pharmaceuticals
SmithKline Beecham (Australia)
VHA Trading
Victorian Department of Business and Employment
Victorian Department of Health and Community Services
Victorian Department of Premier and Cabinet

South Australia

Brauer Biotherapies
F. H. Faulding & Co
Hamilton Laboratories
Sansom, Prof. Lloyd, Chair APAC
Wing, Prof., ASCEPT

New Zealand

New Zealand Ministry of Commerce
New Zealand Ministry of Health
New Zealand Treasury
PharmAc
SmithKline Beecham

Singapore

Australian High Commission
Economic Development Board
Glaxo Wellcome Asia Pacific
Ministry of Health Pharmaceutical Dept
National Science and Technology Board

United States

Bristol-Myers Squibb Company
Food and Drug Administration
Medco
Merck & Co
Pfizer
Pharmaceutical Research & Manufacturers

Ireland

Irish Industrial Development Agency
Irish National Drugs Advisory Board

United Kingdom

Association of British Pharmaceutical Industry
European Medical Evaluation Agency
Glaxo Wellcome
London School of Economics
Medicines Control Agency
National Health Service
SmithKline Beecham

A.4 Roundtable participants

Sydney 16 August 1995

Australian Pharmaceutical Manufacturers Association
Alphapharm
Astra Pharmaceuticals
Bayer Australia
Bristol-Myers Squibb Australia
Ciba-Geigy Australia
CRC in Cardiac Technology
Eli Lilly Australia
Garvan Institute
Hoechst
Marion Merrell Dow Australia
Parke Davis
Parry, Prof. Tom
Pfizer
Roche Products
Schering-Plough
Upjohn

Sydney 17 August 1995

ACIL

Australian Pharmaceutical Manufacturers Association
Australian Pensioners' and Superannuants' Federation
Blackmores
Cenovis
Consumers' Health Forum of Australia
Marion Merrell Dow Australia
National Asthma Campaign
Parke Davis-Wellcome
Pharmacy Guild of Australia
Proprietary Medicines Association of Australia
Reckitt & Coleman
RP Scherer Australia
Schering-Plough
Sterling Winthrop

Melbourne 22 August 1995

Australian Medical Association
AMRAD Corporation
Australian Pharmaceutical Manufacturers Association
CSIRO—Division of Biomolecular Engineering
CSL
F.H. Faulding & Co.
Glaxo Wellcome Australia
Hamilton Laboratories
Institute of Drug Technology
Merck, Sharp & Dohme (Australia)
National Pharmaceutical Distributors Association
RPR Australia
Sigma Pharmaceuticals
SmithKline Beecham (Australia)
Consumers' Health Forum of Australia
Society of Hospital Pharmacists

A.5 Public hearing participants

Sydney—6, 7 and 8 February 1996

Australian Pharmaceutical Advisory Council
Australian Pharmaceutical Manufacturers Association
Astra Pharmaceuticals
Cenovis
Eli Lilly
Garvan Institute of Medical Research
Medical Dynamics Australia
Merck, Sharpe & Dohme
Nutritional Foods Association of Australia
Parke Davis/ Parke Davis-Wellcome
Pfizer
Pharmaceutical Benefits Advisory Committee
Pharmaceutical Health and Rational Use of Medicines Committee
Proprietary Medicines Association of Australia

Canberra—13, 14 and 15 February 1996

Australian Taxation Office
Bristol-Myers Squibb
Department of Health and Family Services—Pharmaceutical Benefits Branch
Department of Industry, Science and Tourism
Pharmaceutical Society of Australia
Pharmacy Guild of Australia
National Drugs & Poisons Scheduling Committee
Therapeutic Goods Administration

Melbourne—20, 21 and 22 February 1996

AMRAD
Andrews, Prof. Peter
Association of Australian Medical Research Institutes
Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists
Boots & Co
CSIRO, Division of Biomolecular Engineering
CSL
Faulding
Glaxo Wellcome
Institute of Drug Technology
SmithKline Beecham

B PHARMACEUTICAL BENEFITS SCHEME—BACKGROUND ISSUES

This Appendix provides background information to the PBS. It details the Council of Australian Governments' health policy proposals which may affect the PBS, PBS expenditure from 1989–90 to 1994–95 and the changes in PBS copayments and safety nets since 1960.

Box B.1: COAG health policy reform proposals

The Council of Australian Governments (COAG) has identified the need to adopt a whole-of-system approach to reform of health and community services, to ensure that all jurisdictions and stakeholders have a joint interest in reform. Key elements of a whole-of-system approach will be:

- new structures including multilateral and bilateral agreements, which enable governments to plan and fund the system on a national basis and set priorities within it;
- new funding arrangements which support services reform, promote cost effective care and provide incentives for appropriate substitution across the whole system; and
- greater coherence in service organisation through the re-design of systems boundaries around the broad types of individual need, defined as 'streams of care'.

The need for effective intervention at a population level as a reform priority has also been identified. Reform objectives for this area could include:

- to plan and develop the population health and wellbeing functions across the system ensuring an integrated and responsive set of activities;
- to respond to recognised emerging population level issues including environmental, social and behavioural health determinants; and
- to survey and monitor the outputs and outcomes of health and community services system activity through comprehensive information collection and analysis.

(cont.)

Box B.1 COAG health policy reform proposals (cont.)

The concept of streams of care is intended to locate the various elements of the system within a coherent planning and management framework with the aim of assisting people in accessing the right mix of services from a range of providers. The three main streams of care being proposed by COAG are:

- *general care*, which people usually access themselves and which meets a wide range of specific or ongoing primary care needs or provides referral to more specialised longer term or complex care;
- *acute care*, which is more intensive, episodic care accessed in emergency situations or by clinical referral and generally associated with an intervention to treat or cure a critical condition or other complex health problem; and
- *coordinated care*, or care of a longer term, more complex or continuing nature which requires the assembly of a mix of services related to those needs and which cannot be adequately self-managed in the general care network.

Source: COAG 1995b

Table B.1: Cost of the PBS, 1989–90 to 1994–95, $ million

	1989–90	*1990–91*	*1991–92*	*1992–93*	*1993–94*	*1994–95*
Commonwealth Government payments on benefit prescriptions[a]						
General						
General 'ordinary' [b]	170.0	157.8	166.0	193.9	224.7	290.8
Safety net level 1 [c]	[c]	[c]	36.4	65.8	78.8	93.4
Safety net level 2 [d]	na	na	18.9	53.1	63.9	0.04
Total General	170.0	157.8	221.3	312.8	367.4	384.2
Concessional						
Concessional 'ordinary' [e]	74.8	342.7	714.6	851.5	1 019.6	1 195.0
Concessional safety net [f]	na	na	196.6	253.2	297.6	302.5
Pensioner [g]	740.7	428.7	na	na	na	na
Cardholders [h]	150.0	165.2	na	na	na	na
Total Concessional	965.5	936.7	911.2	1 104.7	1 317.2	1 497.5
Total Commonwealth payments on benefit prescriptions	**1 135.5**	**1 094.5**	**1 132.5**	**1 417.5**	**1 684.6**	**1 881.7**
Patients' contribution on benefit prescriptions						
General benefit prescriptions	162.6	132.1	135.0	172.9	194.1	230.3
Concessional benefit prescriptions	22.2	91.7	173.2	186.6	201.6	214.2
Total patient contribution	**184.8**	**223.8**	**308.2**	**359.5**	**395.7**	**444.5**
Total cost of benefit prescriptions	**1 320.3**	**1 318.3**	**1 440.7**	**1 777.0**	**2 080.3**	**2 326.2**
Commonwealth Government payments through miscellaneous services [i]	43.9	64.8	100.9	101.6	116.7	109.6
Total cost of pharmaceutical benefits	1 364.2	1 383.1	1 541.6	1 878.6	2 197.0	2 435.8
Total Commonwealth Government payments	**1 179.4**	**1 159.3**	**1 233.3**	**1 519.0**	**1 801.3**	**1 991.3**

a Sourced from PBS claims processing at the Health Insurance Commission and the Department of Health Housing Local Government and Community Services.

b Prescriptions supplied to persons other than those eligible to receive pensioner or concessional pharmaceutical benefits or appropriate safety net benefits.

c In 1991 General Safety Net level 1 costs were included in the Concessional category, as these prescriptions attracted a $2.50 (now $2.60) copayment.

(cont.)

Table B.1: Cost of the PBS, 1989–90 to 1994–95, $ million (cont.)

d This category existed from 1 January 1991 to 31 December 1993; costs in 1991 were included under Safety Net level 1 above.

e Prescriptions supplied to persons eligible to receive concessional pharmaceutical benefits in 1990–91, includes 'pensioner' prescriptions dispensed after 1 November 1990.

f Introduced with effect from 1 November 1990. For 1990–91, these costs are included in the 'pensioner' category.

g Payments for prescriptions dispensed to persons eligible to receive free pensioner pharmaceutical benefits. This category ceased to exist from 1 November 1990 when a patient copayment of $2.50 was introduced and all 'pensioners' were included in the concessional category.

h Prescriptions supplied free to holders of a Pharmaceutical Benefits Entitlement Card. From 1992 these costs are included in their correct categories—either General Safety Net level 2 or Concessional Safety Net.

i In 1994–95 the miscellaneous services expenditure of $109.6 million consisted of:

	$'000		$'000
Highly Specialised Drugs	53 903	Safety Net Card issue costs	3 389
Growth Hormone	23 057	Methadone	2 486
Doctor's Bag	15 781	Colostomy and Ileostomy Assoc	438
IVF etc	9 974	Other	593

Sources: DHSH 1995b, p. 33; DHSH 1995c, p. 87

Box B.2: PBS copayment and safety net changes, 1960 to April 1996

1 March 1960—General copayment of $0.50 introduced

1 November 1971—General copayment increased to $1.00

1 September 1975—General copayment increased to $1.50

1 March 1976—General copayment increased to $2.00

1 July 1978—General copayment increased to $2.50

1 September 1979—General copayment increased to $2.75

1 December 1981—General copayment increased to $3.20

1 January 1983—General copayment increased to $4.00; 'concessional users' category, including unemployed and other low income users (health care card holders) introduced at $2.00 copayment (these beneficiaries had previously paid the general copayment)

1 July 1985—General copayment increased to $5.00

1 November 1986—Numerical safety net introduced for both general and concessional patients (of 52 prescriptions per annum); general copayment increased to $10.00, and concessional copayment increased to $2.50

1 July 1988—General copayment increased to $11.00

1 November 1990—Pensioners included in the concessional user category, with the introduction of a $2.50 copayment. General copayment increased to $15.00. Single tier safety net for pensioners introduced

1 January 1991—Two tier monetary safety net introduced; a single tier safety net for concessionals introduced. General safety net $300, concessional safety net $130

2 January 1991—Indexation of copayments and safety net thresholds introduced

1 August 1991—General copayment indexed to $15.70

1 October 1991—Concessional (including pensioners) copayment indexed to $2.60

1 January 1992—Joint safety net established, including recognised hospitals and repatriation beneficiaries. General safety net indexed to $309.90, concessional safety net indexed to $135.20

1 August 1992—General copayment indexed to $15.90

(cont.)

Box B.2: PBS copayment and safety net changes (cont.)

1 January 1993—General safety net indexed to $312.30

1 August 1993—General copayment indexed to $16.00

1 January 1994—General safety net increased to $400

1 August 1994—General copayment indexed to $16.20

1 January 1995—General safety net indexed to $407.60

1 August 1995—General copayment indexed to $16.80

1 January 1996—General safety net increasing from $407.60 to $600 and concessional safety net increasing from $135.20 to $140.40

Sources: Sloan 1995, pp. 73–75; Willis & Beazley 1995, p. 3-98

C FACTOR F PRICING GUIDELINES

The full text of the Pharmaceutical Benefits Pricing Authority Factor f pricing guidelines 1992, outlining the criteria and conditions associated with Factor f funding, are reproduced in this Appendix.

Pharmaceutical Benefits Pricing Authority Factor f pricing guidelines 1992

Introduction

The Government recognises its policy of securing pharmaceutical products listed on the Pharmaceutical Benefits Scheme (PBS) at the lowest possible cost has restricted the development of the pharmaceutical industry in Australia. The Government introduced the Factor f scheme in 1988 to redress the negative impact on pharmaceutical industry activity resulting from low PBS prices. Under the scheme, companies which make a significant commitment to increased internationally competitive production and research and development (R&D) in Australia are able to achieve higher prices for some of their products listed on the PBS. In order to qualify for higher prices, companies must either meet specific performance requirements in respect of production and R&D or they must demonstrate they are making a significant contribution to increased internationally competitive pharmaceutical activity in Australia.

The first guidelines for the scheme were released by the Minister for Industry, Technology and Commerce and the Minister for Community Services and Health on 25 May 1988. The Government amended and updated these guidelines on 19 November 1990.

The guidelines for Factor f were revised in 1992 following the Bureau of Industry Economics review of the scheme and the Government's decision to extend the Factor f scheme to 1998–99.

Role of the authority

The Authority will:

- consider proposals received from companies for price increases under Factor f;

- recommend approval or otherwise to the Minister for Industry, Technology and Commerce and the Minister for Aged, Family and Health Services, and where appropriate, the value of any price increases to be offered to companies;
- monitor companies' performance against their proposal to ensure price increases are commensurate with the level of activity companies achieve; and
- discuss with companies additional activity or lower price levels in the event a company's performance is below the level forecast in its proposal.

Principles

The Factor f guidelines, under which higher prices will be paid, are based on four fundamental principles:

- prices for pharmaceuticals listed on the PBS should not be an impediment to the significant development of the industry;
- higher prices should only be recommended it they are likely to contribute to the development of significant internationally competitive activity in Australia;
- PBS prices should not exceed the average prices of pharmaceutical products in the European Community; and
- a net benefit to the economy should result from any price increases granted on the basis of Australian activity.

Timeframe

Activity undertaken in the period from 1 July 1992 to 30 June 1999 will be eligible for price increases. Companies may be eligible for price increases from and including the company financial year in which their proposal is lodged with the Authority.

Definitions

Pharmaceuticals are human use pharmaceuticals of the type currently available under the PBS and include biologically active products and systems.

Production is the manufacture for export or domestic sale of pharmaceutical products, raw materials or material inputs into finished pharmaceutical products. Production is

	valued at ex-factory prices.
Exports	includes sales from Australia to other countries of products, active ingredients, raw materials for use in pharmaceutical products and income derived from royalties and similar payments from other countries. The Authority will consider the inclusion of exports of pharmaceutical related services on a case-by-case basis. Exports of pharmaceutical products are valued at free on board (FOB) prices.
Imports	is the landed cost of imported pharmaceutical products, active ingredients and components used in the production or packaging of pharmaceuticals. Landed cost includes expenditure on royalties and similar payments.
Value Added	is the difference between the ex-factory selling price and the landed cost of imported ingredients, materials and royalties and other similar payments. Value added can include income from royalties and similar payments.
Turnover	is total sales of pharmaceuticals at ex-factory prices.
Research and Development (R&D)	is generally R&D as defined by the Industry Research and Development (IR&D) Board for the purposes of applying the IR&D tax concession. To be approved for price increases, R&D will need to have the potential for use in the development of pharmaceutical products and processes or in the application of pharmaceuticals.
New Entrant	is a company which first participates in the Factor f scheme after 1 July 1992.
Continuing Participant	is a company which participated in the Factor f scheme before 1 July 1992.
Base Year	is the year which is used as the base over which increases in activity are measured. For new entrants in the scheme, the base year will generally be the company's operating year prior to approval of a Factor f proposal. Continuing participants in the scheme will generally maintain their existing base year.

Participation in the scheme

To receive price increases under Factor f, companies must lodge proposals with the Pharmaceutical Benefits Pricing Authority detailing the activity they propose to undertake under the scheme.

Proposals for price increases should be detailed plans for new and expanded R&D and production. Companies will need to demonstrate their proposals are integrated with the long term strategic direction of the company as a whole. Companies must also provide forecast data for activity over the period of the proposal and audited data for activity in the base year.

Once the Authority has reviewed a proposal it will make a recommendation on approval to the Minister for Industry, Technology and Commerce and Minister for Aged, Family and Health Services. If the Government agrees with the Authority's assessment that a company has demonstrated it can meet the requirements for entry into the scheme, the company will be eligible for price increases under Factor f.

New entrants to the scheme will be eligible for Factor f price increases if they are able to demonstrate their proposed activity is internationally competitive and will provide significant net benefits to Australia. New entrants will either meet specific eligibility criteria or demonstrate their proposal should be eligible on qualitative grounds.

Continuing participants in the scheme will be eligible for additional price increases where they can demonstrate their proposed new activity is internationally competitive and will provide significant net benefits to Australia. The Authority will discuss appropriate performance targets and price increases with these companies and will make a recommendation to the Minister for Industry, Technology and Commerce and Minister for Aged, Family and Health Services. Details are provided on page 10 [in the original] of these guidelines.

Proposals from companies entering the Scheme after 1 July 1992

All new entrants will be required to demonstrate their proposed activity is internationally competitive and will provide significant net benefits to Australia. Companies will generally enter the scheme by demonstrating their commitment to meet two eligibility criteria within five years of approval. The Authority recognises there may be circumstances in which a company, while making a significant contribution to internationally competitive activity in Australia, is unable to meet these eligibility criteria. In such circumstances, the Authority may recommend price increases on qualitative grounds.

Eligibility criteria

The new entrant must undertake to meet one of the following two eligibility criteria within three years of entry into the scheme and the other within five years of entry into the scheme.

Production	Increase the value added in Australia on pharmaceutical production by 50 per cent over a 3 year period.
Research and development	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.

However, a company able to demonstrate it can meet the eligibility criteria will not automatically qualify for Factor f price increases. 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.

Qualitative proposals

Where a company is unable to meet the eligibility criteria above, the Authority may recommend price increases if the company is able to demonstrate it is substantially increasing its activity in Australia, and the activity is internationally competitive and is likely to lead to significant net benefits for Australia. The purpose of this provision is not to bypass the stringency or intent of the eligibility criteria, but to provide some flexibility in cases where a company's development strategy is no less ambitious.

In deciding whether to recommend approval of a proposal on qualitative grounds, the Authority will consider the activity proposed by the company including:

- 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 program and workplace reform;
- establishment of Australia as a centre for operations in the Asia Pacific region; and
- other internationally competitive activity.

Performance targets after achieving the eligibility criteria

Once a new entrant has demonstrated it can meet its proposed eligibility criteria or has been approved on qualitative grounds, the Authority will discuss with the company performance targets for the:

- remainder of the proposal where a company meets the eligibility criteria; or
- entire proposal where a company has been approved on qualitative grounds.

The targets will initially be determined at the time of approval of a proposal. Performance targets will generally be growth rates for increases in R&D and value added production.

New proposals from participants in Factor f Prior to 1 July 1992

New or revised proposals for price increases under the Factor f scheme from companies participating in the scheme prior to 1 July 1992 must include a detailed outline of internationally competitive activity the company proposes to undertake under the extended scheme. Continuing participants will not be required to meet the entry requirements for new entrants if they have met all their performance requirements under the 1988 guidelines and the 1990 revised guidelines. However, to continue to receive Factor f price increases these companies will be required to demonstrate their continuing commitment to expanding internationally competitive activity by meeting negotiated performance targets or milestones. Continuing participants in the scheme will maintain their existing base year.

Where a company participated in Factor f prior to 1 July 1992 and did not meet its performance requirements under the scheme, its eligibility criteria and base year for the extended Factor f scheme will be negotiated with the Authority, subject to approval by Ministers, based on the company's proposed activity for the extended scheme and its actual performance under past guidelines.

The Authority will evaluate the proposals of all continuing participants to determine 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.

If the Authority considers a proposal is insufficient when measured against these criteria, it will discuss additional activity or higher performance targets with the company.

If the Authority determines the proposal is acceptable, it will discuss with the company the payment rate it will recommend to Ministers for approval of the proposal.

Price increases

Payment rates

Price increases will be calculated on the value of increased activity by the company. The maximum payment rate a company may receive for a proposal will be 25 per cent of the value of the increased activity. The actual level of payment will be based on the Authority's assessment of the benefits to Australia of a proposal.

Production

- Price increases for production activity will be paid on the increase over the base year in value added in Australia. The rate will vary up to a maximum of 25 per cent of increased value added in Australia.

R&D

- Price increases for R&D activity will be paid on the increase over the base year in after tax expenditure on R&D. The maximum payment rate a company may receive for R&D activity will be 50 per cent of the increase in after tax expenditure or 25 per cent of the increase in total expenditure, whichever is the lesser.

Application of price increases

Companies may apply price increases under Factor f to any of their pharmaceutical products listed on the PBS with the agreement of the Authority. Price increases will be paid direct to companies based on the activity they identify in quarterly activity reports. Payments will be made one quarter in arrears of reported activity.

Maximum price increase

Factor f price increases may not increase the price of a product to more than the average price of the product in the European Community (EC). The EC average

price will be based on a simple average of the price of the product in EC countries in which it is sold. Where a realistic EC comparison is not possible, the Authority will determine an appropriate price ceiling.

Monitoring

Performance monitoring and price review

The Authority will monitor the performance of all companies receiving Factor f price increases to ensure price increases paid to companies are consistent with the actual performance of each company. Companies will be required to submit an annual monitoring report within three months of the end of their financial year in accordance with monitoring guidelines determined by the Authority. Payments of price increases will be based on activity reported by companies in quarterly activity reports and annual monitoring reports.

Three year review

The Authority will review the performance of each company after three years in the Factor f scheme. To assist the Authority with its review, companies will be required to submit revised forecasts of activity for the remaining years of the scheme. The review will enable the Authority and companies to review their performance in the scheme and to negotiate revised performance levels and price increases for the remainder of the proposal. The three year review will not preclude companies from lodging new or supplementary proposals. A company's proposed activity may also be subject to review at any time if performance monitoring establishes a company is performing significantly below forecast target levels.

D INTERNATIONAL PHARMACEUTICAL REGULATIONS

This Appendix outlines the regulatory environment faced by the pharmaceutical industry in major overseas markets.

D.1 Introduction

An understanding of the regulation of the pharmaceutical industry internationally is important for the Australian industry and community because of the high degree of internationalisation of the industry and its increased sensitivity to adverse regulatory environments.

Hansen argued that:

> Regulation of the pharmaceutical industry, ... is likely to have effects which go well beyond the borders of the regulating country. While regulations on pharmaceutical manufacturing practices are likely to have primarily national effects with some spillover to international trade, those regulations affecting pharmaceutical innovation may have a major impact on the availability of therapies in other countries. This impact, ... is due to the international nature of the market for pharmaceutical innovations (Hansen 1983, p. 568).

This Appendix deals with regulations in the key areas of:

- tariff and non-tariff barriers to trade;
- drug evaluation and scheduling;
- health insurance;
- pharmaceutical reimbursement;
- price and profit control;
- standards of manufacturing; and
- product liability.

Chapter 16 contains a discussion of patent protection.

D.2 Tariff and non-tariff barriers to trade

Customs tariff rates on pharmaceutical products are generally low and are not considered to significantly affect international trade flows. The increased globalisation of the pharmaceutical industry has meant that tariffs operate less as a protective trade mechanism and more as a tax on imports, simply adding to the cost of the final product. Non-tariff barriers (such as restrictions on imports of pharmaceuticals) are considered to be more important in affecting competitiveness. Nevertheless, selected pharmaceutical products are subject to relatively high tariff rates in some countries and these can have a significant impact on trade and competitiveness. For example, in 1991 Indonesia had tariff rates on some lines of pharmaceutical products as high as 60 per cent, while Bangladesh had rates as high as 100 per cent.

Emerging trade patterns in the pharmaceutical industry have been influenced by the results of multilateral trade negotiations—namely the Tokyo and Uruguay Rounds of the General Agreement on Tariffs and Trade (GATT). National approaches, particularly with regard to tariffs on pharmaceutical and medicinal products, have largely been governed by the GATT agreements. Agreements on non-tariff barriers (such as technical standards and requirements) have not been universally adopted.

During the Uruguay Round, the industry campaigned for the global elimination of tariffs on pharmaceutical and medicinal products. It argued that the existing worldwide tariffs, although generally less than 10 per cent, represent a significant barrier to trade and were in conflict with national cost containment programs. While the pharmaceutical industry did not succeed in eliminating all tariffs, a number of substantial markets, including Japan, the European Union (EU), Canada and the US, did make commitments to eliminate their tariffs (see Table D.1).

D.2.1 Technical barriers to trade

Technical barriers to trade are widespread and are generally justified on the grounds of protecting public health and safety. Under the Uruguay and Tokyo GATT Rounds, exemptions were made for measures which can be justified on public health and safety grounds. However, these must be applied without discrimination. Thus, the international industry and the domestic industry must be regulated in the same fashion.

Table D.1: Tariffs applied to imports of pharmaceutical and medicinal products, pre and post Uruguay Round agreements, 1995, per cent

Country	*Average tariff* [a]		*Per cent tariff*
	pre-Uruguay	*post-Uruguay*	*cut*
Austria	8.9	0.0	100.0
Canada	7.7	0.0	100.0
China	18.1	18.1	0.0
EU	5.8	0.0	100.0
Finland	0.0	0.0	0.0
Hong Kong	0.0	0.0	0.0
India	68.9	36.9	46.3
Indonesia	16.3	2.8	82.7
Japan	4.5	0.0	100.0
Korea	22.4	11.3	49.3
Mexico	50.0	15.0	70.0
Norway	0.0	0.0	0.0
Philippines	19.0	17.3	8.9
Singapore	10.0	0.0	100.0
Sweden	0.0	0.0	0.0
Switzerland	0.2	0.0	100.0
Thailand	29.0	21.9	24.5
US	4.4	0.0	100.0
Average above countries	**8.1**	**2.6**	**57.6**
Australia[b]	0.3	0.3	0.0

a Trade weighted averages based on unbound commitments.

b Australia currently has tariffs of 5 per cent on cotton wadding and bone cements which are included within the trade category of pharmaceutical products, all other products are tariff free.

Sources: DFAT 1995; ACS 1988, Chapter 30

The Uruguay GATT Round provided for two levels of commitment. The first level applies to the signatories of the agreement, the central governments, and is effectively a full commitment. The second, termed ‘best endeavours’, applies to regulatory and technical barriers of local (or state) and non-government bodies. It essentially recognises that, in a federalist system, the central government cannot always enforce international treaties. However, in most countries health

and safety associated with pharmaceuticals are a central government responsibility.

The GATT agreements also recognised the importance of international harmonisation of regulations. The adoption of the International Organization for Standardization (ISO) standards in many industries has been important to achieving common standards. In the pharmaceutical industry, international standards have been slow to develop although recently some progress has been made following the first and second International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceutical for Human Use (ICH) (see Section D.3.4).

A further avenue of harmonisation of standards has been through the adoption of the Good Manufacturing Practice (GMP) guidelines. These specify standards of plant construction and operation and are discussed further in Section D.6.

D.3 Drug evaluation

The evaluation of the efficacy and effectiveness of drugs is a prerogative of all governments and has arisen in response to mishaps in the marketing of drugs in the past. Virtually all nations assess the efficacy of drugs. However, there are often multiple levels of evaluation applicable within jurisdictions. These can include:

- sub-national regulations (for example where the central government does not have the authority to regulate market access); and
- supra-national regulations, such as in the EU, where the European Medicines Evaluation Agency (EMEA) provides an alternative assessment stream.

Table D.2 presents some information on national evaluation processes in a selection of countries.

D.3.1 United States

The US is generally considered to have the most rigorous requirements for assessing drugs. Its arrangements have evolved on a national scale since 1906 when the *Pure Food and Drug Act* 1906 (US) was enacted. Initial regulatory arrangements targeted pharmaceutical products which were fraudulent and dangerous, and the abolition of unsanitary conditions in pharmaceutical manufacturing facilities. Since then, widespread adverse reactions to new drugs, firstly in the 1930s in response to sulphonamide and subsequently to Thalidomide in 1959 to 1962, saw the Act progressively strengthened.

Table D.2: Drug evaluation

Country	*Main national evaluation body*	*Sub-national evaluations*
Australia	Therapeutic Goods Administration	No
Belgium	Ministry of Health, EMEA [a]	No
Canada	Health Protection Branch	Yes
Denmark	National Board of Health, EMEA	Yes
France	Medicines Directorate (DPhM), EMEA	No
Germany	Federal Ministry of Health (BGA), EMEA	Yes
Greece	Ministry of Trade	No
Ireland	EMEA	No
Italy	United Commission for Drugs, EMEA	No
Japan	Ministry of Health & Welfare (*Koseisho*)	Yes, some provincial responsibility
Netherlands	Committee for the Evaluation of Medicines, EMEA	No
New Zealand	Ministry of Health	No
Sweden	National Board of Health & Welfare, EMEA	No
Switzerland	Intercantonal Office for the Control of Medicines	No
UK	Medicines Control Agency (MCA), EMEA	No
US	Food & Drug Administration (FDA)	Yes

a European Medicines Evaluation Agency (EMEA) applies to all EU member states.
Source: USITC 1991

The *Food Drug and Cosmetic Act* 1938 (US) (FDCA) established the Food and Drug Administration (FDA) as the national body responsible for testing and approving pharmaceutical products. The FDCA introduced the requirement for drug evaluation through clinical trials which has since been followed in Australia and elsewhere.

The 1962 Amendments, known as the Kefauver–Harris Amendments modified the FDCA to restrict experimentation with new drugs. The Amendments arose out the Kefauver Hearings by the US Senate Sub-Committee on Antitrust and Monopoly and were originally focused on price collusion and excessive profitability in the pharmaceutical industry. Under the Amendments, the process of seeking investigational new drug approval prior to commencing clinical trials and making application for marketing approval were established.

Finally, the Amendments introduced the process for filing post-approval adverse reaction reports.

In 1984, the FDCA was amended under the *Drug Price Competition and Patent Term Restoration Act* 1984 (commonly known as the Waxman–Hatch Act). This Act addressed the issue of the impact of regulatory approval delay on product patent lengths and resulting profitability. Growing evidence had accumulated to show that the industry's success at R&D was declining. Under the Waxman–Hatch Act, innovative drug companies received partial restoration of their patent term by up to 5 years on new products, depending on the amount of time lost during regulatory review, in return for greater market accessibility for generic products through new procedures for abbreviated new drug applications for generic versions of previously approved drugs.

D.3.2 European Union

In the EU, marketing approval procedures are being standardised. The European Commission (EC) has implemented a two track system of drug evaluation giving pharmaceutical companies the option of using a national regulator, or the EMEA. The Committee for Proprietary Medicinal Products (CPMP) makes technical assessments and recommendations to the EMEA.

The decentralised (or multi-state) approach, permits a company to extend a marketing authorisation issued by one member state to at least two other member states. To qualify, the member states' initial authorisation must comply with EU directives governing member state approval. Applications can then be forwarded to other member states' authorities and concurrently the EMEA should be notified. The member state in which authorisation is sought must then either grant authorisation within 120 days or forward objections to the EMEA. Generally, the EMEA gives its decision within 60 days and the member state then has another 60 days to decide what action to take.

The centralised approach enables important questions relating to quality, safety and efficacy to be resolved within the EMEA/CPMP before any national decision is taken. In this approach, the applicant requests a member state to become a rapporteur, which involves forwarding the application to the EMEA. The rapporteur then establishes a decision date for the EMEA, prepares an evaluation report and forwards this to the member states and the applicant. The member states respond with comments which are then included in a second draft of the rapporteur's report, to which the applicant responds. The EMEA recommendation is concurrently forwarded to member states. Those states in which the applicant has requested approval are then required to finalise their

decisions and forward them to the EC. This process of approval must be used for biotechnological products and novel drugs.

D.3.3 Japan

The Japanese regulatory system is quite different to the US and European systems. The major law regulating the marketing of pharmaceuticals in Japan is the *Pharmaceutical Affairs Law* 1960. Under the law, applications for marketing approval must proceed through various local and federal government bodies. Applications start at the Prefecture Government of the sponsoring company. The application is then filed with *Koseisho* (the Japanese Ministry of Health and Welfare) whose Pharmaceutical Affairs Bureau enforces regulations governing drug usage, approval and efficacy. *Koseisho* has established a drug expert committee linked to the *Chuikyo* or Pharmaceutical Affairs Council consisting of academic, research and medical authorities. The applicant then has the opportunity to respond to *Chuikyo's* decision. Concurrently, the National Institute of Hygienic Sciences and the National Institute of Health verify the specifications and analytical methods used in the application. The applicant is then given an explanation of the results of the Council's deliberation. A hearing may be held on additional documents in answers to directions issued by the Council. Finally, the Minister is requested to approve the drug for marketing. From application to the Prefecture Government to Ministerial approval, average assessment time is normally 18 months for prescription drugs, 10 months for non-prescription drugs, and 6 months for in vitro diagnostics.

D.3.4 International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use

The ICH process involves the EU, the US and Japan. Australia attends as an observer. It was initiated by the EU.

The first conference (ICH I) agreed on guidelines for the detection of toxicity in the reproduction of medicinal products and for studies in support of special populations—for example geriatrics.

ICH II considered:

- population exposure required to address clinical safety;
- management of clinical safety information;

- dose response studies;
- the contents of clinical study reports; and
- ethnic factors in the acceptability of foreign data.

There has been considerable progress towards the implementation of some of the ICH II decisions, although at this stage decisions are still restricted to assembling data and preparing guidelines.

D.4 Drug scheduling

In most countries a scale of drug and poison schedules has been developed in order to regulate access to pharmaceuticals. There are five broad levels of access:

- open access through supermarkets, pharmacists and related outlets;
- supply restricted to pharmacies;
- supply restricted to pharmacists;
- supply only with prescription by General Practitioners (GPs) and related medical professionals; and
- sale only with GP's prescription and with prior approval from appropriate government regulator.

Not all countries utilise all these classes of drugs. For example, Table D.3 lists the countries adopting a class of drugs restricted to pharmacies (incorporating the second and third classes of drugs listed above). The US and Greece are two countries which do not have such classes of drugs.

Scheduling, in contrast to evaluation functions, has traditionally been a local or regional government activity. This is because drugs are often rescheduled in order to prevent localised abuse. However, there is also a recent trend towards developing nationally uniform drug scheduling. This trend is reflected strongly in Australia where the development and adoption of the Standard for Uniform Scheduling of Drugs and Poisons (see Chapter 15) has effectively eliminated local variations in drug schedules.

Table D.3: Intermediate drug schedules

Country	*Sale of some OTCs restricted to pharmacies*	*Country*	*Sale of some OTCs restricted to pharmacies*
Australia	Yes	Italy	Yes
Belgium	na	Japan	Yes
Canada	Yes	Netherlands	Yes
Denmark	Yes	New Zealand	Yes
France	Yes, all OTCs	Sweden	Yes, all OTCs
Germany	Yes	Switzerland	na
Greece	No [a]	UK	Yes
Ireland	na	US	No

a No clear distinction is made between OTC and prescription drugs in Greece due to the lack of general practitioners in the Greek medical profession (OECD 1994, p. 161).
na not available
Source: Spivey, Wertheimer & Rucker 1992

In the EU consideration is also being given to the harmonisation of drug schedules. A recent directive has announced that:

> ... the criteria (toxicity, counter-indications and so on) according to which the arrangements for issuing medicines is established (issued with or without a prescription) when they are being marketed are to be harmonised. Under the system, a clear distinction will be made between medicines that may be issued without a medical prescription and those for which a prescription will be required. In the latter case, European citizens will be a lot better off, for they will be able to acquire the same medicines without a prescription in all the Member States (*Multinational Service*, 1992).

The General Accounting Office highlighted that the EU directive was restricted to providing principles for classifying drugs as prescription only, and stopped short of harmonising intermediate drug classes:

> The EU has set criteria for distinguishing prescription from non-prescription products. However, since EU officials could find no evidence showing the superiority of a particular drug distribution system, each country will decide the nature and number of its own drug distribution classes (GAO 1995, Chapter 0:4.2).

The Pharmaceutical Society of Australia indicated that a recent review of drug schedules in Canada also considered harmonisation of schedules across Canada (sub. 116, Attachment B). In the US scheduling is a state function; however, the broad adoption of just two drug schedules means that variations in drug schedules between states is reduced.

D.5 Health insurance

There are major variations in the level of retail prices of drugs in different countries. This variation can also be observed within the single market of the EU. The variation reflects the diversity of policies and attitudes towards health insurance, pharmaceutical price regulation, reimbursement, industry promotion, scheduling and taxation. A number of alternative health insurance arrangements have been adopted:

- Primarily private insurance is often associated directly with employers and regional funds, and supplemented with government reimbursement schemes for the unemployed, poor and elderly. Such a system has been adopted in the US and Switzerland. However, over 99 per cent of the Swiss population is insured (OECD 1994, p. 286), compared with only 74 per cent of the US population (OECD 1994, p. 318). The Swiss system is also characterised by a risk equalisation fund which cross subsidises funds according to the perceived risk of their cohorts.
- Health Insurance Funds (HIFs, *Krankenkassen* or Sickness Funds), were developed in Germany during the late 19th century. The system has since been adopted in the Netherlands, Denmark, France, Japan and Korea. The system is centred around industry-wide and regional insurers, membership of which is normally compulsory, although choice of fund is possible for some consumers on the margin. Competition between the funds is permitted, although normally this is limited to competition with premium funds which patients can opt into. The HIFs and service providers negotiate budgets, prices and other charges through the formation of regional associations.
- Mutualities are similar to HIFs, however, membership is normally voluntary and the mutualities are owned by non-profit organisations or friendly societies. Mutualities are common in both Belgium and France. Belgium has just five mutualities, in contrast to France which has several thousand. In France mutualities provide supplementary insurance to augment the compulsory HIF insurance. They reimburse patient's expenditure and have no formal relationship with service providers.
- National health insurance has been adopted in the UK, Ireland, Italy, Australia and New Zealand. Nationalised insurers are funded through compulsory levies and general taxation. Patients often opt to supplement nationalised coverage with private insurance.
- Regional health insurers have primarily been established in countries in which the central government does not have responsibility for health—for example in Canada. Regional health authorities have also been established

under the auspices of a national health authority in recent reforms in the UK and New Zealand. Often the taxing and levy powers of the regional authorities are supplemented by federal subsidies.

The financial relationship between insurers and service providers in health care systems falls into three broad categories. Each of these payment systems (or all three) can exist in any of the health insurance arrangements described above:

- Fee-for-service (FFS) relates to a retrospective reimbursement of service providers' expenses. FFS payments can be made directly by the insurer to the provider (for example through bulk billing of physician fees in Australia) or via the patient who may then be reimbursed for a proportion of the service fee. FFS payments are the traditional means of funding health care.
- Prospective payments systems are essentially contractual payments made by insurers in advance of service delivery. Hospitals, for example, can be funded on the basis of the expected casemix (or service demands) of the populations they service. Such arrangements are applied in the US Medicare system.
- Capitation involves an agreement between the regulator and the service provider to share risks through annual payments independent of the volume of services provided. FFS payments may still apply. However normally capitation limits the liability of the regulator and provides incentives to the manufacturer or service provider to contain sale volumes to the cap as sales beyond the cap are unfunded.

D.6 Pharmaceutical reimbursement

Within the context of health insurance generally, countries also operate various schemes for reimbursing a patient's pharmaceutical expenditure. These are listed in Table D.4.

A particular feature of most pharmaceutical insurance schemes is the use of lists of drugs which are covered by insurers. These lists fall into a number of different categories:

- a selected list, where a single national insurer agrees to reimburse only a selected range of pharmaceuticals (for example in Australia);
- a positive list, where a national regulator imposes upon private insurers and the compulsory HIFs a list of drugs which are reimburseable. Those drugs excluded from the list are not reimburseable by the insurers, but may be available for private sale; and

- a negative list, which operates in a similar way to a positive list except that it includes drugs which cannot be reimbursed.

National regulators, such as the Pharmaceutical Benefits Advisory Council in Australia, often make assessments of the relative costs and effectiveness of drugs when deciding whether drugs should be included on their lists.

D.6.1 Reference pricing

Germany has a statutory health insurance scheme which is the main purchaser of pharmaceuticals. In 1989, Germany passed the *Health Reform Act 1989* (HRA). Phase 1 fixed reimbursement levels for products that were off-patent and that had a relatively high volume of use at a level between the generic price and the original manufacturer's price (reputedly closer to the former than the latter).

Under phase 2 of the HRA, a reference price was introduced for products that were 'chemically related and are pharmacologically and therapeutically comparable' (USITC 1991, p. 3-23). In phase 3, a reference price was introduced for '... particular combinations of products which are not necessarily chemically related, but which are pharmacologically and therapeutically comparable' (USITC 1991, p. 3-23).

Reference pricing has since been adopted as a mechanism to contain costs in a number of EU member states and has been considered in Canada and Japan. The attraction of reference pricing, for regulators, is the introduction of an element of market competition. Companies can achieve price premiums through brand promotion but must compete with generic therapeutic substitutes. The price versus quality sensitivity of the consumer then dictates the market shares of the companies.

Table D.4: Health and pharmaceutical reimbursement mechanisms

Country	*Insurers*	*Lists in operation*	*Basis for inclusion on reimbursement list*
Australia	PBS	Selected	Factors a - h, esp. cost effectiveness analysis
Belgium	5 mutualities	Positive	Seriousness of condition and therapeutic value
Canada	Province based	Provincial based	Normally all prescription products, reimbursement based on manufacturing costs
Denmark	Health Insurance Funds (HIFs)	Reference price	Therapeutic clustering excludes drugs which are not economical and of little therapeutic value
France	Statutory HIFs & mutualities	Positive	Therapeutic value, relative price, activities in France
Germany	~1100 HIFs	Reference price & negative	Therapeutic clustering excludes drugs which are not economical and of little therapeutic value
Greece	2 schemes: city based & rural	Positive	A number of funds cover most pharmaceutical products with varying rates of patient copayment, lists are poorly enforced
Ireland	4 schemes differentiated by hardship & need	Positive-General Medical services Code Book	GMS Code Book includes prescription drugs of therapeutic value, other schemes are not selective
Italy	National Health Service (SSN)	Positive	Includes all prescription products not used exclusively in hospitals. The positive list has class A (dispensed without copayment) & class B (subject to copayment)
Japan	HIFs	Positive	The reimbursement rate is unrelated to the price paid for the product
Netherlands	HIFs	Reference prices	Therapeutic clustering, reimbursement to the level of average priced drug in therapeutic class
New Zealand	Regional Health Authorities	Selected	The Drug Tariff, reimbursement to the level of lowest price drug in therapeutic class, based upon price in Aust., the UK and country of origin
Sweden	HIFs	Reference prices	Therapeutic clustering, reimbursement to the level of average priced drug in therapeutic class
Switzerland	~200 private insurers	Recommended positive list, plus compulsory negative list	Varies between insurers, most follow the suggested list of the OFAS which lists according to cost effectiveness
UK	NHS: PBS	Selected	Includes almost all prescription products, cost effectiveness assessment has been considered
US	~1000 private insurers	None	Not applicable

SSN Servizio Sanitario Nazionale
OFAS Federal Office of Social Insurance
Source: OECD 1994; EC 1995

D.7 Price and profit control

Price control strategies (see Table D.5) are another arm of most countries' efforts to restrict the cost burden that universal access to medicines imposes on insurers. Often, regardless of the insurance and reimbursement arrangements, the central government acts on behalf of the insurers to negotiate or control pharmaceutical prices. Centralising price negotiation with the pharmaceutical manufacturers enables the purchaser to maximise its monopsony power to drive down pharmaceutical prices.

There has been increased attention on the impact of domestic prices on domestic activity levels. The industry has long argued that low prices are a disincentive to domestic investment, manufacturing and research, and encourage companies to disinvest. A number of countries have responded by offering higher prices for drugs which represent significant breakthroughs, for example Japan.

D.7.1 European Union

Pricing controls on pharmaceutical products in the EU are implemented by all member states. In 1983 the European Court of Justice ruled in the Duphar case that individual member states can organise their health care and social security systems so as to ensure the financial stability of these systems. Controls on the prescribing behaviour of doctors in which only certain prescribed drugs are reimburseable were declared legal and consistent with the Treaty of Rome. This ruling established the validity of negative lists and other restrictions in the EU (*Duphar vs. The Netherlands*, ECJ Case 238/82 [1984] CMLR 256).

The EC has also attempted to harmonise price regulation procedures in EU member states. This does not imply equalisation of prices but instead refers to the development of common procedures of assessment, reporting, feedback and appeal. Such procedural provisions were incorporated in the EC's Price Transparency Directive in 1990 (EC 1989). Although the status of the Directive appears questionable under European law (failing an appeal by the Belgium Government to the European Court of Justice (Burstall 1992, p. 5)) all EU member states have now implemented the directive.

Table D.5: Price control approaches adopted

	Each drug price controlled	*Better price for local activities*	*Basis of allowed price*	*Body regulating prices & approved list*	*Comparative drug prices*
Australia	Yes, only on schedule	Yes, Factor f	Factors a–h	PBPA Dept of Health	Low
Belgium	Yes	Yes	Transparency Committee, matches price and per unit therapeutic value	Ministry of Economic Affairs & INAMI	Low
Canada	No	No	Primarily by tender	na	Low
Denmark	No, reference pricing	No	'Most competitive priced' drug in therapeutic class	Ministry of Health	High
France	Yes, only on schedule	Maybe	Based upon fixed mark-ups and annual indexations	DPhM	Medium
Germany	No, reference pricing	No	'Most competitive priced' drug in therapeutic class	BGA	Medium
Greece	Yes, only on schedule	No	The lower of the country of origin price and average EU price	Ministry of Trade	Low
Ireland	Yes	No	Priced at the lesser of price in UK and a basket of EU countries	Department of Health	Medium
Italy	Yes	Yes	Costs, including allowance for research content. OTCs referenced to prices in other EU member states	Interdepartmental Committee on Prices	Low
Japan	Yes	na	Relative to existing listed drug treating therapeutic class, otherwise R&D pay back, rates of depreciation apply	Ministry of Health & Welfare *(Koseisho)*	Medium
Netherlands	No, reference pricing	No	'Most competitive priced' drug in therapeutic class	*Ziekenfonds-verzekering*	Medium
New Zealand	Yes	No	Relative effectiveness	PHARMAC	Low

(cont.)

Table D.5: Price control approaches adopted (cont.)

	Each drug price controlled	*Better price for local activities*	*Basis of allowed price*	*Body regulating prices & approved list*	*Comparative drug prices*
Sweden	No, reference pricing	No	'Most competitive priced' drug in therapeutic class	*Apoteksbolaget*	Medium
Switzerland	Yes, drugs subject to price ceilings	No	Price monitoring, control of 'excessive' priced drugs	OFAS	High
UK	No, profit control	Higher profits allowed	PPRS, negotiates a global profit margin with each firm, Rx products only	National Health Service	Medium
US	No	No	na	na	High

BGA Federal Department of Health, Germany
DPhM Medicines Directorate, France
INAMI National Institute for Health, Sickness and Invalidity Insurance, Belgium
OFAS Federal Office of Social Insurance, Switzerland
PBPA Pharmaceutical Benefits Pricing Authority, Australia
PPRS Pharmaceutical Price Regulation Scheme, United Kingdom
na Not available or not applicable
Sources: OECD 1992; OECD 1994; Spivey, Wertheimer & Rucker 1992; EC 1995

D.7.2 Profit control in the UK

The UK pharmaceutical industry is generally viewed as being highly successful in terms of exports and R&D and the UK is considered an attractive location for pharmaceutical manufacturing and research activity.

The UK Department of Health and Social Security is the monopsony buyer of all prescription pharmaceuticals for the National Health Service (NHS). However, the Department does not use its power to directly control the price of NHS drugs. Instead, the Pharmaceutical Price Regulation Scheme (PPRS)—a joint agreement between the UK government and the Association of the British Pharmaceutical Industry—is designed to control the profits that companies may make on NHS sales.

The PPRS has two functions:

- to secure supply of medicines to the NHS on fair and reasonable terms; and
- to promote the UK pharmaceutical industry.

The PPRS sets profitability targets for individual companies, expressed as a return on capital, with a current target range of 17 to 21 per cent. However, the system is flexible. Companies can present a case for retaining above target profits if they can demonstrate new products are due, or if there is improved efficiency. Similarly, a company may obtain a price increase if it can establish that at current prices it cannot achieve its target profit (BIE 1991, p. 147). The UK government recently announced a review of the PPRS.

D.7.3 WHO price monitoring

The Australian Pharmaceutical Manufacturers Association stated that, at the recent International Conference on National Medicinal Drug Policies, the World Health Organisation (WHO) was asked to:

> ... set up a committee of experts which would consider ways to monitor and report on prices and pricing mechanisms of essential drugs and raw materials (sub. 199, Attachment C, p. 2).

Essential drugs and raw materials are those included under the WHO's list of essential drugs. This list has been compiled to provide developing countries with assistance in determining which drugs are necessary and affordable.

D.8 Standards of manufacturing

Standards of manufacturing have been developed by governments worldwide to ensure that pharmaceutical products are of adequate quality. They relate to the manufacturing, processing, packaging and handling of pharmaceutical preparations and other medicinal products.

The purpose of the standards is to ensure that drugs are safe and stable and are manufactured in an environment which minimises the risk of contamination. The standards prescribe quality of ingredients, construction of plants, facilities for employees and the production process, levels of staff training and systems of record keeping and surveillance.

In 1987, the WHO and the pharmaceutical industry established GMP principles. A number of derivatives of these standards have since been developed by individual countries. Amongst the developed economies, the US and the European Free Trade Association have established more rigorous guidelines. In the less developed countries of East Asia and Latin America the standards applied to pharmaceutical manufacturers are less strict (Ballance, Pogany and Forstner 1992, pp. 144–5).

The Australian GMP standards, which are in harmonisation with the WHO standards, are presented in Box D.1.

Box D.1: Australian Good Manufacturing Practice standards for pharmaceutical manufacturing facilities

The Good Manufacturing Practice (GMP) standards have developed over a number of years as a detailed form of quality assurance applicable to the pharmaceutical industry. The Australian standards are broadly consistent with the WHO guidelines. Guidelines covering the buildings and grounds, for example, specify:

- the condition of pipes, ducts and service areas;
- space, layout and compatibility;
- air control;
- floors, walls, ceilings, and associated fittings; and
- goods receival and storage areas.

Standards also prescribe equipment conditions, manufacturing procedures, factory sanitation and personal hygiene, staff training and skills, documentation of activities and products, quality management, testing and feedback, with additional provisions for contaminants.

Source: TGA 1990, pp. 10–14

D.9 Product liability

Product liability laws regulate the ability of consumers to seek redress from the manufacturer in response to injury or loss. One US estimate is that liability insurance and litigation defence costs account for over 95 per cent of the price of a childhood vaccine (USITC 1991, p. 3-26). Approaches adopted around the world vary significantly. The costs derive from insurance and protection against claims and defending the claims themselves. These costs are significantly higher in the US than in the rest of the OECD.

> The US product liability system ... has resulted in a decline in competitiveness of US companies compared with foreign firms. Unlike non-US companies, the US companies must factor the cost of product liability claims into the price of their products (USITC 1991, p. 3-27).

Because there is no national statute governing product liability in the US, product liability laws vary from state to state. This imposes considerable costs on manufacturers. For example:

> A dispute over the safety and efficacy of a drug can lead a manufacturer into extended and costly litigation in fifty separate jurisdictions, so that defenses have to be proven again and again (USITC 1991, p. 3-27).

Harmonisation of product liability laws has occurred in Europe. The EC issued a directive covering liability for defective products in 1985 (EC Directive 85/374/EEC). The Commission's directive proclaimed that:

> ... the differences among member states liability laws distort trade and hamper the free movement of goods and the formation of a common market for consumers (USITC 1991, p. 3-28).

The directive went on to introduce a strict liability regime in which litigants would merely have to show that the product was defective and that injury occurred as a result. This contrasts with the liability regime then in force among most EU member states which required the litigant to show that the producer had been negligent. This would have meant proving, for example, that the company was aware that the product was defective.

The EU directive appears to have been implemented among member states. However, differences in provisions among states remain as the directive allows for member states to implement revisions and additions in relation to legal procedures and particular areas of damage.

The existence of government approval is a defence in a number of countries around the world (such as the UK), but no such defence exists in Australia or the US.

E INTERNATIONAL CASE STUDIES

This Appendix examines the health environment and industry development incentives for several countries that have an established or emerging pharmaceutical industry. It highlights differences in the health environment, approaches to cost containment and industry development policies.

E.1 Introduction

Chapter 6 examined the potential impact of a number of demand and supply-side factors on the development of the international pharmaceutical industry. In particular, the Chapter identified two important factors affecting the structure of the industry: the approach to health cost containment adopted by countries and industry development programs offered by governments.

This Appendix provides information on the health policy environment (focusing on approaches to cost containment) and industry development initiatives in several countries. Countries examined are: Canada, Ireland, Japan, New Zealand, Sweden, Singapore, the UK and the US. These countries illustrate the diversity in approaches to health cost containment and industry development (see Box E.1).

Before examining each country in detail, it is useful to look at the broad picture that emerges from trade data and information on industry assistance.

E.1.1 Trade data

A country's share of world exports can be a useful indicator of the impact of the operating environment and industry development programs on the pharmaceutical industry.[1]

[1] However, as previously noted by the IC (1992, pp. 16-17), to be 'successful', industry development measures would have to do more than increase exports of particular products—they must raise national prosperity.

Box E.1: Country categories

The countries covered in this Appendix can be divided into two broad categories—depending upon the level and type of activity undertaken.

Category A: Countries with an established and sophisticated pharmaceutical industry (including a significant research base). These countries are involved in all stages of pharmaceutical production—they have discovered, developed, produced and marketed a number of new chemical entities (NCEs)—and are the home base for at least one multinational pharmaceutical company. Countries examined from this category are Japan, Sweden, the UK and the US.

Category B: Countries with innovation capabilities that have recently discovered and marketed at least one NCE. These countries have expertise is several stages of production (usually medical research and development capabilities, manufacturing and an area of specialised active synthesis) and have developed domestically-owned companies or extensive links with multinational companies. The countries examined in this category are New Zealand, Ireland, Canada and Singapore. Ballance, Pogany and Forstner also included Australia in this category.

Countries in the two categories can be further classified into those that have specifically targeted the pharmaceutical industry (such as Sweden, Ireland and Singapore) and those which have not (such as the US, the UK and New Zealand).

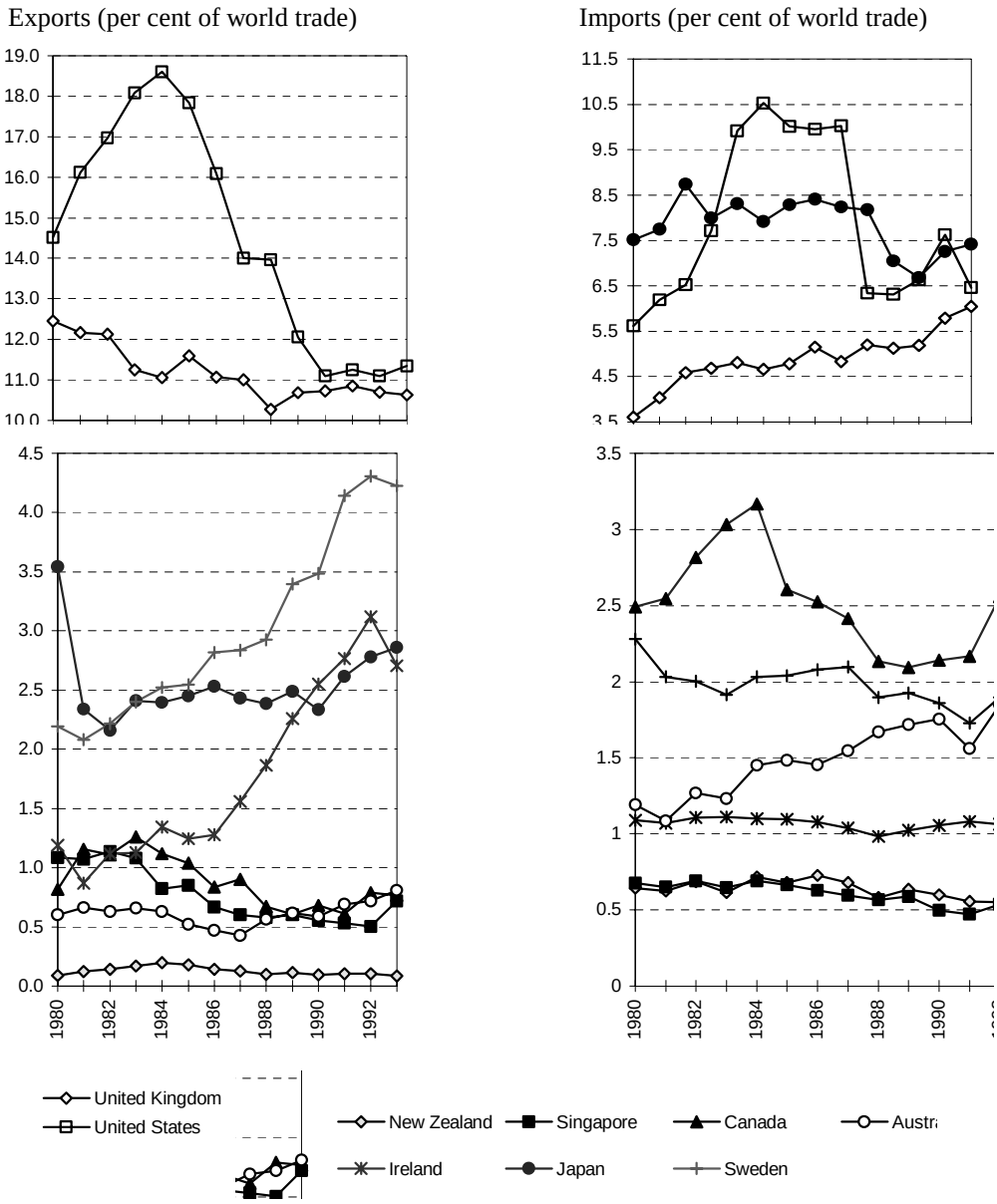
Source: Ballance, Pogany & Forstner 1992, pp. 8–9

Figure E.1 illustrates how the shares of world pharmaceutical trade have changed throughout the 1980s. Since 1987, Ireland, Japan and Sweden have experienced a dramatic rise in their shares of world pharmaceutical exports. Since 1980, export shares have declined slightly for Singapore and Canada and remained steady for Australia and New Zealand.

E.1.2 R&D incentives

Chapter 6 noted that a number of countries have put in place industry development initiatives that benefit the pharmaceutical industry. All of the countries covered in this Appendix use some form of tax concession incentive system to encourage research and development (R&D). Given the important role that R&D plays in the pharmaceutical industry, the level of support afforded by the tax concession provides a useful indicator of the relative

Figure E.1: Country pharmaceutical [a] exports and imports as a percentage of world pharmaceutical exports, 1980 to 1993 per cent



a Defined by Standard International Trade Classification 541: Medicinal and Pharmaceutical Products.
Source: UN 1995

generosity of government support for the industry.[2] Some countries have also adopted a number of non-tax incentives for new investments such as direct

[2] A caveat is that some countries (for example Ireland) have very generous incentive schemes that can assist the pharmaceutical industry. Other countries, such as the UK and the US do not offer specific industry assistance to their pharmaceutical industries.

government debt or equity commitments, tariff concessions and reductions on rates and charges that benefit the pharmaceutical industry.

The relative attractiveness of tax concessions is determined by the level of the incentive and the value of tax payments foregone—the latter is determined by the conditions of the income tax system. The Warda B-index was developed in order to enable cross country comparisons of the impact of R&D taxation incentives. A lower value for the B-index indicates a relatively more generous incentive system. Table E.1 shows the values for the B-index for Australia and some of the countries considered in this Appendix.[3]

Table E.1 shows that Australia's R&D tax concession is relatively attractive compared to most other countries. Only Canada and Singapore offer more generous taxation concessions. However, while the B-index shows that Australia's deduction rate (set at 150 per cent of expenditure) is less generous than Singapore's (200 per cent of expenditure), it does not capture administrative features of the respective schemes. Singapore's scheme tends to be more selective than Australia's, possibly implying that the difference in the incentive effect is less than the B-index would indicate.[4]

Table E.1: Relative incentive provided by R&D tax mechanisms

Country	*B-index*	*Country*	*B-index*
Canada (small company)	0.571	US	0.915
Australia (1985–86)	0.632	Japan (small company)	0.926
Singapore	0.678	Japan (large company)	1.000
Canada (large company)	0.733	UK	1.000
Australia (1995–96)	0.757	Sweden	1.017

Source: IC 1995b, p. 509

The remainder of this Appendix examines the health environment and industry development programs in Canada, Ireland, Japan, New Zealand, Sweden, Singapore, the UK and the US.

E.1.3 The impact of cost containment and consumer preferences

There are a number of determinants of relative expenditure levels across countries:

[3] Data were not available for Ireland and New Zealand.

[4] See IC (1995, pp. 508-511) for a detailed discussion on the use of this approach.

- per capita incomes;
- consumer propensities and preferences for drugs, including such factors as the demographic profile of the nation; and
- the severity of pharmaceutical and health care cost containment measures.

Figure E.2 illustrates the relationship between per capita incomes and expenditure levels on drugs in 1989 across members countries of the Organisation of Economic Co-operation and Development (OECD). While higher per capita income is associated with a higher level of expenditure on pharmaceuticals, at any given level of income there is also a high degree of variation in expenditure. This variation reflects differences in cost containment strategies and consumer preferences.

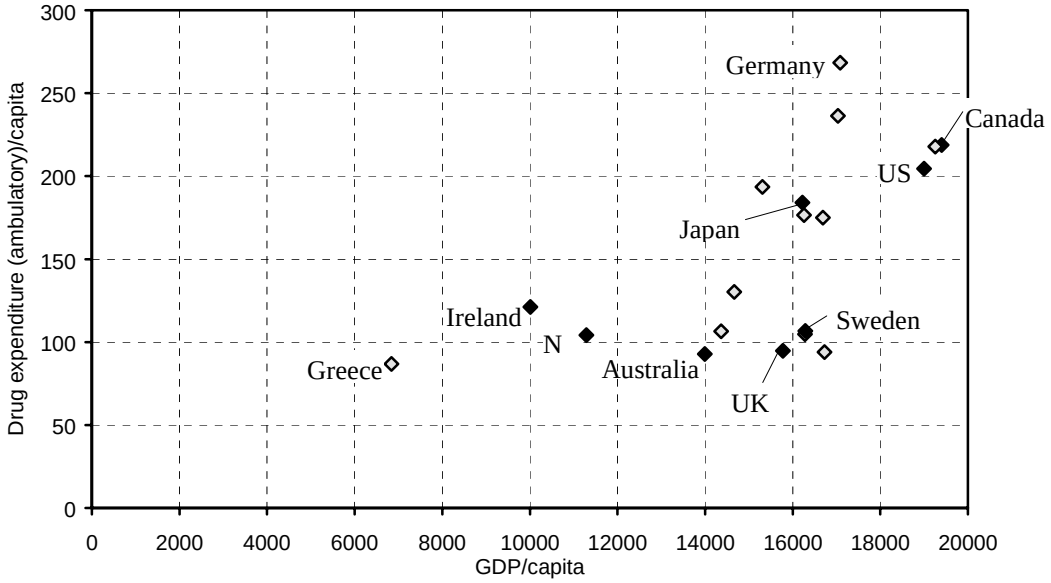
Given the variation in per capita incomes, Figure E.2 illustrates that expenditure on pharmaceuticals is significantly below the average in Australia, the UK and Sweden. Expenditure on pharmaceuticals in New Zealand and Ireland is also low, but so is their per capita income. While the US and Canada exhibit both high per capita income and high expenditures on drugs. The outliers in Figure E.2 are Germany, which recorded the highest per capita expenditure on drugs, and Greece which recorded the lowest.

E.2 Canada

E.2.1 Health care environment

The Canadian pharmaceutical environment is characterised by a series of provincial pharmaceutical insurers each independently deciding upon allocation of subsidies, the level of subsidy and the eligibility of residents for subsidy. Drugs are purchased or subsidised using public tender processes (where multiple sources are available for drugs such as off–patent products) or through negotiation between insurers and manufacturers (for patented products). For new products, the Province of Ontario, has recently introduced a form of cost-effectiveness analysis. Other provincial bodies use a simpler analysis of therapeutic benefit.

Figure E.2: Per capita national income and pharmaceutical expenditure for OECD countries, 1989, $PPP [a]



a Purchasing power parity (PPP) is an alternative to using spot market exchange rate conversions. In this figure national expenditures on pharmaceuticals have been converted to a common currency unit ($PPP) which is equal to US$1.00. National currency values have been weighted according to the relative purchasing power (the proportion of a non-tradeable basket of goods and services purchased with a proportion of national income).

Source: OECD 1993

The Canadian Federal Government operates an additional health insurance scheme which covers war veterans and Canadian natives and is similar in scope to the Australian Repatriation Pharmaceutical Benefits Scheme. Private insurance schemes also augment the provincial schemes and are normally funded by a combination of employer and employee contributions with copayments normally payable by employees. Only selected workplaces in Canada are covered by private health insurance. Few individuals opt into private health insurance of their own accord (OECD 1994, p. 111).

Mechanisms for drug cost containment—specifically directed towards increasing the level of consumer copayments—have received considerable recent attention. This is because the Canadian *Health Act* 1984 forbids the provinces from implementing patient copayments on hospital and physician care and cost containment mechanisms must therefore target pharmaceuticals and other secondary services (Neimeth 1995, p. 40).

British Columbia's insurer (Pharmacare), recently introduced a form of reference pricing. Reference pricing allows branded drugs to attain price

premiums payable as copayments by consumers, with Pharmacare only reimbursing costs to the level of a low priced generic for each therapeutic class.[5] To date only two classes of drugs have been subject to reference pricing, but further classes of drugs will be included (*Scrip*, 15 September 1995, p. 17).

E.2.2 Industry development strategies

R&D expenditure in Canada is funded by business (40 per cent), government (45 per cent) and from overseas sources (IC 1995, p. H.19). The peak government research body is the National Research Council of Canada. It carries out a wide spectrum of scientific and engineering research in response to national, economic and social needs. While, the National Research Council is not highly active in the area of medical and pharmaceutical R&D, other publicly-funded research bodies (universities and research institutes) play a significant role.

Within Canada a number of development policies are available to industry, including the pharmaceutical industry. These include:

- accelerated depreciation of most manufacturing and processing equipment;
- lower provincial taxes for manufacturing and processing companies;
- tax credits for investments in specified regions of Canada;
- full deductibility of current expenses on R&D;
- full deductibility of capital expenses on R&D; and
- a number of provincial and local schemes.

The source of these incentives is largely provincial with the exception of the tax deductibility for R&D expenditure which is provided by the Federal Government (BIE 1991, p. 153).

E.3 Japan

E.3.1 Health care environment

Japan's health care environment is largely based on a system of industry-wide health insurance funds. This model, called the Public Medical Care Insurance

[5] Pharmacare are also beginning to make assessments of the comparative effectiveness of treatments in order to establish the reference prices in each therapeutic class.

System, was introduced to Japan in 1927 and has evolved to reflect the unique environment of Japan. By 1961, the system had achieved total coverage of the Japanese population.

Health insurance, which also covers pharmaceuticals, is divided into two broad categories:

- The Employee's Health Insurance system, which has 1900 health insurance funds covering employees of large companies, and the government-managed Social Insurance Agency which covers employees of small companies.
- The National Health Insurance system, which comprises 3400 smaller insurers covering the self-employed and retired employees. Included are health insurance funds managed by professional associations of doctors, lawyers, artists and so on.

Pharmaceuticals are dispensed to patients through community pharmacies and clinics. There are also a number of dispensing doctors but they are being phased out. Patients generally make a copayment while the appropriate fund reimburses the remainder. The Ministry of Health and Welfare (MHW) has established a "positive list" (see Appendix D) of approximately 13 000 drugs which may be reimbursed. Until recently the prices of these listed drugs were determined by the MHW on a 90 per cent bulk line basis (the price at which the Ministry could secure 90 per cent of the supply of a particular drug). Japan has now adopted a weighted averaging method in which current prices are weighted by previous consumption volumes. Prices to manufacturers in Japan are now largely equal to world prices (OECD 1993, p. 210).

The prices of new drugs are determined according to a 'cost-plus' approach which incorporates an allowance for development costs. A premium price is also applicable to innovative new drugs. Three basic premiums are applied:

- *Kakkisei* is the premium markup applicable to drugs which are researched and developed as an entirely new concept. It is valued at between 10 per cent and 30 per cent. To be eligible the drug must also have demonstrated improved efficacy and safety over existing products, must be based on innovation in manufacturing and have an effect on existing health care systems.
- *Yuyosei* is the premium markup applicable to useful drugs which have a better efficacy profile than existing products. It is valued at between 1.5 per cent and 4.5 per cent. To be eligible the drug could also have an improved safety profile, demonstrated high therapeutic value or represent an innovation in the manufacturing process.

- *Shijosei* is the premium markup applicable to orphan drugs. It is valued at between 1.5 per cent and 4.5 per cent and applies to drugs which treat rare diseases or are expected to serve small markets (Kanavos, Mossialos & Abel-Smith 1994, p. 83).

The Japanese Government also monitors the volumes of drugs and has recently began to revise downward the prices of drugs for which sales volumes greatly exceed original forecasts. This has occurred in a number of instances where recently approved drugs have expanded their approved indications (*Scrip*, 10 November 1995, p. 21).

E.3.2 Industry development strategies

There are over 100 government departmental laboratories in Japan, serving a diverse range of research fields. In total, however, the government accounts for only 8 per cent of research expenditure in Japan. Universities which are government funded accounted for a further 11 per cent, while the private sector accounted for the remaining 81 per cent (IC 1995b, Volume 3, pp. H.6–H.7).

Historically, pharmaceutical industry policies were administered by the MHW. Industry policies affecting other Japanese industries were largely the preserve of the Ministry of International Trade and Industry (MITI).

The MHW's objective was to ensure the provision of high-quality health care to the Japanese people through local supply of safe and efficacious medicines. Since the early 1980s, trade barriers have been liberalised and the MHW has shifted its focus to the encouragement of domestic R&D in the pharmaceutical sciences. This shift has been brought about through:

- easing of restrictions (in 1968) on the formation of joint ventures between Japanese and foreign companies;
- recognising product patents (in 1975);
- allowing (in 1978) brand names to be listed (on the MHW's positive list) rather than generic names providing companies with greater market recognition and marketing returns; and
- extending (in 1979) the period of post–marketing approval surveillance from three to six years (during which a company is guaranteed exclusivity regardless of patent status).

In the late 1970s and early 1980s, developments in biotechnology prompted a number of governments to target this activity as the source of a 'new' pharmaceutical industry. In Japan, this was done by MITI, which established a

program for directing and funding biotechnology research. In 1983 MHW followed MITI by establishing the Office of Advanced Research and Technology of Pharmaceuticals.

A perceived conflict between the objectives of the MHW and the involvement of different agencies in administering industry policy has led to concern about the future direction of industry policy. The MHW faces an internal conflict between its roles of containing pharmaceutical costs and developing a viable domestic pharmaceutical (and biopharmaceutical) industry.

This view is further complicated by competition between the MHW, MITI and a number of less significant agencies for industry promotion measures, particularly in biotechnology.

Kanavos, Mossialos and Abel-Smith (1994, p. 65) argued that the reforms to the Japanese pricing and reimbursement system (described above) have had a number of effects on the Japanese pharmaceutical and biopharmaceutical companies. Changes include:

- the mission of discovery research switching towards breakthrough innovations which receive the high *Kakkisei* premium;
- the industry's pursuit of greater patient outcome data to support breakthrough claims as traditional incremental safety and efficacy data are inadequate;
- sales and marketing activities being increasingly concentrated on demonstrating cost effectiveness; and
- the increased use of contract manufacturing alliances for small production runs of drugs with small markets (the *Shijosei* premium).

E.4 Sweden

E.4.1 Health care environment

Health care services in Sweden are delivered by county councils, which provide budgets and salaries for hospitals, general practitioners (GPs), pharmacists and most dentists. Councils fund approximately 70 per cent of their health care expenses through the tax system. These taxes are paid into the National Social Insurance system. Grants from the National Government account for a further 19 per cent, while copayments and user charges fund the remainder. The sick in Sweden are also eligible for income compensation from the second day of illness. This is paid from the social insurance system administered by the

national government through the National Social Insurance Board (NSIB). There is no significant private health insurance system in Sweden.

For many years, pharmaceutical procurement and supply in Sweden was dominated by the *Apoteksbolaget*. The *Apoteksbolaget* is a monopoly government agency which purchases drugs on behalf of community pharmacies in Sweden. The *Apoteksbolaget* negotiated purchase prices with producers and supplied pharmacies at subsidised prices with the margins borne by the NSIB.

In 1993, the Swedish Government introduced a reference pricing system for off patent products and switched the responsibility for negotiating prices of patented products to the NSIB. The NSIB currently uses the following criteria in pricing decisions:

- the drug's therapeutic value and its estimated contribution in reducing overall health care costs;
- the price of similar products sold in other countries;
- the price of the same product sold in other countries;
- the price of the product in its home market; and
- the drug's projected sales volumes, R&D costs, manufacturing costs, and the manufacturer's legal fees (GAO 1994, Appendix III).

In December 1995 the Swedish Government announced its intention to introduce further reforms to the health care system. The proposed changes cover the pricing and reimbursement of pharmaceuticals—although the *Apoteksbolaget* is likely to retain its monopoly position in supplying community pharmacies. Health insurance will be devolved from the NSIB to the county councils. Price negotiations would then occur between the County Council Association and manufacturers to set pharmaceutical prices, and between the Association and the *Apoteksbolaget* for reimbursement prices. A pricing authority will soon be established to monitor prices adopted by the Association and the *Apoteksbolaget* (*Scrip*, 1 December 1995, p. 2).

E.4.2 Industry development strategies

From about the 1970s, the focus of Sweden's industry policy was on assisting private and state-owned companies in certain sectors of the economy (such as shipbuilding, steel, wood and paper products). The pharmaceutical industry, like many other sectors, received little direct assistance.

In the mid 1980s, the focus of policy shifted towards general or industry–wide assistance. Rather than assisting individual industries or companies, policy

shifted to assisting particular activities such as R&D and export market development, and small businesses. For instance, the Swedish Industrial Fund provides assistance to firms seeking to commercialise new products with grants and loans covering up to 50 per cent of the estimated costs. The Swedish National Board for Technical Development assists joint research by companies and universities through cooperative research institutes—a program similar to Australia's Cooperative Research Centre program. As an R&D intensive industry, pharmaceutical companies are a major beneficiary of Sweden's general assistance policies.

The close link that has been established between industry and academia has been attributed for a large part of the success of the Swedish pharmaceutical industry. Astra, a Swedish-owned pharmaceutical company, submitted to this inquiry that:

> ... it is clear that one of the underlying strengths of Sweden is the close link which has been established and become entrenched between academia and industry (sub. 205, p. 2).

According to Ostholm (1995, pp. 186, 213) two approaches to forging these links have been important. The first has been the provision of targeted assistance by the Swedish Board of Technical Development and its Commission for Drug Research to prospective drug developments. The second factor is the Adjunct Professorship system in which researchers work jointly for industry and academia.

E.5 New Zealand

E.5.1 Health care environment

Until relatively recently, the New Zealand health system was largely centralised. The major funding and service provision bodies were:

- the Department of Health (through its District Health Offices);
- 29 locally elected hospital boards which provided hospital and community based care such as district nursing; and
- private sector service providers including GPs, pharmacists and dentists.

Health services were largely funded through the taxation system. The Department of Health allocated funding to the various functions, including the hospital boards. Private sector service providers were partially reimbursed on a fee-for-service basis with the balance paid by patients. Prescription

pharmaceuticals, pathology and diagnostic services, and hospital care were provided free of charge. Private insurance was and continues to be available.

Reforms to the New Zealand health system began in the 1980s and have led to a regional purchaser–provider system. Initial reforms involved the establishment of 14 locally elected Area Health Boards. These acted as both regional purchasers and providers of health care services on behalf of the local community.

Subsequently the Area Health Boards were consolidated into four Regional Health Authorities (RHAs). Elected officials were replaced by appointed Boards for the new organisations. The RHAs are responsible for purchasing health services from regional public and private providers on behalf of users. Their fixed budgets are determined by the government and funded through general tax revenue.

Publicly-owned hospitals and other health related service providers have been reconstituted as Crown Health Enterprises. The Crown Health Enterprises operate independently under the *Companies Act* and will ultimately operate on a strictly commercial basis—that is, through commercial contracts signed with RHAs and charges levied on private patients and insurers.

The RHAs have established a jointly owned subsidiary called PHARMAC which purchases pharmaceuticals for all of the RHAs. PHARMAC operates a National Pharmaceutical Schedule and negotiates prices for pharmaceuticals with manufacturers. In its negotiations, PHARMAC utilises advice from an independent expert medical committee. The committee determines the relative effectiveness of drugs and considers variables such as health needs, value for money (in terms of the cost of alternatives), availability of substitutes and the budget impact of listing.

E.5.2 Industry development strategies

The Government funds around 64 per cent of New Zealand's R&D expenditure (including the Public Good Science Fund, higher education and government departments). The New Zealand Foundation for Research, Science and Technology allocates the Public Good Research Fund amongst submitted proposals. This ensures that the Government's R&D expenditure is contestable among the 10 Crown Research Institutes and private sector contenders (IC 1995b, pp. H.22–H.25).

Aside from supporting R&D activities, New Zealand has not adopted specific programs promoting the development of the pharmaceutical industry. There is a clear recognition within the New Zealand Government of the trade-off between

ensuring an affordable supply of medicines and promoting the development of a local pharmaceutical industry.

E.6 Ireland

E.6.1 Health care environment

The Irish health care environment is a combination of public and private institutions. Insurance is entirely provided by the government, largely out of general taxation revenue and a 1.25 per cent health premium. Patients have the additional option of joining the Voluntary Health Insurance Board which complements taxpayer-funded services in public and private hospitals. Pharmaceuticals provided through community pharmacies are reimbursed by the taxpayer funded General Medical Services (GMS) Payments Board.

Under the GMS, copayments for dispensed medicines are not payable by Category I patients (those unable to arrange GP services for themselves and their dependents without undue hardship), while Category II patients (the remaining population) are liable for a maximum £28 per annum.

The prices of all pharmaceuticals preparations listed by the GMS, as well as those supplied to hospitals and health boards, are regulated. In 1972, the Department of Health and the Federation of Irish Chemical Industries (FICI) initiated the first 4 year term of the FICI Agreement. Prices of new products were previously linked to those in the UK. However, recent agreements have linked prices to the lesser of the average price of the same product in the UK and a basket of European Union (EU) countries. The FICI Agreement also provides for all products to be granted GMS listing provided they conform with price, advertising and prescription requirements. The most recent agreement has recognised the right of the Department of Health to seek cost-benefit studies (EC 1995).

E.6.2 Industry development strategies

Ireland currently has a policy of explicitly encouraging investment in high technology industries such as the pharmaceutical industry. A number of incentives have been adopted, including:

- a maximum corporate tax rate of 10 per cent to the year 2010;
- capital grants for site, buildings and production equipment;
- reimbursement of the cost of an agreed training program;

- a comprehensive grant package tailored to a company's R&D requirements; and
- no restrictions on profit repatriation.

According to the Irish Development Authority (IDA 1993) 10 of the 15 largest multinational pharmaceutical companies have established manufacturing and research operations in Ireland since these policies were adopted.

E.7 Singapore

E.7.1 Health care environment

The Singapore Government makes no explicit attempt to control pharmaceutical prices and does not operate a national health insurance scheme to supply pharmaceuticals through community pharmacies. The Government, however, does have a major impact on the supply of pharmaceuticals through public hospitals and clinics. The hospitals procure pharmaceuticals largely through tender processes to purchase off patent products and therefore favour generic drug manufacturers, although branded manufacturers are equally eligible to tender (BIE 1991, p. 153).

E.7.2 Industry development strategies

The traditional approach of the Economic Development Board (EDB) of Singapore has been to award development incentives to first mover or pioneer companies. Designated industries were those involving high technology, computers, industrial design and other services.

The recent focus of Singapore's manufacturing industry development efforts has been towards cluster development. According to the EDB (1995), cluster development seeks to exploit opportunities and synergies resulting from linkages and the co-locations of firms within individual industries. Linkages to academic institutions are also supported. The broad range of major investment incentives currently available in Singapore are listed in Table E.2.

Singapore has two additional programs relevant to the pharmaceutical industry. The first is the International Manpower Program which seeks to broaden Singapore's labour resource base by attracting highly talented individuals to work in Singapore. The second is the National Technology Plan which seeks to identify and promote R&D in key technologies. The pharmaceutical industry has been targeted by the National Technology Plan (EDB 1995, p. 21).

Table E.2: Investment incentives in Singapore

Tax incentive	*Tax concession*
Pioneer status	Exemption of corporate tax on income arising from pioneer activity. Tax relief period is 5 to 10 years.
Post-pioneer status	Concessionary corporate tax rate of 10 to 15 per cent for up to 10 years on income from qualifying activities.
Expansion incentives	Exemption of corporate tax on income in excess of pre-expansion level. Tax relief period of up to 5 years.
Investment Allowance Incentive	Exemption of taxable income of an amount equal to a specified percentage, not exceeding 50 per cent of new fixed capital expenditure.
Approved Royalties Incentives	Full or partial exemption from withholding tax on approved royalties.
Approved Foreign Loan Scheme	Full or partial exemption from withholding tax on interest payments. .
Operation Headquarters	Income arising from the provision of approved headquarters services in Singapore will be taxed at 10 per cent. Tax relief period of up to 10 years with provision for extension.
Export of Services Incentives	Exemption of corporate tax rate on 90 per cent of qualifying export income. Tax relief period is 5 years, with provision for extension.
Warehousing and Services Incentives	Exemption of corporate tax rate on 50 per cent of qualifying export income. Tax relief period is 5 years, with provision for extension.
Double Deduction of R&D expenses	Double deduction for approved R&D expenses incurred within a specified period.
Venture Capital and Overseas Investment Incentives.	Losses incurred from sale of shares or liquidation of overseas investments, up to 100 per cent of equity invested, can be set off against the investor's other taxable income.
Venture Capital Fund Incentive	Net gains from divestment and other income from approved overseas investments may be eligible for tax relief for up to 10 years.
Financial Assistance Scheme	*Grant amount*
Initiatives in New Technology Scheme	Grant of up to 90 per cent of S$160 per trainee day for the training of manpower for qualifying activities.
Product Development Assistance Scheme	Grant equal to 50 per cent of approved direct development costs.

Source: EDB 1995, p. 28

E.8 United Kingdom

E.8.1 Health care environment

Until 1990, the National Health Service allocated funding on a fee-for-service basis to health care providers. It now channels funding to RHAs. Funds are raised through the general tax system and national insurance contributions. RHAs then allocate budgets between District Health Authorities, GP fundholders, and Family Health Service Authorities. These three bodies in turn contract with service providers, such as hospitals, specialists, pharmacists and other medical practitioners to purchase health care on behalf of the local community.

Most drugs are dispensed by community pharmacists. The remainder are supplied by hospital pharmacies. GPs who prescribe pharmaceuticals bear the cost in their global budget. The Department of Health monitors these budgets and provides feedback on GPs relative prescribing costs (see Appendix D).

Most patients are required to pay a small copayment for prescription medicines and the full cost of over-the-counter drugs. However, pensioners and the general population can purchase 'season tickets' which in 1991 cost £15.80 for four months and £43.50 for one year (BIE 1991, p. 147).

The Department of Health is considering the introduction of a fourth assessment hurdle for new prescription drugs, the first three hurdles being quality, safety and efficacy. The fourth hurdle would consist of a form of cost effectiveness analysis. In the UK the Office of Health Economics has published guides for industry in conducting cost benefit analyses of medicine.

E.8.2 Industry development strategies

The business sector accounts for approximately two-thirds of R&D expenditure in the UK. The government accounts for most of the remainder. A large part (40 per cent) of government spending is allocated to government research agencies. Research institutes, along with private sector research bodies largely contract with one of five Research Councils. The Medical Research Council is the second largest of the councils and receives 90 per cent of its funding from the government. This money finances R&D undertaken in its own research institutes and in higher education institutions.

The UK Government has not established any pharmaceutical industry-specific development programs.

E.9 United States

E.9.1 Health care environment

The US spends more upon health care than any other nation in absolute terms and as a proportion of GDP. The US health care market, including pharmaceuticals, is notable in the sense that the level of private insurance and funding and private sector provision of hospital, pharmaceutical and ambulatory care is much higher than other OECD countries. Nevertheless, Federal and State governments still retain an active role in regulating and providing health services and insurance.

The two national public insurance schemes are Medicaid and Medicare. Medicaid applies to people on low incomes and the elderly, disabled, pregnant, or single parents. Medicare only applies to the aged and disabled and (unlike Medicaid) only covers acute care, and such services as long term nursing care. Out-patient prescription pharmaceuticals are not covered (OECD 1994, p. 319).

Unlike many other countries, the US has no formal national cost containment policies covering the supply of pharmaceuticals. Prices are generally freely set by pharmaceutical manufacturers. However, escalating costs have forced both public and private insurers to adopt a range of informal and sometimes regional approaches to cost containment.

A common approach adopted in the US has been the formation of Health Maintenance Organisations (HMOs) and Pharmaceutical Benefit Managers (PBMs). HMOs have developed contracts with service providers which have replaced traditional fee-for-service reimbursements. HMOs then limit patients' choice of service provider to those contracted to the HMO.

Patients can join a HMO in a number of ways. Where patients are insured through their workplace, the employer may choose to hand its responsibility for health insurance to a HMO. Similarly, Medicaid and Medicare, and their respective state schemes, can contract a HMO on behalf of eligible patients. Increasingly, individuals who are self insured are also opting into HMOs.

PBMs have developed to manage the drug requirements of HMOs and insurers. The PBMs are liable for the cost of drugs prescribed by doctors and have therefore implemented a number of mechanisms to contain their liabilities. These include:

- cost based formularies;

- therapeutic interchange;[6]
- prior authorisation; and
- aggressive feedback to physicians about their prescribing patterns (Neimeth 1995, p. 26).

E.9.2 Industry development strategies

In the US, industry undertakes 52 per cent of total R&D spending. The rest is financed by governments (42 per cent) and universities (6 per cent). Approximately 15 per cent of government expenditure is channelled through the Department of Health and Human Services. Despite the large share of government funding of R&D, 69 per cent of R&D is performed by industry, and a further 13 per cent by higher education institutions (IC 1995b, pp. H.2–H.4).

The US is generally considered to provide the most favourable environment for pharmaceutical companies. For example, Kanavos, Mossialos and Abel-Smith stated that:

> The US ... currently [has] the most impressive reservoir of bioscience expertise in the world. This is why most investment in biotechnology takes place and materialises within the US (Kanavos, Mossialos & Abel-Smith 1994, p. i).

Kanavos, Mossialos and Abel-Smith also highlighted the major strengths of the US as an investment location in biopharmaceuticals:

> The reasons for this fertile environment for biopharmaceutical companies in the US comprise a number of important factors, such as relative abundance of venture capital, aggressive entrepreneurial ethos, efficient capital markets, priority in public funding, the existence of strong links between industry and academia, a friendly regulatory environment and an adequate system of intellectual property rights protection (Kanavos, Mossialos & Abel-Smith 1994, p. ii).

The bulk of research in both pharmaceutical and biopharmaceutical areas is undertaken privately. However, government has played a crucial role by targeting and funding research in high technologies areas. According to Kanavos (1994, p. 17), the Office of Technology Assessments estimated that the Federal Government accounts for more than half of total biotechnology related research expenditure—of which biopharmaceutical research represents a substantial component.

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[6] Therapeutic interchange is similar to generic substitution in that the pharmacists may substitute a cheaper product to that prescribed by the doctor. Therapeutic interchange, however, allows the pharmacist to substitute a product in the same therapeutic class which is not bioequivalent.

F GENERAL GOVERNMENT INDUSTRY PROGRAMS

The pharmaceutical industry, like all other industries, has access to a range of general government industry programs provided by the Commonwealth and State Governments. Pharmaceutical companies typically access general programs that assist activities such as research and development, exporting and location of regional headquarters. The support available under these programs is quite distinct from that provided by the Factor f program.

F.1 Industry development policy

The Commonwealth Government's approach to industry development policy has evolved in response to a globalising world economy—moving away from industry specific programs, toward general programs designed to help build globally competitive enterprises.

The objective of industry policy under the previous government was to assist Australian industry to internationalise and adapt to the global marketplace. Policy encompassed factors such as innovation, uptake of new technology, business improvement and exporting, as well as reducing the impediments to obtaining inputs and access to government contracts.

Industry specific measures such as quotas, bounties and tariffs—designed to protect local industries from global competition—are in the process of being dismantled for most industries. Import quotas have been abolished, and a program of tariff and bounty reductions has significantly reduced protection in previously protected industries.

However, industry development policy still involves a substantial number of industry specific programs. The pharmaceutical industry is supported by the Factor f program—although the industry is not protected by quotas, bounties or tariffs.

The Factor f scheme is the single largest item of specific sector outlays to manufacturing industry, costing the Government $137 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. In the same year

the computer industry—the next highest recipient of Commonwealth Government outlays in the manufacturing sector—received just under $76 million through the computer bounty scheme (IC 1995a).

Most general assistance programs relate to tax concessions, grants, loans and marketing and advisory services designed to influence the amount and type of research and development (R&D) and exporting activity conducted in Australia.

Other general assistance programs relate to:

- promoting best practice (for example, in leadership and management skills) through programs such as the Best Practice Demonstration Program;
- encouraging intercompany networks through programs such as the National Industry Extension Service and the Enterprise Networking Program;
- access to finance for small and medium enterprises through programs such as the Pooled Development Funds;
- government purchasing to promote Australian industry strategically through programs such as the National Procurement Development Program; and
- promotion of international investment and business linkages through programs such as the Investment Promotion Program.

Working Nation contained an initiative to enable improved coordination and delivery of the Commonwealth Government's assistance programs. The initiative know as AusIndustry, is:

> ... a national delivery network which makes it easier for business to get assistance from government. It uses a comprehensive unified marketing framework designed to streamline the delivery of Commonwealth and State Government assistance programs (DIST, 1995d, p. 112).

F.2 General assistance to the pharmaceutical industry

There are a number of general assistance programs which are particularly relevant to the pharmaceutical industry because of its involvement in R&D, its export orientation and dominance by multinational companies.

F.2.1 R&D assistance programs

R&D assistance programs benefit companies and industries performing R&D and using R&D knowledge.[1] Assistance to industry is provided directly, through R&D programs which support business R&D, and indirectly through R&D performed by public sector agencies. The following discussion is concerned with the former.

Business R&D activity mainly focuses on experimental development. This refers to systematic work using existing knowledge gained from research or practical experience, for the purpose of creating new or improved products or processes. In 1992–93, 69 per cent of business R&D expenditure was experimental development, 25 per cent was applied research and 6 per cent was basic research (IC 1995b).[2]

There are several programs which provide support for business R&D—making up around 15 per cent of all government funding to R&D. In 1992–93 the Commonwealth Government provided around $468 million in support of business R&D.

In recent years, Commonwealth Government outlays to business R&D has been provided directly by a set of schemes administered by the Industry Research and Development (IR&D) Board under the Industry Innovation Program (IIP). The IIP comprises three subprograms:

- the 150 per cent tax concession for R&D;
- Competitive Grants for R&D (CGRD); and
- Concessional Loans for the Commercialisation of Technology.

Commonwealth Government assistance for business R&D is also provided through programs aimed at supporting collaboration (or linkages) between private industry and the public research sector. These programs, which are administered by the Department of Industry, Science and Tourism (DIST, formerly Department of Industry, Science and Technology) and the Department of Employment, Education and Training (DEET). Include:

- the Cooperative Research Centres (CRC) Program;
- the Collaborative Research Grants (CRG) Scheme; and

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[1] For a detailed exposition of the R&D issues discussed in this Appendix, see the Commission's report on Research and Development (IC 1995b).

[2] *Applied research* refers to original work undertaken in order to acquire new knowledge. *Basic research* refers to experimental and theoretical work undertaken primarily to acquire new knowledge without a specific application in view.

- the Australian Postgraduate Awards.

In addition to Commonwealth Government assistance, a number of State Governments also provide assistance for business R&D.

150 per cent R&D tax concession

The 150 per cent R&D tax concession, introduced in 1985, is the main form of business R&D assistance in Australia. The R&D tax concession is a general form of assistance which does not target any particular industry or technology, but is an 'entitlement' for undertaking eligible R&D. In 1992–93 the Commonwealth Government provided $395 million in R&D assistance through the R&D tax concession. In its submission to this Inquiry, DIST (sub. 56) stated that since its introduction in 1985, at least 50 pharmaceutical companies have accessed the scheme.[3] A survey of the Australian pharmaceutical industry indicates that in 1993–94 around 60 per cent of total R&D expenditure (or around $78 million) was claimed as a deduction under the R&D tax concession by companies in the pharmaceutical industry (APMA 1995a, p. 14).

To participate in the program a taxpayer must be either a company incorporated in Australia, a public trading trust or partner in a partnership of eligible companies. The taxpayer must incur R&D expenditure greater than $20 000.

For R&D project expenditure to be eligible for the concession, the project must be based on a core activity involving innovation or technical risk.[4] The project must also be carried out in Australia (except in certain circumstances), have adequate Australian content, and its results must be exploited for the benefit of the Australian economy.

Once eligibility requirements have been met, companies are able to:

- deduct current R&D expenditure at a rate of 150 per cent of costs in the year in which they were incurred;
- depreciate plant and equipment used for R&D over three years and deducted at a rate equal to 150 per cent of the deduction that would otherwise apply; and

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[3] The dollar value of assistance afforded to the pharmaceutical industry through the R&D tax concession is not available.

[4] Innovation or technical risk means having an appreciable degree of novelty or reasonable uncertainty regarding results or alternatives. In terms of the entire innovation process this includes pre-competitive (generic) research, commercial R&D (research and experimental development) and possibly product development (design and development of prototypes) if integral to core R&D activity (IC 1995b, p. 517).

- depreciate buildings over the standard period of 40 years at a rate equal to 150 per cent of the deduction that would otherwise apply.

The tax concession is conventionally thought to be equal to the additional 50 per cent of expenditure that may be deducted. However, as noted by the Commission in the report of its Inquiry into Research and Development (IC 1995b), the concessional arrangement has the additional benefit of bringing forward deductibility.

This compares with the theoretical approach to income definition which matches expenditures, including R&D, with the income that they generate. Given the long lead time before most R&D helps to generate income, the matching principle would lead to deductibility occurring many years after expenditure has actually occurred. Thus, as stated by the Commission:

> ... 100 per cent deductibility for R&D is a significant tax inducement to perform R&D, compared to other investments, in addition to any further concessional deductions (IC 1995b, p. 533).

Under the current company tax regime, generally, the nominal subsidy provided by the 150 per cent R&D tax concession is 18 per cent of R&D expenditure.[5] This varies according to company specific arrangements concerning dividend pay policy, the tax rate of shareholders and dividend imputation effects.

Syndication

The program also has syndication provisions initially intended to deal with large and risky projects that were beyond the resources of a single company to carry out. Currently syndication is mainly used as a means of tax benefit transfer whereby tax loss companies exchange tax losses for R&D funds. Eligibility for syndication is restricted to projects involving R&D expenditure of more than $500 000. Syndicates investing in private tax exempt bodies have been limited to exclude investors who are not fully at risk.

The effective subsidy rates provided by various syndication arrangements range from 15 per cent to a 138 per cent, with an average of 60 per cent (IC 1995b).

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[5] The concessional element of the tax concession is conventionally thought to be equal to the additional 50 per cent of expenditure that may be deducted. Based on this, the benefit of using the 150 per cent R&D concession is 50 per cent of the corporate tax rate (36 per cent). The effective benefit is considered to be even higher than this because the scheme allows firms to deduct R&D expenditure in the year it was incurred as opposed to treating R&D like a normal asset and beginning a process of depreciation (IC 1995b, p. 532).

Competitive Grants for R&D

Prior to 1994 the IR&D Board operated five R&D grant schemes under the IIP. All five schemes were replaced by the CGRD. The CGRD operates on the basis of competitive merit based selection process—unlike the general tax concession which is an 'entitlement' for eligible R&D. In 1994–95 grant payments of around $37 million were awarded under the five IIP to 105 research organisations. None of the 105 grant recipients in 1994–95 was a pharmaceutical company (IR&D Board 1995).[6]

The objectives of the CGRD are:

- to encourage companies, particularly small and medium enterprises to develop internationally competitive goods, services and systems;
- to encourage companies to adopt new products, materials and methods to improve manufacturing capability, productivity and quality;
- to strengthen linkages between technology developers and users;
- to encourage the development of technologies, including emerging and enabling technologies, that are likely to have wide application in Australian industry; and
- to foster collaboration between companies and research institutions (IC 1995b, p. 518).

The maximum grant available is 50 per cent of total eligible project cost. There is no minimum size for projects. Companies' R&D projects will only be considered for a grant by the IR&D Board if projects meet several criteria—some of which target companies that are unable to take advantage of the R&D tax concession.

Concessional Loans for the Commercialisation of Technology

The concessional loans scheme is a new initiative administered by AusIndustry aimed at assisting small companies seeking to commercialise their technological innovations. The scheme has been allocated around $48 million over four years for concessional loans through the Commonwealth Development Bank. In its first year of operation the scheme had about 40 participants. In 1994–95, 10 applications for finance were signed providing loans of over $18 million in total. None of the 10 loan recipients was a pharmaceutical company.

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[6] Grant payments are still being made to recipients under the five old grant schemes, depending on previous commitments made under those schemes. A small number of recipients under these old grants schemes are pharmaceutical firms.

To be eligible for support, projects must meet several criteria. If eligible, companies are provided loans on the following terms:

- the maximum loan agreement period is six years, with repayments commencing after 42 months;
- the interest rate is 40 per cent of the Commonwealth Bank Loan Reference Rate;
- the first three years are interest free; and
- interest and principal is repaid in years four, five and six (IC 1995b).

Cooperative Research Centres

The CRC program, commencing in 1990, is one of the major initiatives in recent Australian science and technology policy. The aim of the program is to develop and improve linkages between universities, government research agencies and industry in Australia.

CRCs have participating organisations—universities, the Commonwealth Scientific and Industrial Research Organisation (CSIRO), other government research agencies, companies and others—contributing cash and other resources and collaborating in the management of production of research over set time periods, mostly seven years.

Nearly $850 million has been allocated to the CRC program over the lives of 61 centres. Funding for the CRC program is estimated to be $127 million in 1995–96 (IC 1995b).

There are seven CRCs currently in operation in the medical science and technology field and relevant to the pharmaceutical industry. These are the CRCs for:

- biopharmaceutical research involving CSL, Peptide Technology and Johnson & Johnson as industry partners;
- vaccine technology involving CSL and Biotech Australia as industry partners;
- tissue growth and repair involving GroPep as the industry partner;
- cellular growth factors involving AMRAD as the industry partner;
- eye research and technology involving Capricornia Contact Lens, Eycon Lens Laboratories, Hydron and Ciba-Geigy as industry partners;
- cochlear implant, speech and hearing research involving Cochlear; and

- cardiac technology involving Telectronics Pacing Systems, St Vincent's Hospital (Sydney), AMRAD and Active Measurement.

Each centre receives between $14 million and $18 million over the life of the joint venture. In July 1995 a new CRC was established in the diagnostic technologies area. The major participants are the Queensland University of Technology, CSIRO Division of Biomolecular Engineering, AGEN Biomedical and PanBio (DIST 1996).

Collaborative Research Grants Scheme

The CRG, which commenced in 1992, was designed to encourage research collaboration between higher education institutions and industry.

Project funding is advised by the Australian Research Committee (ARC), and provided on a dollar for dollar matching basis with industry. In 1994 expenditure on CRGs was $15.6 million (for 180 projects) and is projected to be $16.0 million (for 225 projects) in 1995.

The objectives of the program are to:

- provide support for higher education researchers who wish to bring advanced knowledge to bear on problems or opportunities in order to obtain economic or social benefits for Australia;
- develop cooperative links between higher education institutions, industry and public sector users of research; and
- develop within higher education institutions a greater understanding of industry's needs and how researchers may help to meet them (IC 1995b, p. G.11).

CRG grants are used to support basic, strategic, applied or developmental research in the social sciences, humanities, engineering and the natural sciences, but not clinical medicine and dentistry. Awards are in the form of grants, and from 1995, they could also include industry secondments and postdoctoral fellowships with industry partners, or any combination of these so long as matched funding requirements are met.

Five new grants relating to the pharmaceutical industry were awarded in 1995:

- the University of Adelaide and CSL to develop a biochemical screening method for the pre-symptomatic biochemical detection of lysosomal storage disorders, amenable to a mass screening program, and facing a large potential export market. Recommended funding was $61 800 in 1995, $64 500 in 1996 and $66 500 in 1997.

- the University of Queensland and CSL for research into a possible vaccine for the papilloma virus. Recommended funding was $65 300 in 1995 and $64 300 in 1996.
- the University of Technology (Sydney) and the NSW Blood Transfusion Service for research into a genetically engineered antibody for the prevention of Rh Haemolytic disease of the newborn. Recommended funding was $47 400 in 1995, $47 300 in 1996 and $46 200 in 1997.
- the University of NSW and Johnson & Johnson Research for research into whether malaria and giardiasis can be treated using Gene-Shears technology. Recommended funding was $66 900 in 1995, $67 400 in 1996 and $69 100 in 1997.
- the University of NSW and Biotech Australia into new Urokinase inhibitors. Recommended funding was $120 000 in 1995, $123 700 in 1996 and $125 000 in 1997.

Australian Postgraduate Awards (Industry)

The Australian Postgraduate Awards (Industry) scheme, which commenced in 1990, is similar to the CRG scheme. The scheme was designed to establish linkages between higher education institutions and industry through research students undertaking projects which have been developed jointly by industry and a higher education institution.

Scheme awards are based on the advice of the ARC. The awards for masters degrees (two years) and doctorate degrees (three to three and a half years) are $18 866 for each year of the award, plus relocation, removal and thesis allowance. Industry partners are required to contribute $10 000 for each year of the award ($5000 in cash and $5000 in cash or in kind).

In 1994 funding for 284 continuing awards and 125 new awards was $6.7 million. Projected spending for 1995 is $7.9 million. Of the 195 new awards announced for 1995, 45 per cent were classified into the manufacturing sector, 22 per cent in the field of engineering research, 18 per cent in applied sciences and technologies, and 12 per cent in earth sciences (IC 1995b).

State Government assistance to business R&D

State Government funding to R&D is around 10 per cent of total assistance to R&D, although the exact amount of State funding is unclear. In 1992–93, funding of R&D by State Government departments and agencies was around $510 million. These funds are channelled through numerous State schemes. In most States, relatively little business R&D is funded from State Government

sources—the majority comes from Commonwealth Government sources discussed previously.

Some State Governments assist companies by seeking additional assistance for business R&D from Commonwealth Government sources. For example, the Victorian Government—through the Strategic Industry Research Foundation—seeks additional R&D funds under the 150 per cent tax concession scheme (including syndication) for pharmaceutical companies. The Victorian Government also makes representations on behalf of the pharmaceutical industry for Commonwealth Government R&D assistance generally (DBE 1995).

Pharmaceutical companies may also benefit from State Government schemes designed to encourage collaborative R&D projects between public research institutions and industry generally. For example, the Victorian Government's Strategic Industry Research Foundation committed $16.5 million over three years—funding around 25 per cent of the cost of R&D projects initiated so far (IC 1995b).

In some States, pharmaceutical companies are potentially eligible for assistance from State Government grants for business R&D.

For example, the Queensland Department of Business, Industry and Regional Development administers the Queensland Grants for Industrial R&D, which aims to assist business R&D in Queensland's manufacturing and traded services sector. Since commencement of the scheme in 1991, 36 grants have been awarded involving a commitment of over $5.3 million. Grants are provided for up to 50 per cent of total project expenditure, for projects exceeding $50 000. To date the scheme is not funding any pharmaceutical companies.

In Western Australia funds are provided for eligible R&D through the Western Australian Innovation Support Scheme. Funds are provided on a dollar for dollar basis starting from a minimum grant of $20 000 up to a maximum grant of $50 000. Eligible applicants must be effectively unable to use the 150 per cent R&D tax concession for the duration of the project. To date the scheme has not provided funding for any pharmaceutical companies.

F.2.2 Export assistance programs

Export assistance programs assist local companies in selling their goods and services overseas. Governments employ a variety of measures to enhance exports in the form of both direct assistance such as subsidies and indirect assistance such as R&D assistance. The following discussion is concerned with direct assistance to exports.

The Commonwealth Government commits around $1.5 billion in export assistance per year in recent years—three quarters of which is directed at the manufacturing sector.

Export assistance is provided through a range export programs in the form of grants, loans, insurance, tax concessions and marketing and advisory services. Most export programs are delivered through Austrade—a Commonwealth statutory authority.

The Proprietary Medicines Association of Australia (PMAA 1994) conducted a survey of members with international trade activities. As part of the survey, companies were asked which form of export assistance or advice they had used. The forms of export assistance most frequently used by survey participants were Austrade advice and Export Market Development Grants (EMDG). Table F.1 presents the complete responses.

Export marketing advice

One way Austrade assists exports is by providing exporting and marketing advice, that is, counselling and referral, information and advice, details of export opportunities and market analysis, seminars and workshops. In 1994–95 Austrade's International Business Services program provided companies with around $142 million in assistance.

There are also distinct business units which provide specific services for 20 different industry sectors. The Health Business Unit of Austrade services companies in the health care industry, including pharmaceutical companies. Advisory and marketing services offered by Austrade business units include:

> Export update—information on foreign market requirements is provided by education kits, newsletters etc.
>
> Market opportunities—Austrade is able to 'capture' and distribute information about specific market opportunities.
>
> Market research—is conducted by Austrade, and may range from a brief overview of a market through to the provisions of detailed contact lists and customised market research.
>
> In-market support—includes briefing and counselling for visitors, trade promotions, media liaison, and support of tenders (PMAA 1995a, p. 17).

Pharmaceutical companies are eligible and make use of advisory services provided by Austrade.

Table F.1: PMAA Members' use of export assistance, 1994

Source of Assistance	*Number of times used*
Export Market Development Grants	9
Tax incentives	2
Austrade advice	12
National Industry Extension Service	5
Proprietary Medicines Association of Australia	4
New South Wales Chamber of Manufacturers	1
Australian Prescription Medicines Association	2
Victorian Government	1
Australian Chamber of Manufactures	1
Australia–China Chamber of Commerce	1
Consulates	4
Department of Industry, Technology and Commerce	1
Consultants	4
Other exporters	3
SGS	1

Source: PMAA 1994, p. 14

Export Market Development Grants

The EMDG scheme is designed to encourage small and medium enterprises to develop overseas export opportunities. In 1995–96, Austrade—through EMDG—provided around $237 million or around 15 per cent of total Commonwealth Government export assistance in support of some 3500 exporters. The most recent information indicates that 28 current grant recipients are members of the pharmaceutical industry and that they received a total of over $2 million to cover, in part, expenses incurred during the 1993–94 financial year (Austrade correspondence 27 October 1995).

After the first $15 000 per year, exporters are partially reimbursed at a rate of 50 per cent for the eligible costs incurred in overseas marketing activities. The scheme offers up to $250 000 per year as a maximum grant ($200 000 after July 1996). Exporters are not eligible to apply for a grant if they record export sales of more than $25 million per year (Austrade 1995).

International Trade Enhancement Scheme

The International Trade Enhancement Scheme (ITES) provides concessional loans to assist export marketing activities. Austrade has committed $15 million to the ITES for 1995–96. Most recent information for the ITES scheme indicates that no companies from the pharmaceutical industry have received any loan assistance under the ITES scheme (Austrade correspondence 27 October 1995).

Export Access Program

The Export Access Program provides assistance to small and medium enterprises. The program provides a package of training and practical assistance to companies which may require specialist help to develop successful offshore activities. The program is administered by the private sector through leading industry associations. Austrade has committed $3.1 million to the Export Access Program in 1995–96.

Export finance and insurance

The Export Finance and Insurance Corporation (EFIC) is a statutory authority which facilitates and encourages Australian export trade by providing insurance and financial services and products. EFIC encourages Australian international trade by providing:

- export credit insurance;
- export finance facilities; and
- performance bond facilities.

In 1994–95, EFIC programs provided around $148 million in export insurance and finance (see IC 1994). Over $18 million in export insurance has been provided to pharmaceutical companies through EFIC since October 1994 (EFIC correspondence 3 November 1995).

National Industry Extension Service

Austrade–National Industry Extension Service is a joint Commonwealth–State program which aims to improve the effectiveness and efficiency of small and medium enterprises, thereby increasing their competitiveness in international markets. Its export oriented services include assisting companies in strategic market planning through the world competitive services strategic planning model; and in preparing an export plan through the Preparing an Export Plan Program.

F.2.3 Regional Headquarters Program

The Commonwealth Government's Regional Headquarters (RHQ) initiative—administered by DIST—is designed to induce major international companies to set up their regional headquarters (for the Asia Pacific region) in Australia. The aim of the initiative is to enhance Australia's attractiveness as an RHQ location by promoting it advantages, and by providing incentives. As stated by DIST:

> RHQ status is conferred on a company established for the purpose of providing management, treasury and other services such as data processing, to associated companies in the region (sub. 56, p. 34).

The RHQ Group within DIST provides:

- information on establishing regional headquarters in Australia;
- feasibility study grants;
- streamlined immigration procedures;
- deduction for setup costs; and
- sales tax exemption for imports of computer equipment (Price Waterhouse 1995).

A number of pharmaceutical multinational enterprises have recently applied for tax related incentives provided by the RHQ program—as at April 1996 their applications were still being considered.

G TAXATION ISSUES

This Appendix canvasses major issues raised by the pharmaceutical industry and the Australian Taxation Office on transfer pricing arrangements and the wholesale sales tax exemption for drugs and medicines in the context of their effects on the operating environment, and hence investment decisions, of pharmaceutical companies in Australia.

G.1 Introduction

Taxation policy affects the operating environment of industry in four important ways. Rates affect after–tax revenues, compliance affects operating costs, policy stability affects perceptions of certainty and risk, and administration affects perceptions of hostility.

The corporate tax rate and instability in corporate tax policy have been raised as issues by some pharmaceutical companies. In particular, some companies have expressed concern about the future stability of corporate tax rates given the substantial number of changes to these rates since 1993 (for example, SmithKline Beecham, sub. 13, pp. 19–20). These companies indicated that, while most industries were generally concerned about these aspects of corporate tax policy, they were of particular concern to this industry, given the current environment of rationalisation, and very long planning horizons involved in the industry.

The areas of taxation policy of particular concern to the industry were transfer pricing arrangements and the wholesale sales tax (WST) exemption. The 150 per cent research and development (R&D) tax concession, which is also important to the industry, is discussed in Appendix F.

G.2 Transfer pricing arrangements

The term ‘international transfer prices’ (hereafter, transfer prices) refers to the prices charged for international transactions between related parties. They are significant for taxpayers and tax administrations because they largely determine income and costs, and hence taxable profits, of the related parties in different tax jurisdictions.

Member countries of the Organisation for Economic Co-operation and Development (OECD) have adopted the arm's length principle as a method for arbitrating transfer pricing matters. This principle requires that goods and services are traded between related parties at prices that would have been paid in comparable transactions and circumstances by independent parties acting at arm's length.

The arm's length principle is endorsed in Australian taxation legislation which is interpreted and administered by the Australian Taxation Office (ATO). In particular, it is endorsed in Division 13 of Part III of the *Income Tax Assessment Act* 1936 and in Australia's Double Taxation Agreements (DTAs) with other countries.

G.2.1 Government concern

Tax administrations worldwide have increasingly focused attention on transfer pricing matters because of the expanding role of multinational enterprises (MNEs) in world trade. This expanding role reflects integration of national economies and technological progress which have changed the way business is conducted.

In 1995, the OECD issued detailed guidelines on transfer pricing (OECD 1995) to provide guidance to tax administrators and taxpayers.[1] The OECD's objectives were to secure the appropriate tax base in each jurisdiction and to avoid double taxation, thereby minimising conflict between tax administrations and promoting international trade and investment.

The ATO advised that it follows the OECD guidelines (sub. 92 p. 3, sub. 193 p. 2 and transcript p. 1032). Since May 1994, the ATO has issued two taxation rulings (TRs) and six draft taxation rulings (DTRs) on its interpretation of those guidelines with respect to domestic taxation legislation. It is planning to release at least a further four rulings in the next year.

G.2.2 Importance to industry

Transfer prices are an important issue for the pharmaceutical industry for three reasons.

First, the industry is characterised by a high level of international dealings between related parties. The high cost of R&D, the relatively few countries needed to produce active pharmaceutical substances, and the high value/low

[1] The guidelines are a major revision of their 1979 report (OECD 1979).

mass nature of products and ingredients which enables them to be moved between countries at various product stages at relatively low costs have accentuated the trend toward globalisation in trading activity .

Second, to satisfy transfer pricing guidelines, pharmaceutical companies must conduct comparability studies, but it is difficult for pharmaceutical companies to find comparable transactions between independent parties. The industry is characterised by products and ingredients that are unique, many of which are patented. In addition, companies operate in highly differentiated or niche markets. Each company will generally have its own particular business mix and cost structure.

Finally, a high proportion of the costs for internationally traded pharmaceutical products derive from intangibles such as R&D and trademarks which are inherently difficult to value in an unambiguous way.

G.2.3 Determining the arm's length price

In its guidelines, the OECD published standard methods for determining the arm's length price (OECD 1995). In its TRs and DTRs, the ATO endorsed the OECD's standard methods (ATO 1995b, 1995c, and 1995d). In particular, it endorsed the comparable uncontrolled price method; the traditional transaction based methods such as cost plus method, and resale price minus method; and the use of some other profit based methods.

In TR94/14, the ATO stated:

> In determining the most appropriate method, companies and ATO auditors should bear in mind that ... the Commissioner is under no obligation to accept the particular method chosen by companies unless, on an objective analysis, it produces the most accurate calculation of the arm's length consideration in the particular case (ATO 1994b, p. 19).

In the same TR, the ATO stated that companies could reduce their risks of disputation through documentation which demonstrated that their choice of method was the most appropriate for their circumstances. Companies that considered uncertainty to be a major risk could approach the ATO and negotiate an Advance Pricing Arrangement (APA) (see Section G.2.6).

Collins[2] stated that there were important motivations for related parties in multinational pharmaceutical companies to transact at arm's length, including a need to provide subsidiaries with a fair return on assets, functions, activities and

[2] Former Chairman of the United Nations Group of Experts on International Co-operation in Tax Matters and the Working Party 6 of the OECD's Committee on Fiscal Affairs.

risks (Collins 1993, p. 85). In their evidence to the Commission, most pharmaceutical companies indicated that, by and large, they had actively sought to use the methodology that best reflected an arm's length outcome.

Collins stated that the main methodology used by companies in the pharmaceutical industry was the resale price minus method (or a variant of this method) (Collins 1993, p. 7). This was confirmed by SmithKline Beecham:

> In general, the pharmaceutical industry has historically determined prices on a global basis on a resale minus methodology (sub. 13, p. 21).

Collins stated:

> One of the reasons ... (is) considerable variation in market prices and marketing costs from country to country, which derives from local custom and practice largely outside the industry's control. In consequence, the most convenient way to determine the last transfer price in the chain will be ... to start with the end-selling price and work backwards. Indeed, it is common practice in the industry for sales to independent third parties to be priced on the basis of a target end-selling price to the consumer less a percentage customary in the trade (Collins 1993, p. 85).

G.2.4 Industry view

There were a significant number of companies in the pharmaceutical industry that were extremely critical of the ATO's administration of transfer pricing.

The main problems these companies had with the ATO's administrative approach were:

- it is unnecessarily aggressive;
- interpretation of legislation is unclear;
- it is inconsistent with OECD guidelines;
- it is inconsistent with other tax administrations; and
- it is inconsistent with other government policy.

Unnecessarily Aggressive

Many pharmaceutical companies found that the ATO's current approach to the enforcement of transfer pricing regulations, and in particular the manner in which transfer pricing audits were being pursued, was unnecessarily aggressive and impeded international decision making generally. 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).

Moreover, many pharmaceutical companies considered the industry had been chosen as a target in the ATO's enforcement program. They claimed this attention was unwarranted because they had not abused transfer pricing rules in the past and there was no record of successful prosecution by the ATO. In its submission, the Australian Pharmaceutical Manufacturers Association (APMA) stated:

> ... this same desire to achieve neutrality in the application of tax concessions does not equally apply to the collection of tax. In particular, the pharmaceutical industry has had increasing difficulty with the ... (ATO) in relation to the issue of transfer pricing ... it appears to be a priority 'target' ...
>
> The result of this approach to transfer pricing enforcement by the ATO is a tax environment that appears to be unjustifiably directed against the pharmaceutical industry (sub. 31, p. 42).

SmithKline Beecham stated:

> ... the aggressive stance being undertaken by the ATO in the current environment is unnerving for corporate decision-makers ...
>
> ... the aggressive attitude being adopted by the ATO in pursuing the pharmaceutical industry is seen by offshore investors as being unwarranted, and at times, incoherent (sub. 13, pp. 20–21).

Interpretation

Many pharmaceutical companies indicated that, while the intention of the ATO in issuing TRs and DTRs may have been to clarify domestic taxation legislation on transfer pricing, in fact, the rulings had done very little to resolve uncertainties inhibiting effective self assessment.

According to these companies, the TRs and DTRs are lengthy and complex. The eight TRs and DTRs released since May 1994 total over 700 pages. They have been generally criticised by the Australian business community. One large accounting firm noted:

> It is now virtually impossible for any corporate tax-payer to be confident of its transfer pricing position. These rulings are more extreme than we expected and they raise compliance costs enormously (Featherstone 1995, pp.1,4).

Another stated:

> ... on the strength of these rulings, the ATO expects companies to be tax experts, to be economic experts, to have unlimited time and money, and to have complete access to their competitors information almost immediately (Featherstone 1995, p.1,4).

The APMA was also critical:

> ... 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).

Inconsistent with OECD guidelines

Many pharmaceutical companies considered that while, in principle, the ATO had endorsed the OECD's guidelines on transfer pricing, in practice, it was administering them in a contrary way.

As noted, general practice in the pharmaceutical industry is to set transfer prices based on the resale price minus method. However, many companies considered the ATO had favoured profit based methods over the resale price minus method, based on its own internal perceptions of complexity and uniqueness in related party transactions by pharmaceutical companies. These companies considered that, in the PBS environment, profit based methods were entirely inappropriate (see below). In its submission, SmithKline Beecham stated:

> Whilst still acknowledging the importance of transaction-based methodologies, the ATO guidelines are seeking to discount these methodologies in favour of profit split methods which, we believe, are entirely inappropriate (sub. 13, p. 21).

In basing assessments on profit based methods, the companies considered that the ATO's administrative approach was inconsistent with the OECD guidelines in at least three respects.

First, the OECD guidelines state that transaction based methods are preferable to profit based methods.[3] The latter methods might be used when traditional methods cannot be reliably applied alone or, exceptionally, cannot be applied at all (OECD 1995, p. 39). The APMA stated:

> In recent times, following the ATO's appointment of a US economist, the ATO has adopted in its transfer pricing audits a methodology based upon the comparable profits methodology ... the ATO has utilised the rate of general corporate profitability of so-called comparable pharmaceutical companies in the USA (a free market) in order to test the transfer price of ethical pharmaceuticals

[3] The OECD considers that the traditional transaction methods are the most direct means of establishing whether conditions in the commercial and financial relations between associated enterprises are at arm's length. Hence, they are preferable to other methods (OECD 1995, p. 38).

> sold in the Australian PBS (a controlled market). This approach is not only invalid but is not permitted under OECD rules...
>
> ... Unfortunately, audit experience is such that the ATO appears to move directly to profit methods with no satisfactory explanation as to why a traditional method is inapplicable (sub. 119, p. 18).

Second, the OECD guidelines state that, where possible, tax administrations and taxpayers should begin their analysis from the perspective of the method chosen by the taxpayer. This should ensure that taxpayers' commercial judgments are taken into account and hence that transfer pricing reflects commercial realities. Many companies considered that in 'discounting' the resale price minus method in favour of profit based methods, the ATO's assessments were not reflecting commercial realities. At the public hearings, SmithKline Beecham stated:

> The industry has to the best of my knowledge historically—and acknowledged by commentators in the industry—generally set their prices via a resale minus methodology and therefore you would have thought that in testing those prices, the first point of reference would be to that resale minus methodology. Certainly our experience of their [ATO] application in practice has not been in line with their draft ruling or the OECD but to leap straight into this hybrid profit methodology and they have never actually spelt out exactly what they're seeking to do (transcript, p. 1231).

Finally, the OECD guidelines state that tax administrations should take account of the effects of government policies when evaluating transfer prices. In particular:

> ... it is quite obvious that a country with price controls must take into account that those price controls will affect the profits that can be realised by enterprises selling goods subject to those controls (OECD 1995, p. 24).

Many companies considered that the ATO had refused to accept the effect of the government's PBS pricing policies in constraining the profits that could be made by pharmaceutical companies (see below).

The companies considered that perceived inconsistencies with OECD guidelines had led to a widely held view in the pharmaceutical industry that the ATO approach to transfer pricing was arbitrary. In turn, this had led to a general perception of uncertainty about what would be acceptable to the ATO in the future.

Inconsistent with other tax jurisdictions

Some pharmaceutical companies claimed that in some cases the ATO had rejected the resale price minus method used by multinational pharmaceutical companies globally and accepted by other tax administrations. These companies indicated that inconsistency in transfer pricing approaches across tax

jurisdictions was increasing operating costs for MNEs which not only had to develop but also comply with two different methodologies. More importantly, it could potentially impede the equitable allocation of taxes between jurisdictions and lead to double taxation. In turn, this could impede investment and international trade. In its submission, Blackmores stated:

> Historically, this has been a regulatory nightmare as Blackmores Ltd struggles to comply with two tax jurisdictions if we report to a wholly owned subsidiary in another country ...
>
> Lack of recognition of global market imperatives by government is an impediment to business (sub. 21, p. 7).

Inconsistencies with other tax administrations could also inhibit APAs (see Section G.2.6).

Inconsistent with other government policy

In favouring comparable profit based methods over the resale price minus method, many pharmaceutical companies claimed that the ATO's administrative approach was inconsistent with PBS pricing policies administered by the Department of Health and Family Services.

The companies claimed that due to policies administered by the Pharmaceutical Benefits Pricing Authority (PBPA) they were not able to achieve the profits obtainable in a free market for products listed on the PBS. The companies considered that this fact had been ignored by the ATO. The APMA stated:

> You will be aware that, after some discussions in a joint working party between the ATO and this Association, the ATO came to share our view that the PBS impacts selling prices. However, the ATO does not yet concede that the PBS impacts profits or, rather the ATO does not yet concede the extent to which the PBS impact profits for all purposes, be they commercial, PBS or taxation (sub. 119, p. 17).

SmithKline Beecham stated:

> The thrust of the ATO's position is that Australian participants must obtain an arm's length profit, and that an independent party would not undertake transactions in Australia if it did not obtain an arm's length profit. This ignores the fact that an arm's length price may result in a profit which is less than the entity might normally expect to achieve (sub. 115, p. 5).

As a result, SmithKline Beecham stated:

> ... the ATO is seeking to tax profits that we are not allowed to make under the PBS by refusing to acknowledge the impact the PBS has on local profitability. This approach is clearly against internationally accepted guidelines (sub. 13, p. 21).

In respect of this inconsistency, the APMA stated:

> A proper understanding of the PBS system and agreement by the relevant parties on its elements and impact would ease the enormous time impost on the ATO and our members in the course of transfer pricing audits (sub. 119, p. 17).

The ATO has argued that Australian operations and hence Australian taxable income should not bear the full effect of reduced profitability due to government regulation (see Section G.2.5). Many pharmaceutical companies expressed the view that this inappropriately implies that an independent overseas supplier would first agree to supply Australia in the face of low PBS price offers and second agree to significantly reduce their supply price for the independent Australian buyer.

G.2.5 ATO view

The ATO indicated that it had not deliberately targeted industries but rather focused on industries in which it considered that taxation revenue is at risk. It stated that its approach to transfer pricing matters was open and consultative and consistent with OECD guidelines.

The ATO noted that it had two main areas of disagreement with industry. In particular, the ATO stated that there was often disagreement over the effect of the PBS on company profitability and the company's choice of methodology. The ATO acknowledged problems in its audit processes and procedures.

Focus on the pharmaceutical industry

According to the ATO, its increased focus on transfer pricing matters had been driven by the high and expanding role of transactions between related parties in international trade, and its observations based on audit activity that many companies were 'ignoring' transfer pricing matters. At the public hearings, the ATO stated:

> ... it is incumbent on the Tax Office to make sure that Australia gets its fair share of tax based on economic value added. We're not after more than our fair share and we don't believe that it's in the long-term interests of Australia to take an aggressive approach that seeks to get more than we're entitled to. That will raise disputes between countries' competent authority processes ... and [won't] really add value to administration (transcript, p. 1033).

The ATO published the factors that it considers when categorising taxation risks in transfer pricing arrangements as a guide for companies to minimise their taxation risks (see Figure G.1) (ATO 1995g). The ATO noted that taxpayers may still fall into one of the lower risk categories even though they may not have satisfied every factor in these categories:

> For example, it is possible that a taxpayer could be low risk even where no real bargaining occurred. In this circumstance, the ATO would give consideration to each of the other requirements of the low risk category to ensure that the taxpayer had allocated its income and expenditure in accordance with the arm's length principle (ATO 1995g, p. 10)

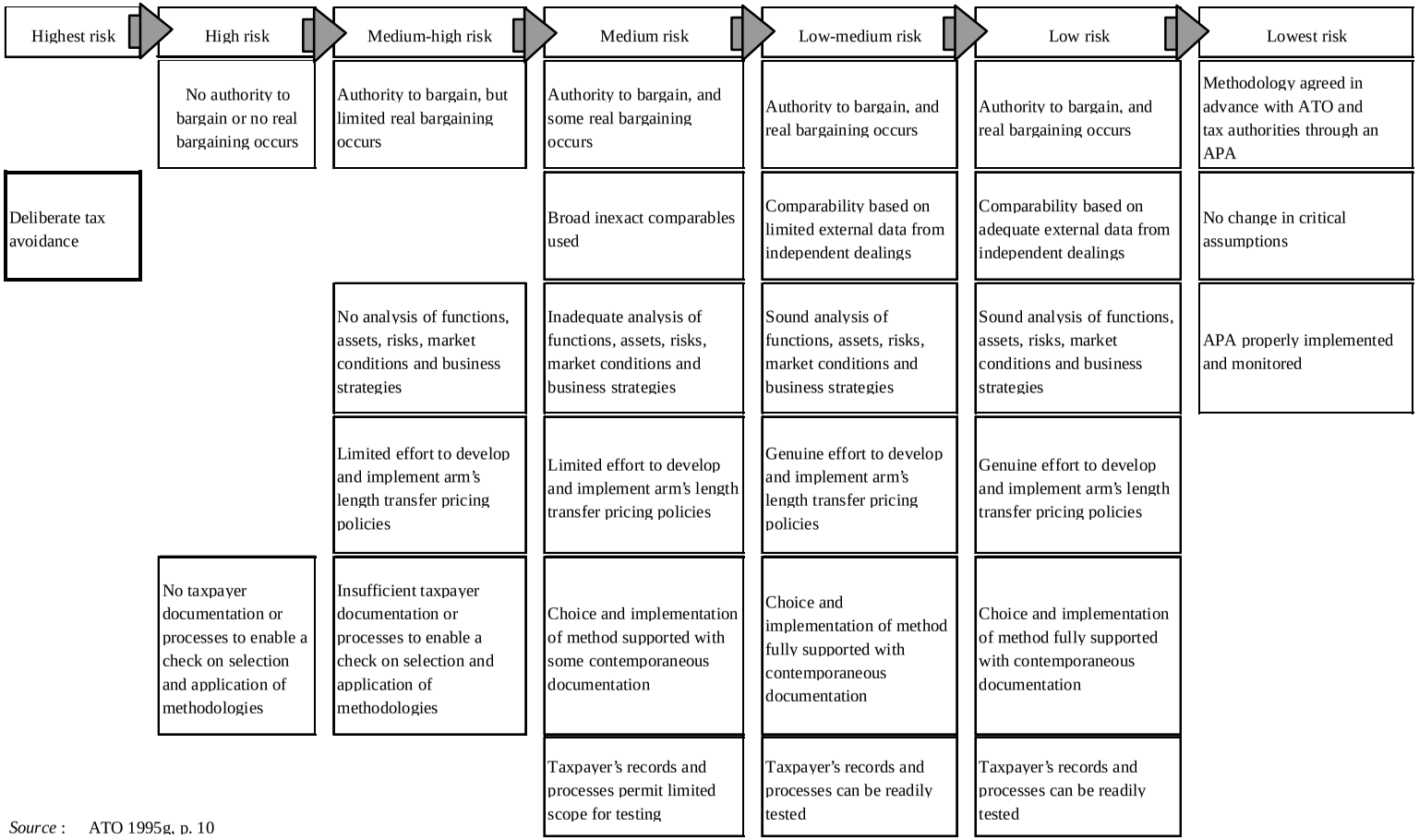
The ATO indicated that it had focused on the pharmaceutical industry based on potential risks to taxation revenue.

The ATO stated:

> Audit activity by the ATO in recent years across all industries has clearly shown that many companies are not addressing transfer pricing issues. When coupled with the fact that there are significant levels of cross–border dealings between related companies in the pharmaceutical industry, then from the point of view of the ATO, the fundamental ingredients for a high risk of non-compliance exist (sub. 92, p. 4).

However, in contrast to the companies' claims, the ATO indicated that the industry had not been especially targeted by the ATO. Rather, any targeting that may have occurred was a result of the ATO's normal risk assessment criteria (see Figure G.1).

Figure G.1: Minimising the taxation risks in international associated party dealing



Source : ATO 1995g, p. 10

The ATO stated:

> ... what we are trying to do is focus on risk assessments right across the whole of the large taxpayer population, regardless of industry, and to give priority to the companies that present the highest risk (transcript, p. 1034).
>
> ... the ATO is examining some companies in the pharmaceutical industry because they present risks of non-compliance and, ... we are focusing on real economic value added, real profits. (I would hasten to add that initial risk assessment work has shown some members of the pharmaceutical industry to be very conscientious about their tax compliance and we had to spend very little time with them) (sub. 193, p. 4).

Consultative processes

In the last three years, the ATO has implemented transfer pricing 'compliance improvement initiatives' that aim for an appropriate balance of help and enforcement activities.[4] The ATO stated:

> Over the past three years, we have also sought to raise the domestic awareness of transfer pricing issues through extensive industry consultation, the Taxation Rulings Program, the revision of the relevant tax return forms and new audit products like the Transfer Pricing Risk Assessment Review (sub. 193, p. 2)

Further, at the public hearings, the ATO stated:

> The Tax Office in recent times is going through a radical change process and in the course of that there has been a significant opening up of our processes, there has been a major push for greater accountability and greater public consultation (transcript, p. 1031).

The ATO indicated that this approach was apparent in processes surrounding development of the ATO Guidelines on Transfer Pricing (see Box G.1). The ATO noted that the National Tax Liaison Group Subcommittee on Transfer Pricing was important to these processes (transcript, p. 1031).

In March 1996, the ATO formally announced that it would be reactivating an ATO/Industry working party for direct consultation with the pharmaceutical industry. The APMA welcomed the ATO's response to its request to reconvene the consultative working party (see Section G.2.6).

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[4] These are described in an ATO speech to the 41st APMA Annual Conference (Killaly 1995).

Box G.1: Development of Transfer Pricing Guidelines by the ATO

January 1993	Established the Transfer Pricing Unit of the International Tax Branch in the Legislative Services Group
August 1993	Issue of Draft Ruling TR 93/D40—Basic concepts of Division 13 on Transfer Pricing
October 1993	Public Seminars in Melbourne and Sydney
December 1993	Establishment of National Tax Liaison Group (NTLG) Subcommittee on Transfer Pricing (TFP)
February 1994	Inaugural meeting of the NTLG Subcommittee on TFP
May 1994	Meeting of NTLG Subcommittee on TFP
May 1994	Issue of TR 94/14—Basic concepts of Division 13
1 July 1994	Establishment of International Tax Division in ATO
July 1994	Draft Ruling TR 94/D32 issued on Advance Pricing Arrangements
August 1994	Meeting of NTLG Subcommittee on TFP
August 1994	Pre-Ruling Consultative Document No 6 issued—transfer pricing methods and documentation
October 1994	Public seminars in Melbourne and Sydney
March 1995	Meeting of NTLG Subcommittee on TFP
April 1995	Draft Ruling issued on income and expense allocation for permanent establishments—TR 95/D11
May 1995	Meeting of NTLG Subcommittee on TFP
June 1995	Issue of TR 95/23—Advance Pricing Arrangements
July 1995	Publication of revised OECD Transfer Pricing Guidelines for Multinational Enterprises and Tax Administrations
August 1995	Meeting of NTLG Subcommittee on TFP
September 1995	Meeting of NTLG Subcommittee on TFP
September 1995	Draft Ruling TR95/D22 (Methodologies), TR95/D23 (Practical Approaches) and TR95/D24 (Penalties) issued
October 1995	Public Seminars in Melbourne and Sydney
November 1995	Draft Ruling TR95/D29 (Inter-group Services and Expense Allocation) issued
December 1995	Draft Ruling TR95/D31 (Operation of Mutual Agreement Procedures of Double Taxation Agreements) issued
February 1996	Further OECD Guidelines on Services and Intangibles due for publication

Source: ATO sub. 167, p. 1.

Commitment to the OECD guidelines

The ATO has re-confirmed commitment to the OECD transfer pricing guidelines. In its submission, the ATO stated:

> It is neither desirable nor sustainable for the ATO or taxpayers to attempt to establish approaches that are not closely aligned with international best practice. For this reason, we have been actively involved in the OECD revision of its 1979 Transfer Pricing Guidelines as a member of a special nine-country OECD Task Force (sub. 193, p. 2).

In transfer pricing assessments, the ATO stated that its objective was to ensure tax is calculated and paid on the basis of real economic value added by functions performed, assets used, and risks assumed by Australian companies, measured according to the internationally accepted arm's length principle. Further, the methodologies that have been developed were intended to systematically test a taxpayer's activity against the benchmark of the behaviour of independent parties dealing at arm's length (sub. 92, p. 3).

Further, the ATO stated that its approach to transfer pricing assessments is consistent with the OECD (transcript, p. 1036). The ATO stated that it had taken account of the issues that were relatively unique to this industry, including the existence of many patented products, a focus on high value production and marketing intangibles, high levels of risk, and substantial government intervention (sub. 92, p. 2).

Significantly, the ATO indicated that it had taken account of the effects of the PBS. Specific reference to this issue has been made in TR95/D22 (ATO 1995a, p. 160). However, the ATO indicated that it would not accept that Australian subsidiaries of multinational pharmaceutical companies would operate on a middle to long term basis if they continually just broke even or made losses as submitted in the returns of MNE subsidiaries (sub. 92, p. 5). In an address delivered to an APMA conference, the ATO stated:

> An arm's length party would expect an economic rate of return on its functions, assets and risks. A multinational group would not allow a subsidiary to incur continual losses unless it was in the overall interests of the multinational group to do so (Killaly 1995, p. 4).

The ATO considered that multinational pharmaceutical companies entered the Australian market with full knowledge of the PBS and its dampening effect on profitability relative to unregulated markets. Hence, the fact that they entered nevertheless implies a belief by these companies that their Australian operations would be profitable for the group (sub. 92, p. 7). On this basis, the ATO stated that it would focus on what constitutes a fair return for the functions, assets and risks of the Australian company, accepting that its return would be somewhat

lower than would be the case in an unregulated market (Killaly 1995, p. 5). As stated at the public hearings:

> ... the Tax Office is (not) trying to tax phantom profits. Our entire focus will be on commercial reality and economic value added, relying on the arm's length principle, Australian law, and a proper analysis of functions, assets and risks (transcript, p. 1037).

The effect of the PBS on profitability

One major difference that the ATO had with industry related to the distribution between Australian and overseas operations of the effects of reduced profitability due to government price regulation under the PBS. The ATO argued:

> One of the difficulties we are facing is that the industry seems to be taking the view that the Australian revenue should bear the full effect of the reduced profitability brought about through government regulation and that the owner of the intangible should be insulated as far as possible (sub. 92, p. 8).

The ATO rejected the industry's view on the basis that it was inconsistent with the arm's length principle.

The ATO acknowledged and stated publicly that price regulation under the PBS system affects prices for prescription pharmaceutical products in Australia (sub. 92, p. 6).

The ATO stated that it understood the effects of the PBS on profitability (sub. 92, p. 7). However, it would not accept industry's representations that the resulting reduction in the profits of MNEs would translate automatically into a reduction in the profits of their Australian subsidiaries. According to the ATO, in an arm's length transaction, the supplier of a product into Australia would bear some of the costs associated with reduced prices in its customer's selling market as a result of government price regulation. The ATO stated:

> The developer and supplier of the pharmaceutical products would be likely to bear sufficient of the primary risk for upward and downward variation in pricing levels to enable the Australian finisher/marketer to still be adequately rewarded with a reasonable return on its operations (sub. 92, p. 2).

In light of the ATO's understanding of the PBS, this concept had implications for gross profit margins. The ATO stated:

> ... if the costs incurred in producing the branded product decreased for whatever reason (exchange rate fluctuations, economies of scale, reduction in transfer prices of active ingredients, etc.), the gross margin of the benchmark product would increase. As the PBPA does not force companies to decrease prices when their costs fall, the higher gross margin would be allowed to continue (sub. 92, p. 7).

In fact, according to cost and profit margin information provided to the ATO by pharmaceutical companies, average gross margins on prescription products were around 40 per cent in 1989 and 1990 and 38 per cent in 1991 and 1992 (sub. 92, p. 7).

Choice of methodology

The second major difference between the ATO and industry related to choice of methodology. In the public hearings, the ATO stated:

> ... for the pharmaceutical industry the choice of methodology is a major issue. It's not clear to us that the industry fully understands the definitional issues that are involved in not only defining methodologies, but even applying OECD standards. [With respect to] the rulings [on methodologies] that we have issued so far for debate, what they are talking about is not really a resale minus method, and that is an important question (transcript, p. 1033).

As noted, the ATO has taken the view that the method used by the PBPA that sometimes applies a 30 per cent rule of thumb in relation to gross profit margins, while relevant, was not determinative of the tax issues and was not an arm's length methodology. The ATO stated:

> The focus here is on business and economic reality and [the ATO] rejects any suggestion that the ATO is attempting to tax profits that the companies did not make. It involves an application of the arm's length principle ... and cannot be determined by the application of some rigid formula or the procedures of the Pharmaceutical Benefits Pricing Authority, though the latter procedures are relevant (sub. 193, p. 2).

For the ATO, transfer prices charged by MNEs for their active ingredients would have a far greater effect on the profitability of their subsidiaries. The ATO stated:

> Such considerations are separate to and operate under different legislation from the considerations by the PBPA of the end selling price of the product (sub. 92, p. 7).

According to the ATO, the primary transfer pricing question was whether the cost of the active ingredient purchased in an international transaction from related parties is consistent with the arm's length principle.

In this respect, the ATO considered it could have regard to the sale price to unrelated parties. Further, it could reliably determine the costs incurred in Australia with unrelated parties. However, it could not know the appropriate gross profit margin that an arm's length company would seek to cover costs and make a reasonable return on functions, assets and risks in the same business environment. The ATO stated it would seek to determine this latter figure by:

- making comparisons with comparable unrelated party operations; or
- if there were no comparables, dividing the channel profit based on economic weightings for each related party's contribution to the channel profit; or
- if there was insufficient information to determine the channel profit, to resort to some other methodology to determine a fair rate of return for the relevant operations of the Australian company (sub. 92, p. 9).

The ATO indicated that its chosen route would depend on the level of information supplied by the company. It indicated that it was only in cases where companies supply insufficient information that the ATO would resort to one sided analysis. The ATO stated:

> We agree with the industry view that the traditional methods are preferable where they're practicable, and it seems to me that a lot of the debate in this area is really about what's practicable (transcript, p. 1036).
>
> ... In the practical application of methodologies the initial focus is on analysing the functions performed by the relevant parties, the assets they use including the intangibles that they might create, and the risks that they assume. The objective is to look at who does what in the process of developing the channel profit and to apply an appropriate reflex so that each party can be properly rewarded.
>
> ... If [we] cannot get information on the full channel profit, and often we cannot because [some] pharmaceutical companies will not tell us what they're doing overseas and they won't provide detailed information on some aspects ... then [we] have to revert to a one sided analysis and try and develop a model that will give us an economic worth of what is done in Australia (transcript, p. 1033).

G.2.6 Reconciling differences

Companies and the ATO can reconcile differences on transfer pricing arrangements through the ATO's audit process or negotiation of an APA. In addition, industry liaison groups have been established to obtain common agreement on matters of significance.

Audit processes

In the past, because many pharmaceutical companies have favoured self-assessment given guidelines provided by the ATO, the audit process has been the most common method used by the ATO to reconcile its differences with a company's transfer pricing arrangements. Under this approach, the ATO has focused on companies which it considered to pose significant risk to taxation revenue (see Section G.2.5) and conducted audits in cases where it did not accept a company's self assessment. There are a number of pharmaceutical companies currently under audit (ATO sub. 92).

Industry view

Many pharmaceutical companies considered that ATO audits were excessively lengthy, expensive, and required an unwarranted diversion of resources. One company's experience is illustrated in Box G.2. The APMA stated:

> We are not in a position to advise the Industry Commission of the costs involved to the government and our members in conducting the transfer pricing audits which have occurred over the last ten years, but they must run into many tens of millions of dollars. On the other hand, it is our understanding that the tax collections may well have been less than ten million dollars (sub. 119, p. 18).

Many companies found the audit process very frustrating. In its submission, SmithKline Beecham stated:

> Furthermore, the level of senior executive time and effort required to drive involvement in such audits is heavy, which can prove most frustrating and aggravating when that involvement is responding to seemingly ill-directed approaches adopted by Taxation Offices (sub. 13, p. 21).

At the public hearings, SmithKline Beecham stated:

> We have had one (audit) going since (19)87, still going, and ... don't know when it will ever be resolved...we went and got legal opinion on this very case. It had gone on for 5 years and three case managers and we spent a hell of a lot of time and effort in trying to defend our position. We gave the legal opinion to the ATO and we sat down in conference with them and they said, 'We agree. Our previous position on paper had no basis', or, 'no strength, but we're going to now attack you via this alternate route of this profit methodology' so now we are back to square one in the whole audit almost because we are starting from a clean base, a clean view of the ATO. You know, who knows where it's going to end up? (transcript, p. 1235).

ATO view

The ATO stated that the main issue underlying audits on pharmaceutical companies was application of Australia's transfer pricing rules. That is, in particular, the transfer prices paid by Australian subsidiaries to foreign MNEs for imported active ingredients from related parties.

The ATO indicated that the main areas of conflict with industry in the audit process were the effects of the PBS on profitability and choice of methodology (see Section G.2.5).

Box G.2: ATO administrative process—one company's experience

Year 1	ATO commences its tax audit.
Years 2–6	Frequent changes in ATO staff frustrate administrative processes. ATO uses three different audit teams who each have to become familiar with the audit and the company's operations. During the six year period, ATO postpones the audit four times for periods ranging from four months to nearly two years. No satisfactory explanation is given for delays.
Year 6	ATO issues assessment rejecting company's arguments and stating additional tax and penalties are to be paid. ATO rejects company's world wide pricing methodology. Company objects to assessment.
Years 6–10	ATO conducts internal review. During the review, continuing changes occur in ATO staff, again frustrating the administrative process. At least four different officers are responsible, again requiring lengthy delays as each becomes familiar with the issues. Company provides a legal opinion on the issue. ATO offers a settlement amount of approximately half the assessment, before withdrawing from discussion without explanation. ATO appoints external legal counsel. Legal counsel will not provide legal advice until ATO obtains an economic report. ATO cannot find an Australian to produce the economic report and contracts a US economist. Senior ATO officers undertake to reach decision on the objection before the end of the tenth year. Undertaking is not met. Company provides ATO with a report from an Australian economist. The US economist employed by ATO issues economic report rejecting ATO's method of assessment and endorsing company's method. ATO issues a position paper based on advice from its US economist reducing assessed tax payable by half. ATO legal counsel's opinion does not eventuate. ATO asks company to comment on report as ATO is unable to make a decision.
Year 10	Penalty interest at 20 per cent per annum continues to run. Company is unable to obtain a formal decision from ATO despite numerous requests to ATO and promises by ATO to finalise the audit. Company is obliged to consider legal action through the courts to force ATO to make a decision.

Source: Confidential

With respect to conflict over these issues in its audit program, the ATO stated:

> We have sought ... assistance of expert advice external to the ATO in order to ensure we have properly understood the industry and are taking an objective view. In some cases that has involved some reworking of cases and, unfortunately, a lengthening of completion times. But this was driven by a desire to ensure that we had approached the cases correctly and the tax assessed in some assessments has been somewhat reduced as a result (sub. 193, p. 2)

However, the ATO acknowledged that the time taken and level of resources employed in resolution of transfer pricing disputes with industry was unacceptable. At the public hearings, the ATO stated:

> ... [the ATO has] a difficulty with a case that goes for 10 years, and a major part of our focus in setting up international tax division was to drive reform processes that would enable all parties to come to a better understanding of the framework for transfer pricing and to limit the area for disputation. I have personally intervened in some cases to bring them to a head, and I intend to continue to do that (transcript, p. 1037).

At the same time, the ATO noted:

> The Commission's draft finding does not have regard to ATO initiatives to improve the efficiency of risk assessment work and the holistic approaches being adopted in relation to compliance measurement and improvement, all of which should improve turnaround times for audits and make issue identification and resolution more efficient and effective.
>
> ... [this is not to say] that the ATO cannot do any better, but on any objective measure it would have to be concluded that we are rapidly progressing in the right direction. (sub. 193, p. 4).

Advance Pricing Arrangements

An alternative approach that companies can take to reconcile differences with the ATO on transfer pricing arrangements is to negotiate an APA with the ATO.

An APA determines, in advance of transactions between related enterprises, how matters of significance in transfer pricing arrangements are to be treated over a fixed period of time. For example, an APA can specify methods, comparables, and critical assumptions about future events. The OECD has indicated that APAs should supplement traditional administrative, judicial and treaty mechanisms used to resolve transfer pricing issues, and are most useful when traditional mechanisms either fail or are difficult to apply (OECD 1995).

The ATO provided its guidelines on APAs in TR95/23. According to this TR:

> An APA represents an arrangement between a taxpayer and a tax authority that establishes the transfer pricing methodology (TPM) to be used in any future apportionment or allocation of income, deductions, credits or allowances so as to ensure arm's length transfer prices or results are achieved for income tax purposes.
>
> ... an APA will specify on a prospective basis which TPM should be used to determine the earnings of the taxpayer to be taxed in relation to cross border transactions, agreements or arrangements (ATO 1995e, p. 1).

Industry view

The Commission has been informed that there is only one pharmaceutical company that has negotiated an APA with the ATO. However, there is a view in the general business community that APAs across all industries will become more widespread—in particular, due to the ATO's recent information and documentation requirements under Schedule 25A (Lawson 1996, p.5). A large accounting firm was quoted:

> ... [Schedule 25A] required companies to supply so much detail on dealings with related foreign parties that they might as well arrange a transfer pricing agreement [APA] ... among other information, ... [Schedule 25A] requested full documentation on how companies arrived at the methodology used to price the goods, and how that methodology was applied to work out the prices. Those two requirements represent a great deal of information—in fact, the same information in the same detail required to negotiate a full transfer–pricing agreement [or APA] (Lawson 1996, p. 5).

Eli Lilly completed an APA with the ATO in December 1995. Negotiations comprised a three step process involving:

- an extensive education process for the ATO about the company, its global operations and the industry in which it conducts business;
- the company drafting and submitting a detailed APA application; and
- the ATO and the company discussing and finalising the terms and conditions of the APA (Eli Lilly correspondence 5 March 1996).

With respect to this 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).

Many other pharmaceutical companies were aware of the benefits of negotiating APAs but remained sceptical about the process. At the public hearings, SmithKline Beecham stated:

> We have explored the potential for seeking an APA. Given the divergence of view between the industry and the Tax Office and the amount of information you would be required to divulge in getting the APA—the APA is restricted to 3 year agreements and therefore we would be opening up ourselves historically and moving forward for only a limited period—it was a lineball decision on whether we decided to go for it or not and we decided not to seek the APA ... If the industry and the ATO can resolve their differences of opinion in the application of methodologies ... we would move closer towards saying, 'Well, yes, I think we should go on APA' (transcript, p. 1234).

SmithKline Beecham also expressed concern about the time and resources spent on education processes with no guaranteed long term outcome:

> ... we would be ... as a single organisation, investing a hell of a lot of time and money in seeking to educate the ATO and the ATO educate us ... the ATO would then possibly seek to put out [our agreement of principle] across all the industry participants.
>
> ... It would be, first of all, a heavy burden to do that and also our opinion, or view of SB, may not equate to those of the other industry participants and therefore we may not get to a proper resolution anyway (transcript, p. 1235).

For this reason, some companies indicated that re-establishment of an ATO/Industry working party, and hence possible reconciliation of differences on methodology, would prove to be more effective in resolving the risks and uncertainty (for example, SmithKline Beecham, transcript, p. 1235).

The APMA expressed the view that the decision to negotiate an APA with the ATO would have to be made by individual companies:

> ... it is going to be a company–specific decision. Advance pricing arrangements may suit some individual companies ... but it may not be appropriate for other companies ... If a company was facing a 10 year audit perhaps it is an obvious solution (transcript, p. 628).

ATO view

The ATO indicated that companies with an APA would be at least risk in taxation risk reviews and assessments (see Figure 1). At the public hearings, the ATO stated:

> ... if taxpayers feel that the uncertainty presents a major risk there is an opportunity for taxpayers to approach the Tax Office and seek an advanced pricing arrangement (transcript, p. 1035).

In its guide to minimising taxation risks in international associated party dealings, the ATO stated:

> The low risk category requires the availability of adequate external data to enable satisfactory comparisons to be made. The ATO accepts that the availability of this data may, in certain circumstances, be beyond the control of some taxpayers. Where this occurs, the taxpayer may request to enter into an APA with the ATO whereby both can agree on an appropriate arm's length transfer pricing methodology to use for determining arm's length prices or results for the associated overseas transaction. Taxpayers would then be in the lowest risk category and would eliminate the risk of an adjustment to their international transfer prices provided the conditions in the APA were achieved (ATO 1995g, p. 6).

APAs can be concluded unilaterally (between the taxpayer and the ATO), bilaterally (including also one other foreign tax authority) or multilaterally (including also two or more other foreign tax authorities). The ATO indicated a preference for at least bilateral APAs. In TR95/23, the ATO stated:

> An APA should, wherever possible, be concluded bilaterally through the Mutual Agreement Procedure Article under the relevant DTA(s) and/or executive power of the Commonwealth conferred to the Commissioner (ATO 1995e, p. 3).

According to TR95/23, companies negotiating an APA would be in a better position to present their case and obtain acceptable outcomes because:

- the APA process is conducted in a cooperative environment;
- APAs are prospective; and
- the ATO (and other tax authorities) wish to comprehensively deal with the matter based on appropriate and workable principles (ATO 1995e, p. 12).

The ATO noted the benefits of the APA process in TR95/23 (see Box G.3).

In terms of the negotiation processes, the ATO stated:

> ... they do have their difficulties but you have got all of the stakeholders there at the one time and they are far more satisfactory from everybody's point of view (transcript, p. 1043).

With respect to time and resources spent negotiating APAs, the ATO stated:

> They are much, much quicker than an audit. The quickest one [APA] that we have done took 4 weeks but on average they take about 9 months ... An audit, as we understood them in the past, could range over several years (transcript, pp. 1042–3).

Based on available evidence, this estimate probably excludes the time spent on preliminary research and education processes undertaken by both parties prior to formal initiation of the APA.

Box G.3: The benefits of the Advance Price Agreement process

In TR95/23, the ATO outlined the benefits of the Advance Price Agreement process as:

(a) may provide solutions to situations where there is no realistic alternative way of both avoiding double tax and of ensuring that all profits are correctly attributed and taxed;

(b) provides certainty on an appropriate transfer pricing methodology for the taxpayer and therefore enhances the predictability of tax treatment of international transactions;

(c) substantially reduces or eliminates the possibility of double taxation in the future;

(d) limits costly and time consuming examinations of major transfer pricing issues which may arise as a result of a future transfer pricing audit and lessens the possibility of protracted and expensive litigation; and

(e) places the taxpayer in a better position to predict costs and expenses, including tax liabilities.

Source: ATO 1995e, p. 12.

APAs are not widespread in the Australian business community. In 1995, only five APAs were agreed between multinationals and the ATO (Lawson 1996, p. 5).

Industry liaison groups

In December 1993, the ATO established the National Tax Liaison Group Subcommittee on Transfer Pricing comprising representatives from the Commonwealth Treasury, Australian Customs Service, all of the accounting and law bodies, and industry (sub. 167, p. 1).

The ATO noted the importance of the Sub-committee in the development of transfer pricing guidelines for industry in Australia (transcript, p. 1031).

However, in a public submission to the ATO on its transfer pricing program, representatives from accounting bodies were highly critical of the consultation process (see Box G.4).

Box G.4: National Tax Liaison Group Subcommittee on Transfer Pricing—the views of representatives from accounting bodies

In a public submission to the ATO dated November 1995, representatives from accounting bodies stated:

> The consultation process which the ATO has adopted with externals on its transfer pricing program has not been successful ... the liaison subcommittee established by the ATO is not operating successfully from the standpoint of our organisations.
>
> ... We acknowledge that there have been benefits to the taxpaying community which have emerged from the operations of the transfer pricing liaison subcommittee ... [and] that there have been many examples where external input into the transfer pricing program has been influential on the outcomes of the program. However, our perception of these benefits and the liaison process generally has been overshadowed by the failure of this committee to meet the prime purpose [to develop 'workable approaches' to transfer pricing which 'factor in the impact on business']... and [the fact] that throughout the history of this liaison subcommittee the ATO has breached a number of the agreed ground rules which formed the basis for our involvement in this liaison process.
>
> ... We consider that the ATO should rethink its approach to, and operation of, its current transfer pricing program. In particular, it should rethink its proposed draft rulings on methodologies and documentation. These should not be released in their current form. ... a revised process for consultation on transfer pricing issues needs to be implemented which is reasonable [and] satisfactory from both the standpoints of the ATO and ourselves.

Source: ICA 1995, pp. 4–5.

In March 1996, the ATO formally announced that it would be reactivating an ATO/Industry working party (sub. 193, p. 3). The industry was hopeful that this working party would go some way to obtaining common agreement on elements and effects of the PBS system in relation to transfer pricing matters and, in turn, resolve at least some of the current conflict and uncertainty. The APMA stated:

> I am pleased to confirm that APMA has now received formal advice ... of the willingness of the Australian Taxation Office to reactive the Joint APMA/ATO Working Party, and that arrangements for a meeting are now underway (sub. 199, p. 3).

> ... And that there would be senior level [ATO] representation on the working party. That was one of the major parts of the recommendation. So we are quite encouraged by that (transcript, p. 599).

At the same time, based on past experience, the APMA was careful to make it clear that there is no guarantee that the newly formed working party would solve the current difficulties of some companies in dealing with the ATO:

> It would be difficult or perhaps even foolhardy to predict the outcome ...
>
> This recent initiative of the re-establishment of the working party should not be seen as the answer to the problems and therefore it can be pushed to one side by the Commission. The matter should still continue to be pursued (transcript, pp. 600, 629).

G.3 Wholesale sales tax exemption

WST is a Commonwealth Government tax levied on the wholesale price of goods sold in Australia. WST is a self–assessing tax. The WST rate depends on the classification of the goods. The general rate of WST is 22 per cent, however, Item 78 in schedule 1 of the *Sales Tax (Exemptions and Classifications) Act* 1992 exempts drugs and medicines from WST. In order to provide guidance to taxpayers, the ATO publishes sales tax rulings setting out its interpretation of the WST legislation.

G.3.1 ATO draft ruling

In March 1995, the ATO released a draft sales tax ruling on the classification of drugs, medicines and sunscreen preparations (ATO 1995a). In this draft ruling, the ATO classified goods as drugs and medicines for the purposes of sales tax if they were 'principally marketed' as drugs and medicines.

In the draft ruling, the ATO stated:

> For goods to be marketed principally as drugs or medicines they must be marketed chiefly or mainly in that way (ATO 1995a, p. 6).

The ATO's classification of drugs and medicines is different to the classification of a therapeutic good by the Therapeutic Goods Administration (TGA). Under the *Therapeutics Goods Act* 1989, a product is a therapeutic good if it is likely to be taken for a therapeutic use or used as an ingredient in the manufacture of a therapeutic good. Therapeutic goods must gain either registration or listing on the Australian Register of Therapeutic Goods (ARTG) if they are to be sold, supplied and marketed in Australia. To gain registration

or listing on the ARTG, a product must satisfy the stringent and mandatory requirements of the Act.

The effect of the ATO draft ruling is that therapeutic goods listed on the ARTG will only qualify for WST exemption if the ATO determines they have been marketed principally as a drug or medicine.

G.3.2 Industry view

The pharmaceutical industry was primarily concerned that the ATO classification of a drug or medicine was based on a marketing test that had not taken account of the stringent and mandatory marketing requirements of the TGA.

The industry considered that the ATO's interpretation of the sales tax legislation, because it was primarily dependent on the way goods are marketed, would result in inconsistent and conflicting classifications and marketing requirements by two different arms of government. 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 this sort of inconsistency was destabilising. The Proprietary Medicines Association of Australia (PMAA) stated:

> ... if we are going to have two separate bits of government defining it differently, then we are always going to have a problem just in knowing where we sit in the market (transcript, p. 456).

Further, the industry considered that inconsistent definitions would feed through to inconsistent policy objectives being pursued by different arms of government. In its submission and at public hearings, the PMAA cited the example of products which contained sunscreening agents. The PMAA stated:

> If for example we know that we have a problem in this country with skin cancer and ... government spends very large amounts of money in public education campaigns, then to make the purchase of those products excessively expensive for the public, and to be on the one hand telling them to use them and on the other hand making them difficult to actually access, that would seem to be a contradiction in two key policy areas, so it is a case again of consistency. What is the actual intent of the policy, and is one contradicting activity in another? (transcript, p. 459).

The industry claimed that such policy inconsistency had led to uncertainty in the operating environment and, in fact, the indirect costs of this uncertainty had outweighed the direct financial effect on profitability (see Section G.3.3).

At a more specific level, the industry had three main problems about particular features of the draft sales tax ruling in its present form.

First, the industry considered that the classification of drugs and medicine was based on a marketing test that was ill defined. According to the industry, companies would be required to individually reconsider the classification of each of their products at substantial administrative expense particularly for smaller companies (see Section G.2.3). As stated by the PMAA:

> 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).

Second, the industry considered that, because the marketing test was subjective, situations could arise where two similar products were classified differently by the ATO, based on subjective assessments of their respective marketing by individual tax assessors. Steifel stated:

> ... what concerns us most, as a small Company, is that the current Sales Tax system makes it possible for two Officers in the same ATO branch to come to two completely different subject conclusions on brands which have the same therapeutic value and the same active ingredients (sub. 171, p. 1).

In this respect, the PMAA stated:

> ... it is untenable that the ATO can ... exercise a subjective judgment to exempt one product and not the other. This does not promote consistency in approaching the classification of products, and makes the task of the industry in self assessing products even more difficult than before (sub. 71, Attachment 10, pp. 11–12).

The industry was particularly concerned about the effects of potentially subjective ATO assessments in classifying toilet preparations—dermatology, vitamin E creams, medicated face washes, medicated confectionary, antiseptics and sunscreen preparations.

In these areas, the industry urged the ATO to recognise that:

- labelling is only one component of the overall assessment of essential character;

- the inclusion of one word or claim that has cosmetic connotations should be considered in the overall context of the product and does not change or diminish the essential character of the product (for example, many treatments involve a cleansing process or a moisturising process); and
- the movement toward consumer friendly packaging to enhance compliance or use and hence ensure the therapeutic effect is not a derogation of the essential character of a therapeutic good.

Finally, the industry was concerned about the discussion in the ATO's draft sales tax ruling about the exclusions from the WST exemption. 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. 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.

For example, the ATO had determined that in all cases vitamin E creams and medicated face washes should be considered 'goods in the nature of toilet preparations' (ATO 1995a, p. 10), and thus be excluded from exemption. According to the ATO, the main purpose of vitamin E cream was to soothe and soften dry or chafed skin and the main purpose of medicated face washes was to cleanse the skin (ATO 1995a, p. 10). Because toilet preparations were excluded from the WST exemption, the ATO maintained that all vitamin E creams and medicated face washes will consequently be subject to WST.

The industry was concerned that the ATO had made its ruling even though there would be some cases where these products were manufactured, marketed and sold for medicinal purposes. Blackmores provided the example of its vitamin E cream. This product is designed to provide relief from injuries and skin conditions, such as cuts, burns and dermatitis. According to the instructions, this product is only meant to be applied to the part of the body that is injured or affected by a skin condition. Blackmores 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).

Proctor & Gamble supported these arguments with respect to the classification of its products, Clearasil Medicated Face Wash and Clearasil Medicated Foam (sub. 184, p. 2).

G.3.3 Costs to industry of current situation

The industry indicated that the ATO's position outlined in the draft sales tax ruling would increase direct financial costs in terms of additional taxes that must be paid. More importantly, the industry claimed that uncertainty over the ATO's position had increased substantially the indirect costs associated with administration and compliance and could negatively affect perceptions of decision makers in foreign head offices.

Direct financial costs

It has not been possible for the Commission to obtain an overall estimate of the financial cost to industry as previously exempt goods become subject to tax. 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 could pass higher taxes on to consumers in the form of higher prices. However, six companies were able to provide the Commission with estimates of the additional tax that they could be expected to pay on their products under the draft sales tax ruling. In total, these companies have estimated that they could be expected to pay an additional $12.1 million in tax.

Costs of uncertainty

The industry indicated that there were high costs associated with risks and uncertainty over which products could become subject to tax because the ATO had not clarified its position.

The industry stated that uncertainty over the ATO's position would require reconsideration of the WST position of all OTC products at substantial administrative expense (see Section G.3.2). The National Pharmaceutical Distributors Association (NPDA) considered its members carry a considerable tax risk:

> NPDA members therefore carry a potential and significant exposure where, due to lack of advice by the manufacturer, they can innocently sell a product sales tax exempt, but the ATO determines the product should carry a sales tax. As the last supplier in the chain, prior to retail, the fine would rest with the NPDA retailer (or any other wholesaler in a similar position) (sub. 9, p. 10).

Some small companies claimed that it was almost impossible to present an appropriate case for WST exemption without employing the services of professional consultants. Steifel stated:

> We have first hand experience of this and have invested upwards of $20,000 in the past 12 months alone with a leading accounting firm in an effort to have our major brands assessed.
>
> This may not seem like a lot of money to many of the multinationals, but it represents 1 per cent of our turnover value.
>
> As it stands, we are still left in a situation where we really do not know what will happen next and, faced with such a scenario, it is next to impossible for us to consider any long term thinking (sub. 171, p. 2).

Uncertainty was also imposing costs on future planning and budgeting decisions. The PMAA stated:

> ... because our year starts 1 April, what do we assume for our selling price, what do we assume for gross profit advertising and product contribution, and what do we assume with this contingent liability sitting in our balance sheet, and in our case the range of products is quite extensive and the costs are quite considerable.
>
> Really the costs—apart from the P and L hit of the provisions ... are the costs of uncertainty. How do you plan when you don't know what the situation is? (transcript, pp. 456–457).

Australian subsidiaries of MNEs indicated uncertainty over what should be a straightforward taxation issue is having the effect of communicating instability in the operating environment to decision makers in foreign head quarters. The PMAA stated:

> ... most of the companies here are subsidiaries of overseas owners, and the problem is credibility. I mean, we're putting up investment proposals against other countries' investment proposals, and there are finite resources to support the proposals ... how do you measure the impact on industry on the lack of credibility that this gives us with our shareholders back in our home countries? (transcript, p. 457).

In January 1994, the ATO indicated that it would issue a final ruling to resolve the current level of uncertainty. However, a final ruling has not been issued to date. The PMAA stated:

> ... at best it can be said that they have been willing to discuss, they have come to meetings with industry to explain their position and to hear industry's views, but in terms of taking definitive action and coming to decisions that they are able to come back with and presenting draft rulings, it has been extremely slow (transcript, p. 458).

G.3.4 Industry recommended approach

A submission to the ATO on its draft sales tax ruling prepared by Price Waterhouse acting for the PMAA argued that the TGA requirements complemented WST marketing requirements and that, in meeting TGA requirements, therapeutic goods would also satisfy WST exemption requirements (sub. 71, Attachment 9). According to a further submission to the ATO on the draft sales tax ruling:

> The PMAA's submission dated 9 November 1994 discusses in detail and we believe demonstrates that adoption of the TGA definitions does not conflict with the ATO objective of limiting exemption to products marketed as drugs or medicines. It would provide industry with consistent anti-discriminatory rules. Competitors would be treated identically. More importantly the requirements would be understood by industry and easily applied to individual products (PMAA sub. 71, Attachment 10, p. 4).

The PMAA therefore recommended:

> ... that the ATO should adopt an interpretation of Item 78 which exempts all goods on the ARTG from sales tax (sub. 71, p. 41).

In its view, this would remove the inconsistencies in classification and marketing requirements between the TGA and ATO and reduce administrative costs for pharmaceutical companies.

The Nutritional Foods Association of Australia (sub. 108, p. 25), the NPDA (correspondence 6 March 1996), and numerous submissions from individual companies have also recommended this approach. The main reasons for industry's endorsement of the PMAA's recommendation were clearly stated by the NPDA (see Box G.5).

Alternatively, if the ATO cannot adopt an interpretation of Item 78 that exempts all goods on the ARTG from sales tax, then the PMAA argued that legislation should be brought in to 'take the matter beyond doubt' (sub. 71, p. ii). The PMAA stated:

> If the Tax Office is unwilling or unable to find a straightforward solution to this matter, ... then legislation [should] be prepared to do so (sub. 120, p. 2).

Many companies commented that past attempts to increase the range of goods subject to sales tax have almost always been made through Parliament, with appropriate review and publicity. There is a view in the industry that the ATO has used administrative policy to circumvent this process and hence avoid proper consideration of commercial comment on the process.

The ATO stated the intentions of the draft sales tax ruling as:

> ... to provide clear guidelines so that the industry can self assess and not experience inconsistency regarding liability to sales tax.
>
> ... to enable ATO staff and taxpayers to decide objectively on the sales tax status of a wide range of goods using the same principles and guidelines (sub. 193, p. 5).

Box G.5: Reasons why therapeutic goods listed on the ARTG should be exempt from Wholesale Sales Tax (WST)—the industry's view

The NPDA endorsed the PMAA recommendation that the ATO use the status and definition of therapeutic goods already legislated by the TGA when determining sales tax exemption status because:

- the similarity of intended coverage of the definition in the sales tax legislation and the TGA legislation is established;
- the requirements for sales tax exemption and TGA listing/registration are complementary;
- clarity and consistency in the sales tax exemption definition would significantly reduce the time required to administer the sales tax legislation;
- certainty in the exemption status ensures equity in the market place;
- the TGA is the major government regulatory body for the OTC pharmaceutical industry;
- the existing TGA legislation imposes stringent mandatory requirements on manufacturers, importers and wholesalers of OTC therapeutic goods;
- the costs of this compliance are significant; and
- identification of sales tax exempt products is facilitated by TGA's labelling and presentation requirements.

Source: NPDA correspondence 6 March 1996

In responding to industry criticisms on its draft sales tax ruling, the ATO highlighted that the purpose of therapeutic goods legislation is different to that of sales tax legislation. In particular, the ATO noted that the purpose of therapeutic goods legislation was to ensure the safety and efficacy of certain goods before they are made available to the public. In contrast, the purpose of sales tax legislation was to raise revenue in that 'it determines which goods are subject to sales tax and which are exempt' (sub. 193, p. 2). The ATO stated:

> ... 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. 2).

The ATO indicated that it had not 'invented' the marketing test. In particular, the ATO stated:

> Item 78 in the sales tax law, which exempts drugs and medicines, has a marketing test; ie goods must be marketed principally as drugs and medicines. Paragraph 3.3 of the draft ruling outlines the factors to be considered in satisfying the marketing test for particular goods (sub. 193, p. 5).

With respect to stated exemptions on toilet preparations—dermatology, vitamin E creams, medicated face washes, medicated confectionary, antiseptics and sunscreen preparations, the ATO stated:

> ... these goods ... do not in fact qualify under the existing wording in the legislation (sub. 193, p. 5)

The ATO indicated that it recognised and understood industry's request to exempt all goods listed on the ARTG from WST. However, it stated that this would require an amendment to sales tax legislation, and in the absence of a legislative amendment such a situation would reflect an incorrect interpretation of the sales tax law (sub. 193, pp. 5–6).

The ATO stated that one of the purposes of the draft sales tax ruling was to receive constructive comment from industry which it would then use to prepare a quality 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.

The ATO stated:

> The final version of the taxation ruling will not require companies to review the classification of all their products. It is envisaged that the guidelines in the final version of the ruling will provide certainty to companies to self assess their sales tax liability in relation to the vast majority of goods ... They will need to approach the ATO only if they are in any doubt and taxpayers will be invited to contact the ATO if they need assistance (sub. 193, p. 6).

H DRUG PRICE COMPARISONS

It has long been contended that PBS pricing policies have resulted in the prices of PBS drugs in Australia being generally lower than prices overseas. The relatively low level of PBS drug prices is a central justification for the Factor f scheme. This appendix outlines the problems in comparing international drug prices, and summarises previous drug pricing studies and data received from participants relating to the relative prices of individual products compared with prices in other markets. Details of an APMA pricing study undertaken specifically for this Inquiry are also provided.

H.1 Methodological issues

International pricing comparisons are becoming increasingly important due to their use by governments in pricing decisions. An understanding of the appropriate methodology for making comparisons of international drug prices, and of the various qualifications applying to them, is essential background to a consideration of their findings.

H.1.1 Theoretical qualifications

Price comparison studies typically have been based on small samples of leading brand prescription drugs, excluding generic and over-the-counter drugs. Results are sensitive to judgments made about sample selection, unit of measurement for price and volume, the relative weight given to different drugs in the countries under comparison, and the exchange rates used.

The ideal price index measures the expenditure required for a purchaser to maintain a given level of utility, when faced with an alternative set of prices, relative to the expenditure required given a base set of prices. To derive welfare inferences from index numbers, four assumptions about the drug market must be met, all of which are difficult to achieve in practice:

- the observed prices and quantities should reflect informed consumer choices. However, the presumption that consumers lack adequate information to make rational decisions in the market for pharmaceuticals underlies government regulation of this market in all countries;

- choices should be made in competitive markets. However, drugs are subject to government control, patent protection, and a significant proportion of drug costs are paid through public or private insurance programs in most countries;
- the range and quality of products available to consumers should be identical in the countries under comparison. However, there are significant differences in the range of drugs and the mix of dosage forms and strengths available between countries; and
- the pattern of drug preferences should be the same in both countries, although the specific utility may differ. However, there are significant differences in consumer preferences from one country to another. (Danzon 1995, pp. 1–6).

Given these departures from the theoretical ideal, all drug price comparisons based on indices should be treated with some caution.

Price qualifications

Apart from these theoretical concerns, the Pharmaceutical Benefits Branch has noted that drug price comparisons may themselves be misleading for a number of reasons (sub. 11, p. 15).

First, price comparisons made by industry tend to be between the prices of specific brands of a selection of drugs in different countries, rather than the prices of selected drugs in different countries. That is, they exclude the options of brand and generic substitution. In many countries the price of some brands is over double that of others and generic equivalents are significantly cheaper than branded products.

Second, unlike in Australia, the list prices of drugs in other countries may bear little resemblance to the actual prices paid. For example in the US many brand name drugs are purchased by Health Maintenance Organisations (HMOs) for a fraction of their list prices.

Third, from an Australian perspective, the introduction of the minimum pricing policy means that suppliers of originator brand drugs have the choice of charging a higher price (a brand premium) at their discretion. In addition, Factor f provides some companies with notional price increases in return for increased Australian activity. These increased prices are paid directly to the company and may not be included in price comparisons.

Fourth, government policies such as taxation concessions for research and development and other general industry assistance programs in Australia and

overseas can provide significant non-price benefits to companies (see Chapter 7).

H.1.2 Appropriate methodology

When making international price comparisons, it is important to consider three methodological questions.

- What is an appropriate benchmark country?
- What is an appropriate basket of goods?
- How should this basket of goods be weighted?

An appropriate benchmark country

As noted by the Bureau of Industry Economics (BIE), there are considerable differences between average drug price levels between overseas countries (BIE 1991, p. 36). Using Intercontinental Medical Statistics (IMS) data for 1991, the BIE found that ex-factory prices in the most expensive country (the US) were between 50 and 100 per cent higher than the world average. At the other extreme, average price levels in the cheapest countries (such as Italy and Spain) were only between 20 and 30 per cent of those in the US.

For a large number of reasons, international prices will always differ to some extent:

- as mentioned above, countries have different prescribing and consumption patterns due to differing abilities to pay and consumer tastes;
- variations in the rates of patient contributions towards drug purchases are likely to mean that harmonised producer prices will not lead to harmonised consumer prices;
- rates of value added tax and sales tax on pharmaceuticals vary across countries; and
- distribution costs of drugs also vary between countries.

It is therefore difficult to identify an appropriate benchmark country for Australian prices in the absence of the Pharmaceutical Benefits Scheme (PBS).

It is not clear that a relatively deregulated market is the appropriate benchmark. The US market has the least government intervention in price setting—even though countervailing power is used by HMOs and Pharmaceutical Benefit Maintenance organisations. It also appears to have the highest level of drug prices. However, nearly all countries regulate pharmaceutical prices or

pharmaceutical company profits to at least some extent (see Appendix D for a discussion of international pharmaceutical regulations). In the absence of the PBS, it is likely that the government would impose some other form of price discipline on companies.

The BIE (1991) noted that the increase in prices required to take Australian prices to world average levels was of the order of 80 to 100 per cent and that increases of around 40 per cent would be needed to take prices to European Union (EU) average levels. However, the great majority of companies predicted price increases of only between 5 per cent and 20 per cent in the absence of the PBS. The BIE concluded:

> It therefore appears that companies typically do not expect Australian drug prices would be increased to world average levels, and that even the EU average would appear to be very much an upper limit to the price levels which might prevail, at least initially, in a deregulated pricing environment (BIE 1991, p. 39).

The Commission concurs with the BIE that EU prices appear to be a more appropriate benchmark than world prices. The reduction of trade barriers in the EU and recent acceptance of mutual recognition of drugs create a reasonably competitive pharmaceutical industry environment, with a variety of government regulatory approaches to cost containment. The resultant 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.

Appropriate basket of drugs and price weighting

There are also issues involved in selecting an appropriate basket of drugs for which to compare Australian prices with those in other countries.

The basket of drugs should as far as possible reflect the relative importance in the Australian market of products listed on the PBS. This suggests that it should focus on the highest expenditure items on the PBS. Australian prices of products in the basket relative to their prices in the benchmark countries should then be weighted according to their PBS sales volumes since this best reflects the impact of PBS prices on company sales revenues in Australia.

The above approach cancels out the influence of different prescribing or consumption patterns in other countries. However, it does not allow for

situations where low PBS prices or restrictions on the PBS subsidised market have reduced market shares or even prevented some drugs from being marketed in Australia. The effect of the PBS on drug availability was discussed in Chapter 8.

H.2 Previous drug price comparisons

Various studies have attempted to estimate the effect of the PBS on the level of drug prices in Australia by comparing them with prices in other countries. Common to all these studies is a selection of a basket of products and a group of countries with which to compare prices.

Many of these studies compare unweighted average prices. In addition to the difficulties described above, which apply to all indices, unweighted averages, because they do not take into account the relative importance to purchases of the drugs included in the basket, give an inferior comparison to indices which weight prices by appropriate purchase volumes.

H.2.1 Ralph inquiry

The Ralph inquiry (Ralph 1979) compared Australian prices of 25 branded PBS drugs in 1978 with the prices of those products in other developed countries.

The countries investigated included the UK, New Zealand, South Africa, Germany, France, Italy, the Netherlands, Japan, US and Canada.

Unweighted average Australian prices were found to be the lowest of the sample of 10 countries studied (Ralph 1979, pp. 45–51).

H.2.2 Industries Assistance Commission Inquiry

An Industries Assistance Commission inquiry (IAC 1986b) examined price data from various sources including:

- a study by Reekie (1984);
- an Australian Pharmaceutical Manufacturers Association (APMA) price comparison;
- participants' data; and
- a direct comparison with New Zealand.

Reekie

Reekie (1984) examined the major selling drugs of nine multinational drug suppliers in 1982. He found that on an unweighted average basis for standardised dosage units, ex-manufacturer prices were 65 per cent higher in the US than in Australia, and prices in the UK and Europe exceeded Australian prices by 40 per cent and 16 per cent respectively (Reekie 1984, pp. 71–77).

APMA

The APMA price comparison was based on 1982 prices and covered 58 drugs which accounted for about 54 per cent by value of PBS sales. Comparisons were made with both an OECD 12 country basket and a nine Organisation for Economic Co-operation and Development (OECD) country basket, which excluded the Federal Republic of Germany, Japan and the US, the three countries with the highest drug prices.

The APMA concluded that unweighted average prices were 78 per cent higher than in Australia in the basket of 12 OECD countries and 40 per cent higher in the basket of nine countries.

Participants' data

A number of participants submitted international price data. For example, Merck, Sharp & Dohme submitted data on 1985 prices of a basket of 17 drugs, accounting for over 90 per cent of the company's PBS sales. It found that on an unweighted average basis, Australian prices were 47 per cent of the average for a group of 19 OECD countries (IAC 1986b, p. 93).

IAC comparisons

The Industries Assistance Commission (IAC) also compared Australian and New Zealand prices in 1985, for a basket of nine of the ten most prescribed drugs under the PBS, weighted by Australian consumption patterns. Drug prices in New Zealand were 37 per cent greater than those in Australia (IAC 1986b, p. 251).

The IAC concluded that the available international price comparisons left little doubt that, in aggregate, PBS pricing policies had reduced prices for PBS products below the levels that would prevail in the absence of the scheme (IAC 1986b, p. 94).

However, the extent of the reduction was considered to vary. The IAC concluded:

> ... for the great majority of originator brand drugs supplied under the PBS the Department of Health has considerable negotiating power which it has used to secure prices from drug suppliers which are low by international standards (IAC 1986b, p. 95).

H.2.3 Parry and Thwaites

Parry and Thwaites (1988) cited a 1987 IMS world pricing study. The study compared the ex-manufacturer prices of the 80 highest selling products in Australia with the unweighted average prices of those products in major overseas markets. The results were based on 1986–87 sales and exchange rates. The countries used to construct a 'world' average were Austria, Belgium, Canada, Finland, France, Japan, New Zealand, Spain, the UK, the US and West Germany.

The study estimated that Australian prices were, on average, about 55 per cent of world average prices. For any given product, the Australian price was generally less than prices in most other countries identified. For about 90 per cent of the products the Australian price was less than the world average price.

Parry and Thwaites concluded that:

> ... the significant discrepancy between Australian prices and world prices quite clearly demonstrates that prices in Australia are certainly well below those achieved elsewhere (Parry & Thwaites 1988, p. 49).

H.2.4 Parry and Creyke

Parry and Creyke (1991) used an IMS Pollard index of pharmaceutical prices to estimate that Australian prices were, on average, about 50 per cent of world average prices.

Parry and Creyke concluded that:

> While international price comparisons need to be treated with caution, the significant differential between Australian prices and world prices clearly demonstrates that prices in Australia continue to remain well below those achieved elsewhere. (Parry & Creyke 1991, p. 6).

H.2.5 Bureau of Industry Economics

The BIE (1991) summarised previous international comparisons of drug prices. The 1982 data were those prepared for the IAC inquiry (IAC 1986b) (see Section H.2.2). The 1987 IMS results cited by Parry and Thwaites were

outlined in Section H.2.3. The comparison between these two studies is reproduced in Table H.1.

Table H.1: Comparison of average ex-factory drug prices, Australia and OECD averages, per cent

	1982[a]			*1987*[b]	
	Australia	*12 OECD countries* [c]	*9 OECD countries* [d]	*Australia*	*11 OECD countries* [e]
Patented drugs	55	100	90	42	100
Off patent drugs	57	100	69	59	100
All (sampled) drugs	56	100	79	55	100

a The sample covers 58 PBS drugs representing 54 per cent of total Australian PBS sales.
b The sample covers the 80 largest selling products marketed in Australia
c The 12 countries are Austria, Belgium, Canada, Finland, France, Germany, Italy, Japan, the Netherlands, Spain, the UK and the US.
d Same countries as (c) but excludes Germany, Japan and the US.
e Same countries as (c) but excludes Italy.
Sources: IAC 1986b, p. 94; Parry and Thwaites 1988, p. 49; BIE 1991, p. 36

The BIE also presented individual country data from the IMS survey for 1991, which is shown in Table H.2. The indices were unweighted averages calculated for two baskets of products, the 24 largest selling products in Australia, and the 80 largest selling products in Australia.

The BIE noted the considerable dispersion of average price levels among the countries studied. Depending on the products included in the basket, ex-manufacturer prices in the most expensive country (US) were between 50 and 100 per cent higher than the world average. Average price levels in the cheapest countries (Italy and Spain) were only between 20 and 30 per cent of those in the US. The comparisons showed Australia to be amongst the lowest of the developed countries surveyed:

> For the basket comprising 20 of the 24 top-selling products, ex-factory prices in Australia are, on average, 55 per cent of the EC average. For the basket sampled from the 80 largest selling products, Australian ex-factory prices are, on average, about 70 per cent of those received in Europe and the EC (BIE 1991, p. 37).

The BIE concluded that 'since the inception of government regulation of pharmaceutical prices in September 1963, the Pharmaceutical Benefits Pricing Bureau and the Pharmaceutical Benefits Pricing Authority (PBPA) have been successful in restraining prices to suppliers of PBS drugs' (BIE 1991, p. 35).

Table H.2: Comparison of average ex-factory drug prices in 1990, by country, per cent

	53 of the 80 largest selling products in Australia		*20 of the 24 largest selling products in Australia*	
Country	*World average = 100*	*EC average = 100*	*World average = 100*	*EC average = 100*
US	155	177	211	242
Canada	155	177	137	157
UK	135	154	99	114
Ireland	125	143	107	123
Netherlands	123	140	120	138
Germany	122	139	155	179
New Zealand	112	128	48	56
Japan	109	124	123	141
Finland	107	122	120	139
World average	**100**	**114**	**100**	**115**
Europe average[a]	**89**	**101**	**90**	**104**
EC average[b]	**88**	**100**	**87**	**100**
Belgium	84	96	75	86
Austria	83	95	91	105
France	72	82	71	82
Australia	**60**	**69**	**48**	**55**
Portugal	60	68	73	84
Greece	54	61	79	91
Italy	52	59	41	47
Spain	51	59	48	56

a Europe is represented by the Austria, Belgium, Finland, France, Germany, Greece, Ireland, Italy Netherlands, Portugal, Spain and the UK.

b The European Community (EC) is represented by Belgium, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain and the UK. Data for Denmark and Luxembourg are not available through IMS.

Source: BIE 1991, p. 37

H.2.6 Peat Marwick

Peat Marwick (1991) compared ex-manufacturers prices for a basket of 22 drugs between Australia and five European countries, three Asian countries, the

US, Canada and New Zealand on an unweighted basis. The drugs chosen included the 10 largest selling products in Australia in 1988 and a selection from various therapeutic groups.

The overall average of Australian price to foreign price comparisons was 59 per cent. The findings are presented in Table H.3. The US had the highest prices, with Australia paying around a quarter of US prices. France was the only country found to have lower average drug prices than Australia.

H.2.7 Balasubramaniam

Balasubramaniam (1995) compared the retail prices of a limited number of widely used essential drugs in a range of developed and less developed countries on an unweighted basis. Price data for the developed countries are given in Table H.4.

Note that Australian prices are expressed relative to foreign prices. Comparisons were made with the median for each drug across countries rather than mean drug prices because of the prevalence of some outliers. Overall, the Australian median price was estimated to be 75 per cent of the median overseas price.

H.3 Participants' data

The Commission received information from a number of companies outlining the price differentials experienced for their products between Australia and other countries. Overall, prices submitted by the companies were significantly lower than European average prices. A selection of these data are presented below.[1]

[1] The samples cited below were self-selected by companies and may not be representative of relative prices of their full range of products.

Table H.3: Comparison of International Drug Prices1988, selected countries, per cent [b]

Item (brand)	*UK*	*France*	*Germany* [a]	*Spain*	*Switzerland*	*US* [a]	*Canada*	*New Zealand*	*Malaysia* [a]	*Taiwan*	*Singapore*	*Average per drug*
Allopurinol (Zyloprim)	9	49	53	34	17	22	41	53	26	11	10	30
Amoxycillin (Amoxyl)	46	na	33	45	6	56	57	84	41	na	na	46
Atenolol (Tenormin)	30	103	40	64	32	23	31	55	60	43	33	47
Beclamethasone (Becotide)	50	68	25	73	33	17	40	44	51	35	35	43
Captopril (Capoten)	80	126	59	91	103	56	58	97	83	35	81	79
Cephalexin (Keflex)	51	na	na	43	na	14	58	66	56	48	41	47
Cimetidine (Tagamet)	87	90	39	281	42	35	73	72	55	na	na	86
Chlorothiazide (Chlotride)	140	na	na	54	na	53	na	55	45	na	na	69
Clofibrate (Atromid)	101	187	44	95	42	12	49	85	57	36	25	67
Diazepam (Valium)	88	107	32	46	22	8	37	49	58	35	35	47
Diclofenac (Voltaren)	39	75	48	33	26	12	22	53	41	21	31	36
Doxycycline (Doryx)	na	na	na	77	na	19	18	42	na	na	na	39
Enalapril (Renitec)	102	164	na	131	95	na	54	134	170	na	133	140
Erythromycin (Eryc)	na	na	na	13	na	43	42	84	na	na	na	46

(cont.)

Table H.3: Comparison of International Drug Prices 1988, selected countries, per cent [b] (cont'd)

	UK	*France*	*Germany*[a]	*Spain*	*Switzerland*	*US*[a]	*Canada*	*New Zealand*	*Malaysia*[a]	*Taiwan*	*Singapore*	*Average per drug*
Isotretinoin (Roaccutane)	135	297	103	99	na	na	135	95	na	62	89	127
Methyldopa (Aldomet)	55	88	na	53	26	22	33	75	49	36	33	47
Metoprolol (Betaloc)	79	95	na	na	na	na	24	46	23	29	22	45
Oxazepam(Serapax)	na	122	na	131	14	9	87	194	na	na	na	93
Prazosin (Minipress)	53	37	30	62	40	16	19	70	53	63	na	44
Propranolol (Inderal)	60	43	na	86	36	5	15	35	36	14	34	36
Ranitidine (Zantac)	53	84	39	36	37	36	39	76	59	32	na	49
Salbutamol (Ventolin)	109	114	na	77	50	30	37	118	164	24	na	80
Mean	**72**	**109**	**45**	**77**	**39**	**26**	**46**	**79**	**63**	**35**	**46**	**59**
Range	9–140	37–297	25–103	13–281	6–103	5–56	15–135	35–194	23–170	11–63	10–133	
# above 100	5	8	1	3	1	0	1	3	2	0	1	

a Wholesale comparison.
b Australian prices relative to foreign price data in selected countries.
na not available
Source: Peat Marwick Management Consultants 1991, Appendix C

Table H.4: Retail drug price comparison [a] selected countries, per cent [b, c, d, e]

Drug	*Strength in mg*	*Belgium*	*Canada*	*France*	*Germany*	*Greece*	*Italy*	*Nether-lands*	*NZ*	*Switz-erland*	*UK*	*US*	*Median per drug*
Amoxycillin	250	na	463	95	62	na	231	103	168	36	529	185	168
Amoxil	250	na	286	108	na	na	na	100	182	na	148	111	130
Capoten	25	19	na	30	na	33	35	30	30	na	na	17	30
Cimetidine	200	na	200	na	20	na	na	19	38	12	91	14	20
Tagamet	200	17	40	24	16	42	34	16	38	9	44	11	24
Cotrimoxazole	480	833	1250	469	417	na	na	289	577	119	1500	326	469
Septrin	480	na	1250	357	153	417	577	268	395	86	313	79	335
Diazepam	10	93	2600	100	163	na	na	87	217	50	1300	14	100
Valium	10	80	160	146	42	na	57	100	na	36	na	14	69
Diclofenac	50	49	63	76	86	na	na	na	91	40	119	na	76
Voltaren	50	47	48	73	60	92	105	na	96	24	79	20	67
Erythromycin	250	242	483	97	48	414	na	42	121	26	483	74	109
Erythrocin	250	54	322	97	43	na	83	37	na	na	138	145	90
Frusemide	40	44	1600	100	44	na	na	53	267	24	na	89	71

(cont.)

Table H.4: Retail drug price comparison [a] selected countries, per cent [b, c, d, e] (cont'd)

Drug	*Strength in mg*	*Belgium*	*Canada*	*France*	*Germany*	*Greece*	*Italy*	*Nether-lands*	*NZ*	*Switz-erland*	*UK*	*US*	*Median per drug*
Lasix	40	32	160	80	na	57	133	47	114	18	na	33	57
Adalat	10	48	na	18	na	na	80	na	40	na	na	na	44
Propranolol	40	58	na	78	na	na	na	na	100	na	na	47	68
Inderal	40	58	na	na	na	117	na	na	64	na	na	14	61
Zantac	150	16	25	20	13	28	26	15	39	7	28	12	20
Median		**49**	**286**	**95**	**48**	**74**	**81**	**50**	**100**	**26**	**143**	**33**	**75**

a Prices undated in original.
b Retail drug prices of 100 units (tablets/capsules) of 22 commonly used drugs in 29 countries. All values are given in US dollars at current exchange rate.
c Personal communication from HAI partners in the respective countries.
d $Purchasing Power Parity ($PPP)—UNDP (United Nations Development Program) 1994, *Human Development Report*, Oxford University Press, New York.
e Australian prices relative to foreign price data in selected countries.
na not available
Source: Balasubramaniam 1995

H.3.1 Merck, Sharp & Dohme

Merck, Sharp & Dohme provided relative prices for a range of patented and non-patented PBS drugs, as well as hospital and private prescription drugs. Generally, the hospital and private prescription drug prices were the most comparable to overseas prices, while the prices of patented and non-patented PBS products were relatively lower compared to the overseas average provided (sub. 27, Schedule 4) (see Table H.5).

Table H.5: Relative wholesale prices of Merck, Sharp & Dohme products, 1995[a]

	Australia	*OECD average*	*Europe average*	*Aust. as a per cent of OECD*	*Aust. as a per cent of Europe*
	$US	*$US*	*$US*	*%*	*%*
Private prescription/ Hospital products					
Mefoxin—1 gm inj	6.67	7.57	7.77	88	86
Proscar—5 mg 100 tabs	141.25	135.12	135.05	105	105
Primaxin—500 mg I.V 500 mg	16.94	20.79	21.74	81	78
Patented PBS products					
Pepcidine—40 mg 100 tabs	54.54	145.86	157.47	37	35
Renitec—5 mg 100 tabs	32.67	39.45	34.61	83	94
Timpilo	8.02	13.07	13.92	61	58
Zocor—10 mg 100 tabs	73.76	100.49	97.39	73	76
Out of patent PBS products					
Aldomet—250 mg 100 tabs	4.29	11.75	10.93	37	39
Clinoril—100 mg	6.52	21.73	21.56	30	30
Dolobid—500 mg 100 tabs	12.00	34.27	31.76	35	38
Indocid—25 mg	3.43	10.59	8.22	32	42
Moduretic	5.18	19.43	17.87	27	29
Sinemet CR—50/200 mg 100 tabs	35.49	56.12	58.19	63	61
Timoptol—0.25% 5CC	3.58	6.90	6.33	52	57

a June 1995 exchange rates, US dollars, adjusted for pack size.

Source: Merck, Sharp & Dohme sub. 27, Schedule 4

H.3.2 SmithKline Beecham

SmithKline Beecham provided the data shown in Table H.6 as an illustration of price differentials experienced between Australia and Europe for a selection of its products (sub. 13, Attachment 4).

Table H.6: SmithKline Beecham, Australian pharmaceutical prices compared with average European prices, per strength unit

Product	*Form*	*Australian price*	*European average*	*Ratio of Aust. to European*
		$A	$A	%
Amoxil	Capsule 500 mg	0.297	0.602	49
Amoxil	Syrup/suppression 250 mg	0.041	0.071	58
Amoxil	Sachet 3g	3.320	4.596	72
Augmentin	Syrup/suppression 156.25 mg	0.058	0.101	58
Augmentin	Tablet 375 mg	0.476	1.055	45
Floxapen	Capsule 500 mg	0.499	1.151	43
Floxapen	Vial 1 mg	3.100	6.795	46
Floxapen	Syrup 125 mg	0.049	0.068	73
Tagamet	Ampoule/Vial 200 mg	0.732	1.028	71
Tagamet	Tablet 800 mg	0.724	1.619	45
Tagamet	Effervescence	0.724	1.785	41

Source: SmithKline Beecham sub. 13, Attachment 4

In response to a Draft Report request for further information regarding relative prices of individual products in Australia and comparable countries, SmithKline Beecham provided the additional example in Table H.7 of the price received for Augmentin (an antibiotic) in various countries (sub. 115, p. 3).

H.3.3 Faulding

Faulding stated that it generally sells products at higher prices overseas than in Australia, and provided the data for two products in Table H.8 as an illustration (sub. 85, p. 3).

Table H.7: Price of Augmentin [a] in Australia compared to prices in other countries [b], $ Australian

Country	*Cost per tablet*	*Country*	*Cost per tablet*
Australia	0.68	France	1.19
Austria	1.33	Germany	1.18
Belgium	1.25	Spain	0.64
Brazil	2.22	Switzerland	2.65
Canada	1.37	US	2.92

a 625 mg tablet used as example as it is the major presentation by value in local market. Other presentations show similar patterns.
b Prices are at manufacturer's wholesale selling prices.
Source: SmithKline Beecham sub. 115, p. 3

Table H.8: Faulding case study of relative prices

Description	*Country*	*Relative price*
Carboplatin 450 mg/45 ml	Australia	100
	Canada	284
	Portugal	418
	Belgium	670
	Singapore	110
Vancomycin 500 mg F.D.	Australia	100
	UK	200

Source: Faulding sub. 85, p. 3

In response to a Draft Report request for further information regarding relative prices of individual products in Australia and comparable countries, Faulding provided the additional examples in Table H.9 of the prices received for selected products in Australia compared to average European prices (sub. 129, Attachment 1).

Table H.9: Faulding comparison of Australian and European prices for selected products

Product description[a]	*Average selling price*		*Australian price as a percentage*
	Australia	*Europe*[b]	*of European price*
	$A	$A	%
Vancomycin	76.34	78.20	98
Glyceryl	12.26	17.97	68
Carboplatin	101.32	320.36	32
Fentanyl	3.77	2.32	163
Dopamine	12.26	7.18	171
Dobutamine	19.27	17.78	108
Ephedrine	17.75	3.87	459
Cisplatin	12.82	20.33	63
Cytarabine	29.32	39.46	74
Dexamethasone	8.25	6.42	128
5FU	12.48	28.20	44
Doryx	4.55	13.38	34
Eryc	3.75	12.50	30

a Some products are converted for varying pack sizes.
b European prices converted at £0.478 = $A1.
Source: Faulding sub 129, Attachment 1

H.3.4 Glaxo Wellcome

Glaxo Wellcome provided comparisons with EU average prices for a number of its products (see Table H.10).

Glaxo Wellcome also provided details of prices for three different drugs across a range of European countries.

The PBS price proposed by PBPA for the 100 mg tablet of Imigran in Australia is $2.10 (ex-manufacturer). This compares with prices of $15.20 in the UK, $15.72 in the Netherlands, $15.53 in Germany, $16.41 in Sweden and $17.57 in Italy, per 100 mg tablet. The average EU price is $18.00.

Table H.10: Glaxo Wellcome Australian prices relative to European Union prices, per cent

Product	*Australian price as a percentage of EU price*
Becotide inhaler 100 µg	50
Becloforte inhaler 250 µg	40
Lamictal tablets 100 mg[a]	75
Serevent inhaler 25 µg	75
Ventolin inhaler 100 µg	37
Zantac tablets 150 mg	33
Flixotide 250 µg	80
Imigran 100 mg	11

a Per cent of UK price.
Source: Glaxo Wellcome sub 143, Attachment, p. 7; sub 144, Appendix. 1

The Australian PBS price for the 25 µg Serevent presentation is $0.28/dose (ex-manufacturer), compared with $0.45 in the UK, $0.38 in the Netherlands, $0.36 in Germany, $0.34 in Spain, $0.39 in France, and $0.32 in Italy. The EU average price is $0.37 per dose.

The price of Flixotide 250 µg inhaler is $61.10 in Australia. The EU average price is $75.87 (subs. 143 and 144).

H.3.5 Astra

Astra submitted price comparisons with European Community (EC) prices for a number of its key products as at December 1995. The EC average price shown is the average of EC countries where equivalent dosage is available (see Table H.11) (sub. 141, p. 16).

H.3.6 CSL

CSL responded to the Draft Report request by providing details of the relative prices for three drugs:

- plasma pharmaceuticals—CSL currently receives 67 per cent of the prices received in the UK, Germany, Netherlands, Denmark and Japan, which are all major producers of these products;

- childhood immunisation vaccines—CSL receives approximately 20 per cent to 40 per cent of the prices in the EC and US; and
- Clavulin—CSL receives less than 50 per cent of the European average for this antibiotic product (sub. 118, pp. 16–17).

Table H.11: Astra price comparison, December 1995[a]

Product	*Australian price*	*EC average price*	*Australian price as a percentage of EC price*
	$A	$A	%
Losec 20 mg	2.20	3.43	64
Bricanyl Turbuhaler 500mg 200d	0.046	0.110	42
Plendil ER (2.5 mg)	0.325	0.687	47
Plendil ER (10 mg)	0.786	1.045	75
Pulmicort Turbuhaler 400 u/d 200d	0.16	0.64	25
Pulmicort Turbuhaler 200 u/d 200d	0.100	0.343	29
Imdur 60 mg	0.510	0.680	75

a Prices are $A per tablet or device.
Source: Astra sub. 141, p. 16

H.3.7 Eli Lilly

Eli Lilly provided two examples of relative prices:

- Prozac—the Australian price is 96 per cent of the EC average price, but Eli Lilly argued there are severe restrictions on its use; and
- Ceclor—the Australian price is 59 per cent of the EC average (sub. 142, p. 7).

H.4 APMA survey

During the course of the Inquiry, the APMA provided the Commission with three versions of an IMS study first undertaken for the Draft Report. The versions vary in terms of the range of products used and in the use of unweighted and weighted relative prices.

Version 1: broadest range of products, unweighted comparison

An APMA (1995b) study undertaken specifically for the Draft Report presented a comparison of prices paid in a range of OECD countries sourced from IMS raw data for the month of June 1995.

Price comparisons were made on the basis of reference products within product ranges. Reference products were the products with the largest Australian sales in terms of volume. Generic and non-PBS drugs were included in the comparison.

Price data were collected for the US, UK, France, Japan, Germany, Canada, Italy, Australia, Spain, the Netherlands, Belgium, Portugal, Greece, Austria, New Zealand, Turkey, Finland and Ireland.

Only those countries selling the reference product were used in the price comparison for that product. Where the brand sold in Australia was not available, an arithmetic average of the other brands of the reference product was used to calculate the price for that country. There was no aggregation by strength or dosage form.

An arithmetic mean of the price per standard dose unit for the countries selected was calculated. This world mean price for the selected reference product was compared to the Australian price and expressed as a percentage.

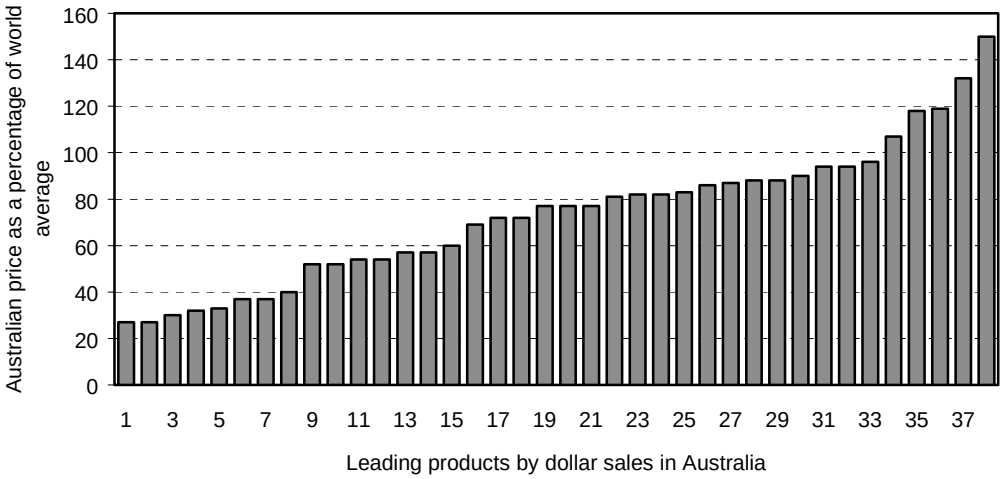
Calculations were performed for two groups of products, leading products and new products:

- the 38 leading products accounted for approximately the top 50 per cent of the Australian prescription market by sales as at June 1995, as defined by IMS Australia; and
- 27 new products launched in Australia since 1 January 1993. These products were selected on the basis that they have achieved annual sales of $500 000 or greater as at June 1995, and accounted for approximately 2 per cent of the Australian prescription market as at June 1995.

Graphic illustrations for each product of its price in Australia compared to the arithmetic mean of the unweighted prices in those countries where it is sold are provided in Figures H.1 and H.2.

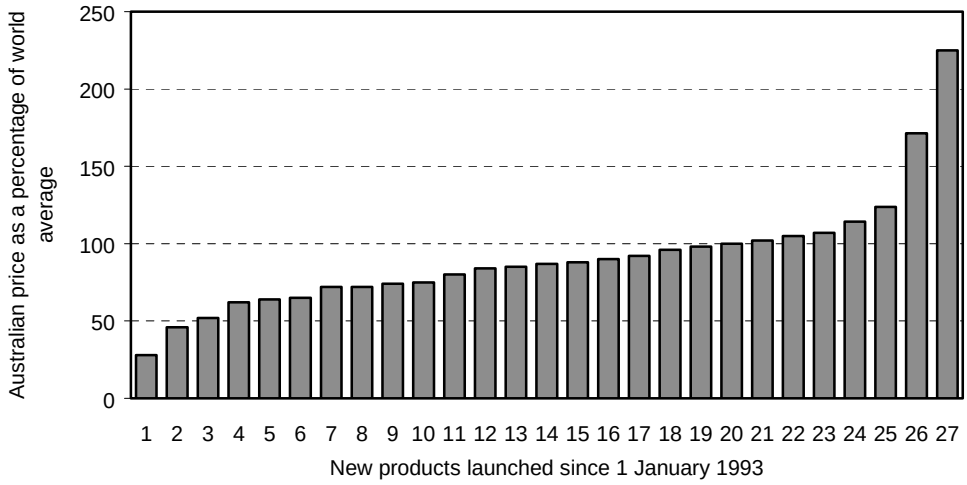
All eligible products, whether on the PBS or not, were included in both groups of products. One product appears in both categories. The non-PBS products in Figure H.2 include drugs 24–27 (APMA 1995b, pp. 1–2).

Figure H.1: Australian price as a percentage of world average, leading products by Australian dollar sales[a]



a Australian price as a percentage of world average. Average of countries where product sold.
Source: APMA 1995b

Figure H.2: Australian price as a percentage of world average, new products [a, b]



a Australian price as a percentage of world average. Average of countries where product sold.
b Launched since 1 January 1993.
Source: APMA 1995b

The key conclusions in relation to average prices were:

- the unweighted average Australian price for the 38 leading products by dollar sales was 73 per cent of the estimated world average price; and

- the unweighted average Australian price for the 23 new PBS products was 79 per cent of the estimated world average price.[2]

This suggests that prices for products launched since January 1993 may, on average, be higher than prices for other products.

Version 2: generic and non-PBS drugs excluded

This study provided both unweighted and weighted average prices with slightly modified data. Modifications to version 1 data consisted of the following:

- the exclusion of generic products from the comparison—from within each product range only one dosage form, representing the highest sales in terms of volume of product sold, was chosen to avoid repetition by active substance. This product was termed the reference product, and resulted in the exclusion of generic products;
- the exclusion of all non-PBS products, and repatriation only PBS products;
- recalculation of all products to reflect the PBS status at June 1995; and
- minor corrections to data identified as a result of the third calculation.

The impact of these modifications was to reduce the number of new products from 27 to 19.

Two comparisons were made:

- graphic illustrations for each product of its price in Australia compared with the arithmetic mean of the unweighted prices in those countries where it is sold (see Figures H.3 and H.4); and
- a comparison of the weighted average prices for products being compared for Australia and other countries.

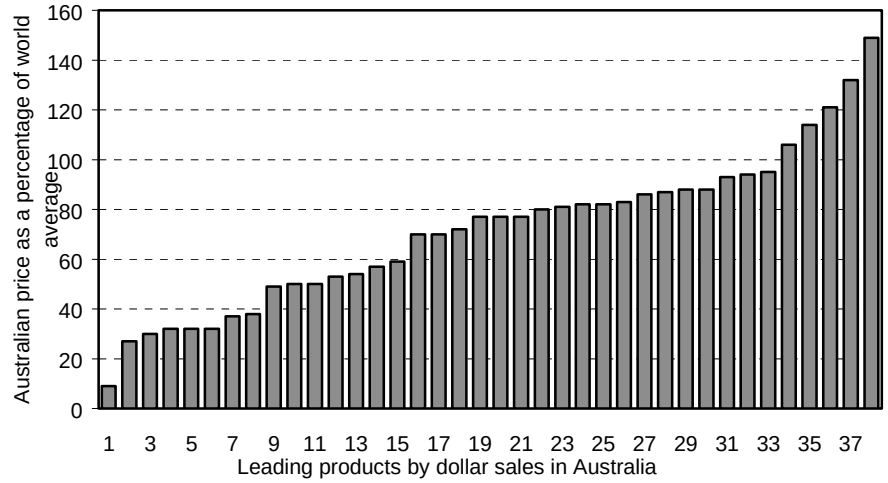
Unweighted average price results

The key overall conclusions in relation to unweighted average prices were:

- the average Australian price for the 38 leading products by dollar sales was 71 per cent of the estimated world average price; and
- the average Australian price for the 19 new PBS products was 85 per cent of the estimated world average price (see Table H.12).

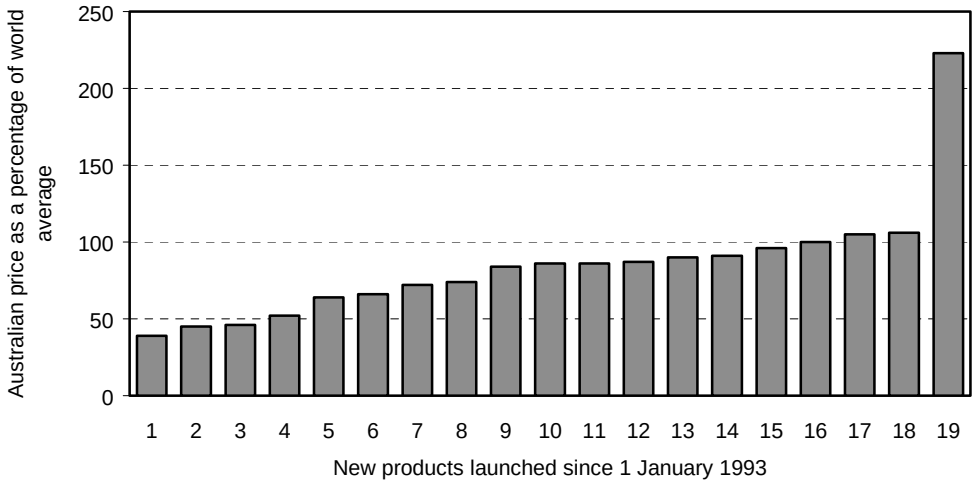
[2] The non-PBS new products were excluded from the mean of 79 per cent.

Figure H.3: Australian price as a percentage of world average, leading products[a] by Australian dollar sales



a Generic and non-PBS products excluded.
Source: APMA sub. 119, Attachment 4, p. 4

Figure H.4: Australian price as a percentage of world average, new products [a,b]



a Launched since 1 January 1993.
b Generic and non-PBS products excluded.
Source: APMA sub. 119, Attachment 4, p. 5

Australian prices weighted by Australian volumes, world prices weighted by world volumes

Other country prices were weighted by world sales volumes (excluding Australian sales) to establish a weighted world price. The Australian prices were similarly weighted by Australian sales volumes to establish a weighted Australian price. The Australian price as a percentage of weighted world price was then calculated using these two figures.

It should be noted that the weightings used to calculate the weighted world price, namely the world sales volumes, do not reflect the relative importance of products in Australia.

The key overall conclusions from the comparisons of weighted prices calculated as described above were:

- the average weighted Australian price for the 38 leading products was 35 per cent of the world average price; and
- the weighted average Australian price for the 19 new PBS products was 68 per cent of the estimated world average price.

Version 3: Australian prices weighted by Australian volumes, world prices weighted by Australian volumes

The Commission considers weighting of world prices by Australian product volume more accurately reflects the impact of the PBS on company returns in Australia. Weighting according to Australian product volumes cancels out the influence of differing prescribing or consumption patterns in different countries.

To get the most accurate measure available, the Commission requested the APMA to provide a calculation using Australian product volume weightings. Using such weightings, the Australian price of the leading products was 54 per cent of the world average price, whereas for the new products the average was nearly 70 per cent of the world average price. Table H.12 summarises the various weighted average prices.

Table H.12: Unweighted and weighted price comparisons for Australia and the rest of the world, APMA data, per cent

Basis for comparison	*Leading products*	*New products*
Unweighted Australian price as a percentage of world price	71	85
Weighted by volume of sales:		
Using world volume weights for world prices and Australian volume weights for Australian prices	35	68
Using Australian volume weights for world prices and Australian volume weights for Australian prices	54	70

Source: APMA correspondence 7 February 1996

H.5 PBPA data

The PBPA (1996) provided the Commission with relative UK and Australian prices for lists of innovative, new forms and strengths, and me-too products.

Innovative drugs (category 1) were classed as unique, break-through drugs that are the only effective form of treatment and where there is no direct comparator considered for listing since 1 January 1993. New forms and strength drugs (category 2) were defined as drugs that are first in a new therapeutic class with equivalent efficacy as other drugs but with quality of life and/or safety improvements. Me-too drugs (category 3) were defined as drugs in the same chemical family with no additional benefits.

Prices were based on the Australian manufacturers' pack to reflect a price for the same pack.

H.5.1 Unweighted price comparisons

Unweighted UK and Australian ex-manufacturer prices were compared for a number of groups of products as at January 1996. The comparisons were all in terms of the relative prices only, the actual prices were confidential.

The unweighted average Australian price of innovative, new form and strength, and me-too items was 91 per cent of the UK price. The comparisons for the three categories individually are presented in Table H.13.

Table H.13: Unweighted price comparison for Australia and UK drug prices, innovative and new drugs, January 1996, PBPA data

Drug category	*Number of products*	*Unweighted Australian price as a percentage of UK price* [a,b,c,d,e]
Innovative drugs	36	92
New forms and strengths	46	96
Me-too drugs	83	86
All drugs	**165**	**91**

a Prices are at ex-manufacturer level.
b The UK prices assume a 10 per cent wholesale margin.
c Suppliers in the UK are able to set their own prices.
d The prices were obtained from the UK *Chemist and Druggist*, which is provided on a monthly basis.
e UK prices are for the same pack size as Australia wherever possible—where the UK pack is not the same as the Australian pack, prices have been adjusted on a *pro rata* basis.
Source: PBPA correspondence 12 April 1996

For the 69 most prescribed and/or highest cost patented products the average unweighted Australian price relative to the UK price was 84 per cent. The unweighted average price for 17 of the 20 highest sales value drugs launched since 1991 was 81 per cent of their unweighted average price in the UK (see Table H.14).

H.5.2 Weighted comparisons

The Commission weighted the prices of the 50 highest cost drugs by their script volumes to generate a weighted price comparison. At January 1996, the weighted average price of the 50 highest cost drugs on the PBS was 67 per cent of the weighted average price of the same products in the UK. The weighted average price for 17 of the 20 highest sales value drugs launched since 1991 was 83 per cent of the UK price (see Table H.14).

The Commission also separated the 50 highest cost drugs by their script volumes drugs into patented and non-patented drugs. The weighted average price for patented drugs was 65 per cent of the UK price. For non-patented drugs, the weighted average price was 72 per cent (see Table H.15).

Table H.14: Unweighted and weighted price comparisons for high cost major drugs launched since 1991, January 1996, PBPA data

	High cost drugs	*Major drugs launched since 1991*
Unweighted Australian price as a percentage of UK price	84[a]	92[c]
Weighted Australian price as a percentage of UK price	67[b]	83[d]

a Based on 69 highest cost drugs.
b Based on 50 highest cost drugs.
c Based on 36 drugs launched since January 1993.
d Based on 20 highest selling drugs in 1994–95 that were launched since 1991. UK pricing data were available for only 17 of these drugs.
Source: PBPA correspondence 12 April 1996

Table H.15: Weighted price comparison between Australia and UK drug prices, high cost drugs, January 1996, PBPA data

Drug category	*Weighted Australian price as a percentage of UK price*
Non patented	72
Patented	65
All drugs	**67**

Source: PBPA correspondence 12 April 1996

I ECONOMIC ANALYSIS IN PBS LISTING

This Appendix outlines the background to the introduction of mandatory economic analysis in applications for drugs to obtain Pharmaceutical Benefits Scheme listing. It also provides a summary of the guidelines and the economic analysis methodologies that are to be adopted and a brief discussion of industry concerns with the guidelines.

I.1 Introduction of economic analysis requirements

To obtain Pharmaceutical Benefit Scheme (PBS) listing for a drug, a sponsor makes an application to the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC, after considering the application, makes a recommendation to the Minister, or to Cabinet if the annual cost of subsidy is likely to exceed $10 million per annum.

The PBAC bases its recommendations on the requirements of the *National Health Act* 1953. The role of a drug product in meeting the health needs of the Australian community is of primary consideration. For drugs considered appropriate for PBS listing on medical grounds, economic factors, including cost effectiveness, are also taken into account.

The use of economic analysis in the PBAC's deliberations is of recent origin. A 1987 amendment to the legislation required the PBAC to consider effectiveness and cost when recommending drugs for PBS listing.

At the time the legislation was introduced, no other countries were evaluating drugs on the basis of cost effectiveness, so no relevant manuals or guidelines existed. However, there was a considerable health economics literature available which addressed the issues of health care, cost benefit and cost effectiveness techniques.

In 1989, the Commonwealth Government commissioned a group of academics to prepare a background document (DHHLGCS 1990). This document was released in 1990 and a revised version was published in November 1993.

One of the recommendations in both the original and the revised document was that the requirement for economic analysis should be introduced gradually. Rather than requiring economic analysis for every drug, it was suggested initially that the PBAC should request economic analysis for high cost drugs

only. Accordingly, in the two years prior to January 1993, the use of economic evaluation for listing was optional. However, since that date it has been mandatory.

The reason given for the gradual introduction of the requirement for economic analysis was that the data required for pre-marketing approval by the Therapeutic Goods Administration (TGA) were not suitable for conducting economic analysis. Consequently, sponsors needed to commission and complete new studies. The background document suggested that, by making the data requirements for economic analysis known prior to making it mandatory, sponsors would be encouraged to modify pre-marketing trials to collect the required information.

In addition to the background document, the then Department of Human Services and Health (DHSH) (now Department of Health and Family Services) released other documents to assist sponsors preparing applications for PBS listing. These included:

- Guidelines for the Pharmaceutical Industry on the Preparation of Submissions to the Pharmaceutical Benefits Advisory Committee, Including Submissions Involving Economic Analyses (DHHCS 1992);
- Manual of Resource Items and Their Associated Costs for Use in Submissions to the Pharmaceutical Benefits Advisory Committee Including Submissions Involving Economic Analyses (DHSH 1993); and
- Roles and Responsibilities of the Pharmaceutical Benefits Advisory Committee (DHSH 1995d).

A comprehensive set of draft guidelines was released in August 1990. Subsequently, pharmaceutical companies, the Australian Pharmaceutical Manufacturers Association (APMA) and independent experts provided detailed comment on the guidelines. These were reviewed and a first revision of the draft was circulated for comment in August 1992.

At the beginning of 1993, the Economics Sub-committee (ESC) was formed by the PBAC. As part of its charter the ESC reviewed the guidelines and has sought comment from the industry. A further revision of the guidelines (hereafter referred to as the guidelines) was published in November 1995 (DHSH 1995e).

I.2 The guidelines

The most recent guidelines are comprehensive and prescriptive, comprising some 80 pages (including 15 appendices). The primary objectives are to define the format of data requirements and to provide advice on the type of analysis most appropriate for a particular type or class of drug. They also specify the processes to be followed in considering applications.

I.2.1 Data requirements

The guidelines state that the PBAC has a strong preference for data based on 'head to head' randomised trials that directly compare the proposed drug with the comparator. However, the guidelines indicate, because of the lack of data from 'field' analysis, where trials were not designed to collect data for economic analysis, 'desk top' analysis will suffice.

The guidelines also state that, if claims are not supported by clinical data which enables a judgment regarding clinically effective doses, submissions are unlikely to be successful.

I.2.2 Submission considerations

Submissions are assessed at three levels: by the Pharmaceutical Evaluation Section (PES) of the Department of Health and Family Services (DHFS), by each ESC member, and by each PBAC member.

The PES and the ESC each carry out a detailed evaluation of the submissions and provide advice to the PBAC. This advice is provided in the form of a summary of the therapeutic claims, evidence and the analyses provided in the application.

I.2.3 Categories of drugs

The economic analysis specification requires a comparison to be made between the costs and benefits of the drug for which listing is sought and the costs and benefits of the alternative drug or therapy (the comparator).

The type of economic analysis required depends upon the category into which the drug falls. The categories specified are:

- the drug has significant clinical advantages over the main comparator:
  - it has significant advantages in effectiveness over the main comparator and is associated with similar or less toxicity;

  - it has similar effectiveness to existing therapies but has less toxicity; or
  - it has significant advantages in effectiveness over existing therapies but is associated with more toxicity;
- the proposed drug is no worse than the comparator in terms of effectiveness and toxicity; and
- the proposed drug is less effective than the main comparator but is associated with less toxicity.

For drugs falling into the first category, which provide significant clinical advantages, the importance of any advantages needs to be considered in the context of the increased benefits and costs. As a result, applicants are requested to quantify the increase in benefits and compare these with the increase in costs. Cost effectiveness analysis or cost utility analysis are regarded by the PBAC as suitable forms of evaluation for drugs in this category.

Drugs falling into the second category are regarded as therapeutically equivalent to existing drugs and the type of economic evaluation required is cost minimisation analysis (CMA). Effectively, this means that the proposed drug will need to be at the same price or cheaper than the comparator in order to obtain PBS listing.

For drugs in the third category, the therapeutic advantage is less clear as there are clinical and cost trade offs. In this situation, the guidelines request an evaluation of adverse outcomes.

I.2.4 Types of economic analyses

As indicated above, the type of economic analysis required depends on the category into which the drug falls. The data requirements, methodologies and the assumptions differ for each type of analysis.

Cost effectiveness

CEA is used when the proposed drug is demonstrated to offer more of a given outcome. This goes beyond cost minimisation. For example, a drug may have a higher suggested price but may achieve the desired clinical outcome in a higher proportion of patients than the comparator. The outcome indicators reported from the randomised trials may need to be adapted in a model to reflect expected outcomes in the market.

The overall measure of a CEA is the incremental cost per additional unit of achieved outcome.

Cost utility

Cost Utility Analysis (CUA) is used when the ultimate benefit of improved health is the restoration of opportunities to undertake activities of daily living. This attempts to identify the value placed by patients, professionals and the general public on different activities restored and the quality of life achieved.

CUA presents the outcomes in terms of an extension of life and the utility value of that extension. For example, Quality Adjusted Life Years (QALYs) have been used to compare the benefits of kidney transplants and hip replacements. The latter does not extend life but improves the quality of the years of life left to a patient. A quality weighting, based on the activities restored or quality of life improvement achieved by an operation, can be used to compare the difference in the life extension and/or the improved quality achieved.

Cost minimisation

CMA is used when the proposed drug is demonstrated to be at least no worse therapeutically than other drugs at the same or a lower price. Generally, the PBAC will recommend PBS listing of alternative therapies provided outcomes can be achieved at lower cost.

Cost benefit

In contrast to other forms of analysis, cost benefit analysis (CBA) expresses all outcomes in monetary units rather than physical units. This requires a monetary valuation of these outcomes and often relies on calculations of indirect costs and benefits. There are problems with this type of analysis, the prominent one being the difficulty in putting a value on human life or a particular quality of life. Consequently, the guidelines state that the use of CBA is not encouraged. However, applications making appropriate use of this technique will be considered on a case by case basis.

I.2.5 Other guideline requirements

Final and intermediate outcome indicators

Both final and intermediate outcome indicators are used in economic evaluation of drugs. The outcomes specified in the guidelines include:

- final outcomes such as deaths prevented;
- life years gained; and
- QALYs gained.

Also to be considered are any adverse outcomes of the drug compared to those of the comparator as they may contribute to the costs of the therapy. Adverse outcomes could be reflected in:

- reduced quality of life particularly if it is to be tolerated over long periods;
- the use of complementary therapies; and
- unintended hospitalisation and additional procedures.

Final indicators measure the change in the health state. An example of final outcome indicator would be the number of deaths, or the number of years of life saved, because of a reduction in blood pressure and consequently a reduction in the number of people suffering a stroke or heart attack.

Intermediate indicators measure the change in a physical outcome which is believed to be associated with an improvement in health status. For example, control of blood pressure can be an intermediate outcome of the treatment of hypertension.

The ultimate aim of drug therapy is to improve health as reflected by changes in final outcome measures. For some outcome measures, research has shown that intermediate outcomes are predictive of final outcomes. For example, blood pressure control, an intermediate outcome, prevents death from stroke. However, in other instances, the connection between intermediate and final outcomes is not clear. For example, the treatment of asthma cannot be used to predict the occurrence of hospitalisation or death of an asthma sufferer.

The guidelines state that most clinical trials produce information about intermediate outcome indicators. However judgments need to be made about final outcome indicators because it is not always clear what the final outcome will be and how it should be valued.

The guidelines require the sponsor to provide an evaluation of the net cost of resources and the consequences of using the proposed drug and the main comparator. A DHSH (1993) manual provides the recommended prices to be used for costing resource use. Where the future benefits and costs fall over an extended period of time, they are to be discounted at a rate of 5 per cent per annum.

Because the estimates used in economic evaluations are imprecise, the guidelines require sensitivity analysis. Upper and lower confidence limits of 95 per cent are specified.

Need for modelling

The guidelines allow models to be used to address the limitations of randomised evidence of clinical trials. For example:

- to link surrogate outcomes in trials to final outcomes and to extend the range of outcomes beyond the limits of the available data. In such cases, the trial results may be supplemented with estimates from observational studies, epidemiological data, market research data or expert consensus;
- to extrapolate outcomes beyond the duration of trials and duration of therapy within trials;
- to examine the impact of the likely differences in outcomes observed in clinical trials and those which may occur in clinical practice if the drugs were available through the PBS;
- if the trials were conducted overseas, to modify the resource use patterns to reflect those of Australia more closely; and
- to include any differences in resources used but not measured in trials.

For models, estimates are required of the population for which the drug is aimed, the resources required, the final outcomes of treatment and the time horizon for any follow up treatment.

In presenting the results using models, applicants are requested to supply information for each alternative, each resource use and final outcome (in natural units) and the value of resources used appropriately discounted over time. They are also requested to present the cost per unit of outcome.

If the proposed drug is more expensive but more effective than the alternative treatment, applicants are asked to provide information on how much extra it would cost to achieve the extra units of outcome. Because assumptions are used in modelling, applicants are also requested to provide sensitivity analyses to reflect possible variation in the parameters used.

Financial implications of PBS listing

As listing of a particular drug will result in that drug being subsidised, the PBAC needs to consider the heath benefits and the net costs from the viewpoint of society as a whole. The Commonwealth Government will also need to make provision for the necessary funds for the subsidy. For this purpose, applicants are asked to provide estimates of:

- use of the proposed drug for each of the first two years;
- the extent of substitution for other drugs;

- the financial implications for the PBS, taking into account expected sales, the net subsidy on both the proposed drug and drugs to treat side effects and the reduction in the subsidy of alternative drugs displaced (both for the general copayment and the concessional copayment); and
- the financial implications for government budgets. This includes not only the implications for the PBS but also the costs of treating side effects met by Commonwealth and State Governments through subsidised doctor visits, hospital stays and other health services as wall as the saving made from treating fewer side effects of competing drugs and the reduction of the costs of providing other medical services.

Assessment of costs, benefits and consequences

The guidelines require that the costs, benefits and consequences should be assessed at four levels:

- for the well being of individuals;
- for therapeutic class;
- for health care cost minimisation; and
- the benefit for the wider community.

For the well being of individuals, on the cost side, consideration is given to the dispensing price of the drug if the drug is listed. On the benefit side, the extent of improvement in the well being of the patient taking into account quality of life measures, intermediate outcomes and final outcomes is considered.

For the therapeutic class, on the cost side, consideration is given to the relative costs of the proposed therapy compared to the alternative therapy. On the benefit side, consideration is given to the extra benefit the drug may provide (less any adverse effects) compared to the alternative.

For health care cost minimisation, the costs be the estimates of the subsidies required if the drug was listed and the benefits include the savings which would be made elsewhere in the health care system. These savings may occur as a result of reduced hospitalisation, less home care services, less Medicare resource requirements and less need for other therapies and diagnostic services.

From the perspective of the wider community, the costs include the subsidy if the drug obtains PBS listing; and the benefits would include all those achieved in health care cost minimisation plus those which would arise from reductions in social welfare payments (for example, sickness benefits) and improvements in the well being of the community more generally.

Outcomes not included in economic evaluations

Currently, the indirect costs and benefits of changes in the productive capacity of the community or improvements in the well being of persons currently not employed as a result of using certain therapies or medical treatments are usually excluded from the costs, benefits and consequences in the economic analysis.

In general, sponsors are not encouraged to include changes in productive capacity as an outcome of therapy in submissions to the PBAC. The PBAC, however, will consider evidence of changes in productive capacity case by case. The guidelines suggest that, while drugs may result in improvement in quality of life, it should not be assumed that there is an economic benefit to society through the patient's return to productive capacity.

The reasons given in the guidelines for this are:

- 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.

The guidelines state that, in Australia, the economy is constrained by macroeconomic factors rather than by the lack of healthy workers and productivity estimates give the misleading impression that additional output in the economy will pay for the additional drug consumption.

The guidelines also state that, if there are particularly pressing reasons for considering such indirect benefits in the submission, the following standard economic practice should be adopted:

- present the results both with and without the indirect benefits and costs; and
- when assigning a monetary value to the estimate of potential working time gained or lost in time units, the underlying assumptions which are made must be explicit. For example, the claim that there has been recovery of production lost due to illness is dependent on demonstrating that:
  - the worker returns to work;
  - the worker is productive;
  - the work lost is not made up elsewhere by others in the company or the same worker following a return to work; and
  - no temporary replacement from outside has been employed (namely that there is full employment).

I.3 Industry concerns with the guidelines

There is an ongoing debate between the industry and the administrators (PES, ESC and the PBAC) on the methodology and data requirements specified in the guidelines. The guidelines have undergone several revisions since they were originally drafted in 1990. Each draft has been circulated to industry for comment. Most recently, in July 1995, a draft of the latest guidelines was circulated for industry comment. The Health Economics Subcommittee of the APMA provided detailed comments on this draft (APMA 1995c) and the DHSH responded to their comments (DHSH correspondence 31 October 1995).[1] 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. The following sections outline the APMA's main areas of concern:

- the prescriptive and inflexible nature of the guidelines;
- the theoretical basis of the guidelines;
- the indication(s) used in the submission(s)
- the comparator(s) used in the submission(s);
- the use of expert opinion;
- the modelling of data;
- the presentation and analysis of clinical trial evidence; and
- the nature of the consultation process.

I.3.1 Prescriptive and inflexible nature

Since the cost effectiveness guidelines were introduced, concern has been expressed by the APMA subcommittee at the level of detailed information and analysis required in applications for PBS listing. The APMA suggested that the new guidelines are more onerous and less flexible. It also stated that there has been a change in emphasis in relation to the type of submissions required and the type of evaluations expected. It suggested that the earlier guidelines specified the use of the best available evidence, whereas the revised guidelines specify the type of evidence which is acceptable.

[1] The Health Economics Subcommittee of the APMA established a Technical Review Working Party to comment on the revised PBAC guidelines.

The DHSH argued that the more prescriptive nature of the guidelines 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 submitting less than satisfactory submissions. As a consequence, the DHSH (PES, ESC and the PBAC) in consultation with industry has addressed the areas of the guidelines where there may be some ambiguity in the type of evidence and analysis required.

The DHSH also said that in other parts of the guidelines, for example, the section concerning modelling, the guidelines have become less prescriptive.

I.3.2 Theoretical basis

The main criticism by the APMA subcommittee was the use of randomised clinical trial evidence when it is possible to conduct more appropriate economic analysis using all available information which reflects actual clinical practice. While economic evaluation has been expanded to include the use of models to reflect clinical practice, the requirement for economic evaluation based on randomised trials remains.

In discussions with the representatives of the PES, ESC and the PBAC, the Commission was told that there is no absolute requirement for head to head randomised trials. Where no evidence was available from head to head trials, other forms of evidence will be accepted. The PBAC said that it would not expect companies to carry out head to head trials solely for the purpose of economic evaluation. However, there is still a preference for evidence based on randomised trials to ensure scientific rigour and to minimise bias.

The guidelines do allow for the use of models reflecting clinical practice and the expected response of consumers. This is because it is possible that evidence from randomised trials could provide misleading results because of the way the trials are designed and run. Trials to determine clinical effectiveness normally use placebos, involve adult subjects and use dosage levels which may not apply in actual clinical practice. Drugs, once approved for marketing, could be used over a greater range of patients (including children) and prescribed for a broader range of indications, than applied in the trial. As such, evidence based on randomised trials is unlikely to reflect the market place use of a drug.

I.3.3 Indication(s) to be used in submission(s)

The APMA subcommittee said that the APMA had requested clarification of the use of a main or dominating indication in submissions. It said that the issue of the use of first line data to support second line listing has not been resolved.

The final guidelines have addressed the issue of the main indication by allowing a single submission to suffice where an indication dominates for a general listing. For 'restricted' or 'authority' listings, or where no single indication dominates, the new guidelines require a separate economic analysis for each indication. According to the APMA, this adds to the volume and complexity of submissions.

The DHSH suggested that the APMA's main concern appears to be based on the need to provide evidence from randomised trials for each indication. This has been addressed above.

I.3.4 Comparator(s) to be used in submission(s)

The APMA subcommittee expressed concerns about the choice of a comparator and the uncertainty of its acceptance by the PBAC and stated that the guidelines are too restrictive in this respect. It believed it is unreasonable to impose a comparator which would be unique to Australia and that comparator(s) used internationally should also be acceptable.

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.

Because of costs involved in conducting clinical trials and preparing applications for PBS listing, some participants suggested it was important to select and get agreement early in the process on the most appropriate comparator to be used. This was not always possible. Some participants noted that although the PBAC, the subcommittees and the PES are available for consultation on matters such as the selection of a comparator, the PBAC could provide no guarantee that any one comparator would be accepted in its considerations.

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, on the basis of 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 drugs, another drug could be introduced into the market which could become the relevant comparator.

The PES, ESC and the PBAC stated that although price is a determinant in CEA, it was not the sole determinant in the choice of a comparator. If the drug

and the comparator were equally clinically effective, price would be a determinant in achieving PBS listing. However, if the drug proposed for PBS listing provided significant clinical advantages over the comparator, then the cost effectiveness would be taken into account when recommending PBS listing, even though the requested dispensing price was higher than the dispensing price of the comparator.

I.3.5 Expert opinion

The APMA subcommittee said that in 1994 the APMA sought guidance on the use of expert opinion and argued that the value of expert opinion should be acknowledged. At that time, the APMA questioned the inconsistency in the standards required of the industry and PBAC in relying on expert opinion. The subcommittee acknowledged that although the first issue had been addressed, the description is restrictive and some evaluation criteria are onerous. However, it stated that the issue of inconsistency of standards has not been addressed in the new guidelines.

The DHSH stated that the guidelines provide details of when expert opinion is required. The guidelines suggest that 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.

I.3.6 Modelling of data

The APMA subcommittee suggested that there is some confusion over the use of models. The APMA views the use of modelling to emulate actual clinical practice as an alternative to evidence based on randomised trials. It appears from the guidelines that models are to be used to supplement evidence from randomised trials. The subcommittee is critical of the fact that the data to be included in the model are to be extrapolated from randomised trials rather than to reflect realistic clinical practice.

The PES, ESC and the PBAC stated that there was a preference, to avoid bias, for scientific evidence to support the parameters contained in the modelling rather than estimating what clinical practice might be.

I.3.7 Presentation and analysis of clinical trial evidence

The APMA subcommittee said that during the 1994 workshops, the ESC addressed issues associated with ‘intention to treat’ analysis, measures of

effectiveness and multiple end points. The APMA objected to the amount of data required and the practical relevance of these in the decision making process.

I.3.8 Consultation process

The APMA subcommittee was critical of the consultation process. It argued that revision of the guidelines after the first period of their mandatory use should have been undertaken with the intent of examining their validity and practicality.

The subcommittee stated that the revision was conducted internally by the DHSH and the ESC with little regard to the industry's contribution. It also expressed concern that insufficient time was given for the preparation of a response to the draft guidelines and about input of economists on the ESC to the process. Its concerns are that principal issues were not addressed.

The DHSH provided details to the Commission of the consultation process in developing the guidelines and the reasoning behind any action or inaction on the APMA comments on the guidelines. The DHSH, through the PES, ESC and the PBAC, appears to have actively sought industry input.

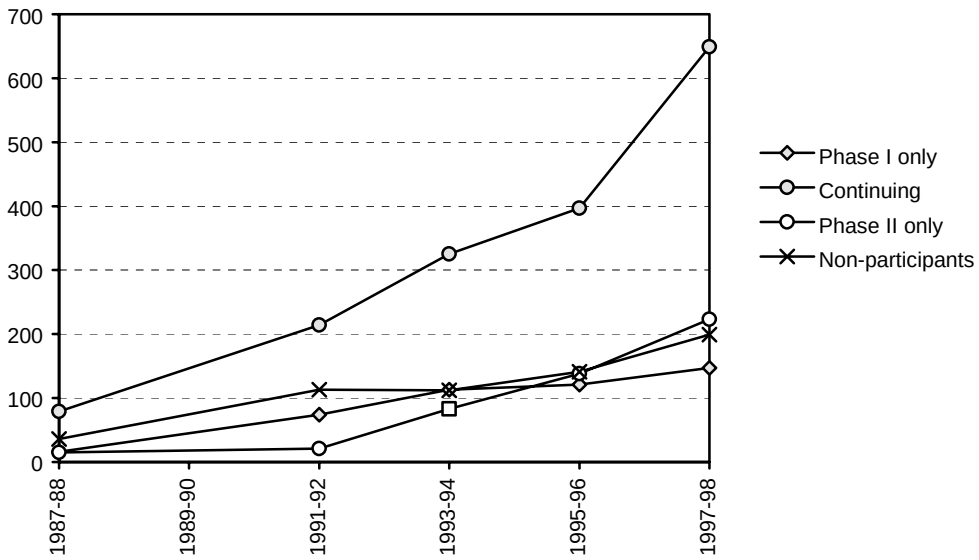
J RELATIVE PERFORMANCE OF FACTOR F PARTICIPANTS AND NON-PARTICIPANTS

This Appendix contains further information to that in Chapter 11 on the relative performance of Factor f and non-participants. It is based on information provided to the Commission by the Australian Pharmaceutical Manufacturers Association.

J.1 Exports

Exports by Factor f companies have all grown faster than non-participants. The group predicting the largest increase over the decade are Phase II only firms, which expect their 1997–98 exports to be more than 14 times the size of their 1987–88 exports. Non-participants expect exports to increase by more than three times over the decade. Historic performance and projections are shown in Figure J.1.

Figure J.1: Total human use exports, 1987–88 to 1997–98, $ million

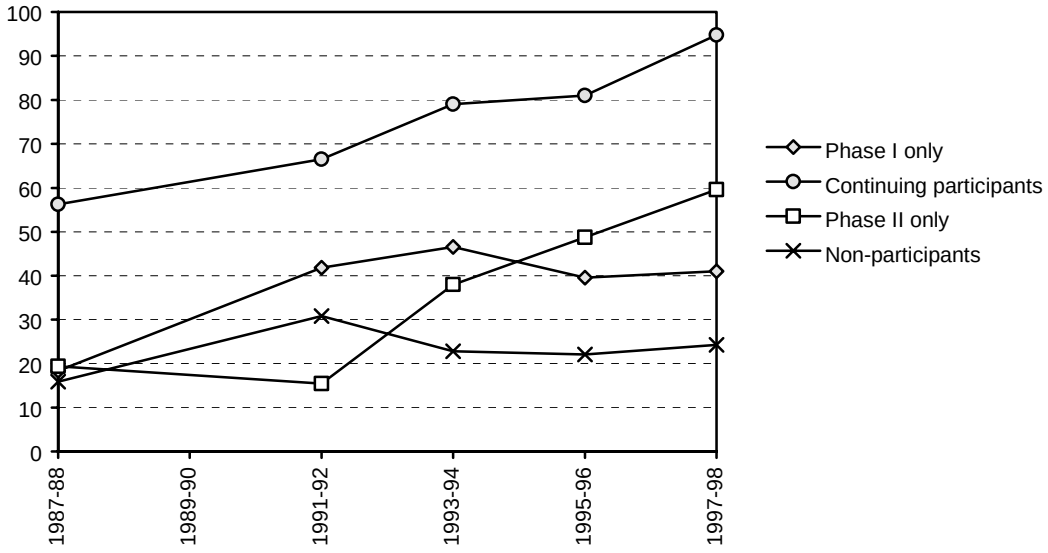


Source: APMA sub. 119, Attachment 1, Appendix A, p. i

Export/import ratios also differentiate Factor f companies significantly from non-participants. Continuing participants expect to achieve a 95 per cent export/import ratio at the end of the decade, compared with a 24 per cent ratio

for non-participants. Even for Phase I only participants, the export/import ratio is expected to be 41 per cent by the end of the decade (see Figure J.2).

Figure J.2: Export/import ratios 1987–88 to 1997–98, per cent



Source: APMA sub. 119, Attachment 1, Appendix A, p. i.

J.2 Value added

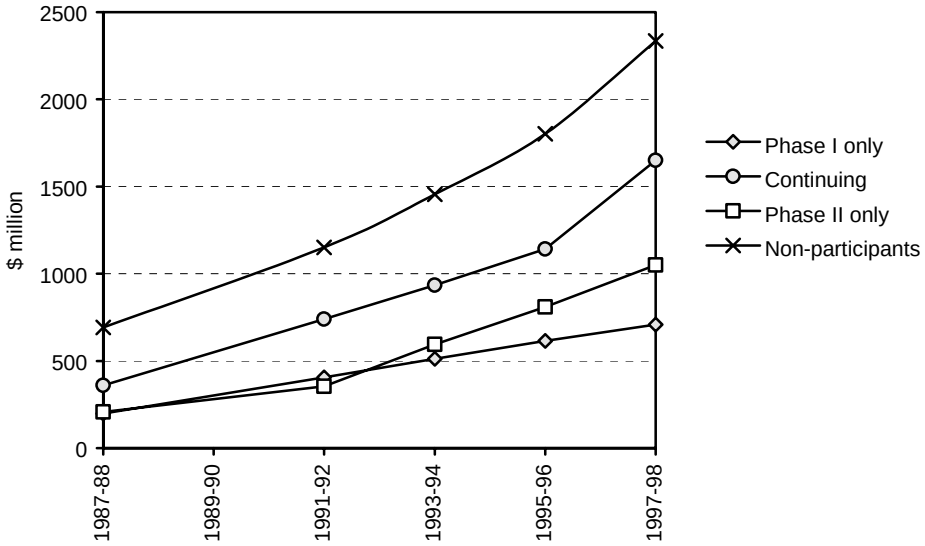
All groups of companies are increasing their value added in Australia. While Factor f companies appear to be growing faster than non-Factor f companies, the difference is not large. Phase I only participants' growth has not been as great as continuing and Phase II only participants' growth, or as strong as non-participants' growth (see Figure J.3).

J.3 Manufactured output

Regarding manufactured output, Factor f companies have grown less quickly than non-Factor f companies from the years 1991–92 to 1993–94.[1] Over this period non-participants increased their manufacturing output by 188 per cent, while Factor f firms increased their manufacturing output by 147 per cent (see Figure J.4).

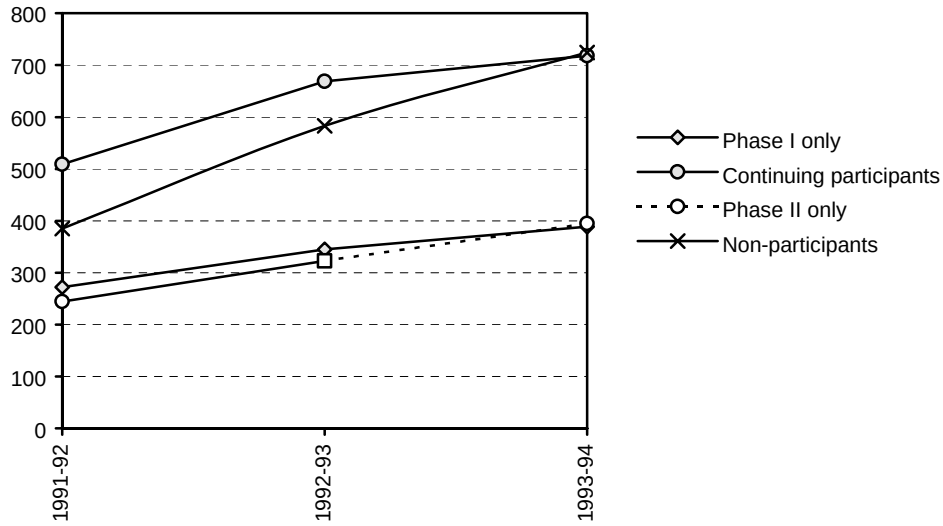
[1] This time period corresponds to that in the data provided by the APMA.

Figure J.3: Pharmaceutical value added, total human use (turnover minus imports), 1987–88 to 1997–98, $ million



Source: APMA sub. 119, Attachment 1, Appendix A, p. ii

Figure J.4: Pharmaceutical manufactured output 1991–92 to 1993–94, $ million

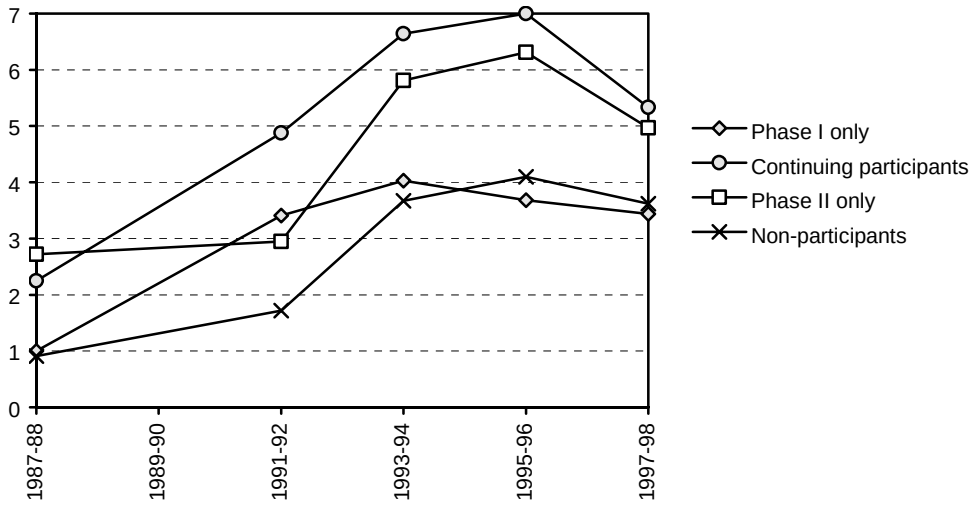


Source: APMA sub. 119, Attachment 1, Appendix A, p. ii

J.4 Research and development

Regarding research and development (R&D), non-Factor f companies 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-Factor f firms 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 J.5).

Figure J.5: R&D/turnover ratio, per cent



Source: APMA sub. 119, Attachment 1, p. 5

All Factor f Phase II participants (including continuing participants) expect to have higher R&D to turnover ratios than non-Factor f companies at the end of the decade. The highest ratio is predicted for continuing participants, which expect a ratio of 7 per cent in 1995–96 falling to 5 per cent in 1997–98, compared to a ratio of about 4 per cent for non-participants over this period. All categories of companies expect a decline in their R&D/turnover ratios from 1995–96 to 1997–98. The Australian Pharmaceutical Manufacturers Association (APMA) suggests that any such decline may be explained by strong growth in turnover (primarily exports) compared with a lower rate of growth in R&D. The APMA also argues that the projections might reflect uncertainty regarding the future of government policy relating to the industry and difficulties in predicting future technological developments and associated R&D that arise from such developments (sub. 119, Attachment 1, p. 5). In 1993–94,

all company categories met the Factor f hurdle of 3 per cent of turnover devoted to R&D.

Factor f companies tend to do different types of R&D in Australia to other companies. They undertake more than six times the amount of basic and preclinical research of non-Factor f companies.

Of the non-participating firms, four of the companies which applied but were unsuccessful in obtaining Factor f funding account for between 20 per cent and 30 per cent of the R&D carried out by non-participants. The APMA claim that this R&D was largely set in train in anticipation of Factor f funding. One of these companies has a strong R&D base for over-the-counter products.

K RECALCULATION OF BIE RESULTS UNDER DIFFERENT ASSUMPTIONS

The BIE undertook a study to help the Commission to evaluate the effectiveness and efficiency of the Factor f scheme. Part of that study was to calculate the benefits required to meet its costs. This Appendix contains further information to that in Chapter 11 about the Commission's recalculations of the BIE results under different assumptions.

K.1 Changing the assumptions

K.1.1 Commission recalculations

The Commission recalculated the Bureau of Industry Economics (BIE) break even points (benefits required per dollar of induced activity for the scheme to break even in a welfare sense) with different assumptions to determine their sensitivity to changes in the model's underlying assumptions.

First, the Commission changed the marginal excess burden of taxation to 33 per cent, the level assumed in previous IC (Industry Commission) work (the BIE used 20 per cent).[1] Since this increases the social cost of raising funds, the 'gap' which needs to be filled by benefits in order for the scheme to be welfare enhancing becomes larger.

The benefits required per dollar of induced activity for break even with the BIE and an alternative IC marginal excess burden of taxation assumptions are shown for export value added (EVA), domestic value added (DVA) and research and development (R&D) in Table K.1.

[1] See IC 1995b

Table K.1: Benefits per dollar of induced activity required for break even, new assumption for the marginal excess burden of taxation

	Export value added	*Domestic value added*	*R&D*
BIE assumption—20% MEB[a]			
Foreign participants	0.27	0.20	0.22
Australian participants	0.05	0.04	0.04
All participants	0.22	0.17	0.11
IC assumption—33% MEB[a]			
Foreign participants	0.30	0.22	0.25
Australian participants	0.09	0.07	0.07
All participants	0.25	0.20	0.14

a MEB—marginal excess burden of taxation.
Source: BIE correspondence 3 April 1996

Second, it was assumed that 100 per cent of payments to foreign companies for non-induced activity leaked overseas, compared to the BIE's 50 per cent. This also increased the gaps on exports for foreign participants. The results are described in Table K.2.

Table K.2: Benefits required per dollar of induced activity for break even, new assumption for the leakage rate for non-induced activity

	Export value added	*Domestic value added*	*R&D*
BIE assumption—50% leakage for non-induced activity for foreign participants	0.27	0.20	0.22
IC assumption—100% leakage on non-induced activity for foreign participants	0.31	0.21	0.26

Source: BIE correspondence 3 April 1996

Third, a lower rate of leakage (50 per cent) on induced foreign activity was assumed (the BIE used a 100 per cent rate). This significantly reduces the break even figures for foreign participants, as described in Table K.3.

Table K.3: Benefits required for per dollar of induced activity for break even, new assumption for the leakage rate for induced activity

	Export value added	*Domestic value added*	*R&D*
BIE assumption—100% leakage rate for induced activity for foreign participants	0.27	0.20	0.22
IC assumption—50% leakage rate for induced activity for foreign participants	0.18	0.16	0.19

Source: BIE correspondence 3 April 1996

Fourth, a 70 per cent inducement rate for DVA was assumed (the BIE used 90 per cent). This increased the benefits required for foreign participants for DVA. Similar results would be obtained by reducing the inducement rate for all activities. The results are shown in Table K.4.

Table K.4: Benefits required per dollar of induced activity for break even, new assumption for the inducement rate for domestic value added

	Domestic value added
BIE assumption—90% inducement rate for DVA for foreign participants	0.20
IC assumption—70% inducement rate for DVA for foreign participants	0.24

Source: BIE correspondence 3 April 1996

Fifth, the combined effect of these different assumptions was calculated. The results were similar to the BIE's original estimates, with DVA and R&D break even points being marginally higher, as shown in Table K.5.

Table K.5: Benefits required per dollar of induced activity for break even, combined new assumptions

	Export value added	*Domestic value added*	*R&D*
BIE assumptions—20% MEB[a], 50% leakage on non-induced activity, 100% leakage on induced activity, 90% inducement rate for DVA			
Foreign participants	0.27	0.20	0.22
Australian participants	0.05	0.04	0.04
All participants	0.22	0.17	0.11
IC assumptions—33% MEB[a], 100% leakage on non-induced activity, 50% leakage on induced activity, 70% inducement rate for DVA			
Foreign participants	0.25	0.22	0.22
Australian participants	0.08	0.08	0.07
All participants	0.22	0.20	0.13

a MEB—marginal excess burden of taxation.
Source: BIE correspondence 3 April 1996

Further recalculations included:

- benefits required per Factor f dollar spent to break even, rather than as per dollar of induced activity. This is an alternative way of presenting the issue. The results are presented in Table K.6;
- lower leakage rates for foreign induced activity of 10 per cent and 20 per cent (the BIE used a 100 per cent rate for induced activity and a 50 per cent rate for non-induced activity). A lower rate of leakage reduces the social costs (and hence the break even point). The results are shown in Table K.6;
- the use of a variety of inducement rates:
  - First, a high inducement rate of 90 per cent for both foreign and domestic firms for all activities was used. The BIE assumed a 90 per cent inducement rate for all new participants, but lower rates for continuing participants, reflecting the fact that Phase II base year arrangements rewarded companies for continuing activity levels that were established in Phase I. This reduces the social costs for foreign companies (and the average for all participants). It does not reduce the social cost for domestic companies, since this is a transfer regardless of whether the activity is induced or not.

Table K.6: Benefits required per Factor f dollar spent, various new assumptions

	Foreign firms			*Domestic firms*			*All participants*		
	EVA	*DVA*	*R&D*	*EVA*	*DVA*	*R&D*	*EVA*	*DVA*	*R&D*
BIE assumptions	0.73	0.81	0.70	0.14	0.14	0.14	0.59	0.67	0.35
IC assumptions									
MEB[a] =33%	0.82	0.90	0.80	0.23	0.23	0.23	0.68	0.76	0.45
100% leakage for foreign non-induced activity	0.84	0.84	0.84	0.14	0.14	0.14	0.67	0.70	0.41
50% leakage foreign induced activity	0.49	0.65	0.60	0.14	0.14	0.14	0.41	0.55	0.31
70% DVA inducement rate	0.73	0.74	0.70	0.14	0.14	0.14	0.59	0.62	0.35
Combination of changed assumptions	0.69	0.69	0.72	0.23	0.23	0.23	0.58	0.60	0.42
Combination + 10% leakage on foreign induced activity	0.50	0.49	0.55	0.23	0.23	0.23	0.44	0.44	0.35
Combination + 20% leakage on foreign induced activity	0.55	0.54	0.59	0.23	0.23	0.23	0.47	0.48	0.37
Combination + 20% leakage on foreign induced activity + 90% inducement rate	0.43	0.43	0.43	0.23	0.23	0.23	0.38	0.39	0.31
Combination + 20% leakage for foreign induced activity + 50% inducement rate	0.65	0.65	0.65	0.23	0.23	0.23	0.55	0.57	0.39
Combination + 20% leakage for foreign induced activity + 50% inducement rate for R&D, 90% inducement rate for EVA and 60% inducement rate for DVA	0.43	0.60	0.65	0.23	0.23	0.23	0.38	0.52	0.39

a MEB—marginal excess burden of taxation.

Source: BIE correspondence 3 April 1996

– Second, at the other extreme, 50 per cent inducement for all activities and all firms was used. This had the opposite effect.

– Third, 50 per cent inducement was used for R&D (since the trends for non-participants seem to be closer to Factor f companies than they do for manufacturing (see Chapter 11 and Appendix J)), 90 per cent inducement was used for EVA (since non-participants do not appear to be heavily export oriented) and 60 per cent inducement was used for DVA (since non-participants' manufacturing activity had not declined, it could be expected that participants would have maintained at least half of their domestic activity). The results are in the final row of Table K.6.

K.1.2 Astra recalculations

Astra also recalculated the BIE's results under different assumptions.

Astra firstly changed:

- the tax clawback rate to the full 36 per cent tax rate;
- the cost of foreign companies' subsidy by assuming that there was no leakage overseas; and
- the inducement rate for all activities for foreign companies to 90 per cent .

These changed assumptions resulted in smaller benefits required for break even than estimated by the BIE. The final results for foreign companies and the total program are shown in Table K.7.

Astra then recalculated the benefits required to break even assuming the same inducement rates as the BIE. The benefits required were still smaller than those of the BIE, but not as small as for their first set of assumptions. The results are presented in Table K.8.

K.2 Changing the subsidy rates

The Commission also recalculated the model using different subsidy rates—20 per cent, 15 per cent, 12 per cent, 10 per cent and 5 per cent payment rates were assumed. The same inducement rates and activity levels were assumed for all calculations.

Table K.7: Benefits required per dollar of induced activity for break even, Astra's first set of assumptions

	Export value added	*Domestic value added*	*R&D*
BIE assumptions—30% tax clawback rate, 50% leakage on non-induced activity, 100% leakage on induced activity, 90% inducement rate for DVA, 68% inducement rate for EVA and 61% for R&D (foreign companies).			
Foreign participants	0.27	0.20	0.22
All participants	0.22	0.17	0.11
Astra assumptions—tax clawback rate 36%, 0% leakage on foreign induced and non-induced activity, 90% inducement rate for all activities.			
Foreign participants	0.12	0.11	0.09
All participants	0.11	0.10	0.06

Sources: Astra sub. 141, Appendix A; BIE correspondence 3 April 1996

Table K.8: Benefits required per dollar of induced activity, Astra's second set of assumptions

	Export value added	*Domestic value added*	*R&D*
BIE assumptions—30% tax clawback rate, 50% leakage on non-induced activity, 100% leakage on induced activity, 90% inducement rate for DVA, 68% inducement rate for EVA and 61% for R&D (foreign companies).			
Foreign participants	0.27	0.20	0.22
All participants	0.22	0.17	0.11
Astra assumptions—tax clawback rate 36%, 0% leakage on foreign induced and non-induced activity.			
Foreign participants	0.16	0.11	0.14
All participants	0.14	0.10	0.08

Sources: Astra sub. 141, Appendix A; BIE correspondence 3 April 1996.

The other assumptions were:

- 100 per cent leakage on non-induced activity;
- 50 per cent leakage on induced activity;
- 33 per cent marginal excess burden of taxation; and
- the same inducement rates as the original BIE calculations, except for DVA, where a 70 per cent inducement rate was used.

The results show that reducing the payment rates significantly reduces the benefits required for break even proportionately, that is, if the payment rate is halved, the benefits required are roughly halved. The results for export value added (EVA), DVA and R&D are presented in Table K.9.

Table K.9: Benefits required per dollar of induced activity for break even, different payment rates

	Export value added	*Domestic value added*	*R&D*
Payment rate of 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
Payment rate of 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
Payment rate of 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
Payment rate of 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
Payment rate of 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

L ECONOMY-WIDE EFFECTS OF FACTOR F

The Factor f scheme is designed to encourage production and research and development in Australia by the pharmaceutical industry. In this Appendix, the MONASH model is used to illustrate the impact of Phase II of the scheme on the economy.

There is a lot of uncertainty about the industry's response to the Factor f scheme. If the industry is characterised as very exposed to foreign competition, modelling suggests that the Factor f scheme is associated with a large increase in the Australian production of pharmaceuticals. If it is characterised as reacting in accordance with the commitments firms made under the scheme, the increase is smaller. In either case, modelling results indicate that the impact of Factor f on the rest of the economy is small.

L.1 Introduction

The Factor f scheme is designed to encourage activity in the pharmaceutical industry. This activity does not occur in isolation from the rest of the economy, nor from those parts of the pharmaceutical industry not covered by the scheme. Industries upstream and downstream of the pharmaceutical industry may be stimulated, but payments to participants need to be funded and increased demand by the pharmaceutical industry for resources may adversely affect other sectors of the economy.

The aim of this Appendix is to illustrate the industry effects and estimate the 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 (see Box L.1). The model can be used for forecasting or for policy analysis. The latter, which is used in this Appendix, involves using MONASH to provide annual forecasts of the economy with and without a policy change. The comparison of the base

Box L.1: The MONASH model

MONASH is an applied general equilibrium model of the Australian economy, the latest in a succession of models based on the work of Dixon *et al* (1982). Several features of MONASH distinguish it from its predecessor, the ORANI model (Adams, Dixon & McDonald 1994).

- MONASH is a multi-period model. Periods are linked via equations explaining capital accumulation.
- The input–output core of the MONASH model has been updated to 1991–92 on the basis of detailed work on input–output data (Dixon & McDonald 1993a & 1993b).
- MONASH can incorporate forecasts on various aspects of the economy and indeed contains a standardised set of macroeconomic and other forecasts. These are used by the model to provide annual forecasts at a disaggregated level.

A major advantage of the MONASH model's dynamic structure is its ability to handle timing issues in regard to policy experiments. For instance, in this Inquiry the model explicitly takes account of the time profile of additional activity and payments under the Factor f scheme. This is not possible in comparative static models.

The standard inputs to MONASH forecasts are drawn from a variety of sources:

- macroeconomic forecasts from Syntec Economic Services;
- forecasts of tariff movements from the Industry Commission;
- forecasts for traditional exports from the Australian Bureau of Agricultural and Resource Economics and for tourism exports from the Bureau of Tourism Research; and
- forecasts of changes in technology and tastes based on trends estimated by the Centre of Policy Studies/Impact Project.

In translating from theory to practice, the model incorporates a number of assumptions in relation to the functioning of markets, consumer behaviour and the technology underlying production, in particular:

- perfectly competitive markets;
- utility maximisation by a representative household; and
- constant returns to scale in production.

case with an alternative scenario (with the policy change) provides an estimate of the effect of the policy change.[1]

The policy analysed is Phase II of the Factor f scheme. Because the response of firms to this scheme is uncertain, two different scenarios based on different responses are explored. These scenarios depend on different views of the world in which the Factor f scheme is being implemented. Scenario A incorporates results from a recent Bureau of Industry Economics (BIE 1995) report on the effect of Factor f. In scenario B, the industry is modelled to be very sensitive to foreign competition and the Factor f scheme.

In the context of this Inquiry, the base case includes Factor f Phase II while the alternative scenarios exclude it. That is, the alternative scenarios estimate what the economy would be like if Phase II had not been implemented. Estimates of the economy-wide effects of Phase II are obtained by comparing the MONASH base case forecasts of the economy (which includes Phase II) with those for the economy without Phase II.

To facilitate the modelling, the MONASH database has been modified to provide a more detailed representation of the pharmaceutical industry. The characterisation of the industry used in this process is described in the following section.

L.2 The pharmaceutical industry

The Australian pharmaceutical industry is involved in a number of activities. These may be divided into:

- the production of ethicals (prescription products);
- the production of over-the-counter (OTC) drugs; and
- research and development (R&D).

For the most part, these activities in Australia may be regarded as facing strong international competition.[2] A multinational enterprise's decision to locate production or R&D activity in a particular country depends significantly on the local costs of conducting that activity relative to those associated with costs in other countries. Also, the production of some drugs by local firms faces

[1] This Appendix is largely based on work described in Adams, Malakellis and Parmenter (1995) and Adams and Cole (1994). Both reports are available on request from the Commission.

[2] The main exception is the production of specialised pharmaceuticals for the Australian market (for example snake bite anti-venoms).

competition from imports and an Australian company may always transfer production or R&D overseas. Therefore, the production of pharmaceuticals in Australia faces significant competition in both domestic and export markets.

The production of ethicals and OTCs in Australia predominantly involves the formulation, manufacture and final packaging stages of pharmaceutical production (APMA 1995a). These stages of the production of pharmaceuticals are assumed to have relatively constant marginal costs. This is in contrast to the production of active ingredients (by and large not occurring in Australia) which probably involves variable returns to scale.

The output of the R&D activity in Australia may be viewed as technical reports on the properties of various chemical substances. In addition to providing knowledge to the pharmaceutical industry, R&D is claimed to have spillover effects on the rest of the economy.[3] Such effects are assumed to improve the productivity of other industries. These possible effects are not taken into account in this study.

R&D, which accounts for 5 per cent of the value of the Australian pharmaceutical industry's output, is also represented as an export-only activity. The reason for this is that current expenditure on R&D is not an input into current production. It should not, therefore, be represented as an intermediate input to the current production of ethicals and non-ethicals. If it were, then any increase in the Australian production of pharmaceuticals would necessarily involve an increase in R&D. Representing R&D as an export-only activity reflects the view that (except as required by the Factor f scheme) there need be no link between the scale of current Australian production and the scale of current R&D expenditure.[4]

A snapshot of the structure of the pharmaceutical sector is provided in Table L.1 for the year 1991–92. The cost and sales structures depicted were estimated using the MONASH database, a variety of published and unpublished Australian Bureau of Statistics' data (ABS 1994a and 1994b) and the

[3] Further discussion of such spillover effects or externalities is provided in Chapter 11 and BIE (1995).

[4] Current expenditure on R&D may also be regarded as an investment linked to future production. However, the exact nature of this link is uncertain. This is because the time to fruition and the eventual product of R&D are often uncertain. Further, a significant amount of R&D undertaken in Australia may be commercialised overseas. This makes treating R&D as an investment particularly difficult. Treating R&D as an export only activity, with no link to current or future Australian production, overcomes these problems, and does so in a way which emphasises the competition between countries to undertake pharmaceutical R&D.

Department of Industry Science and Technology survey of the Australian pharmaceutical industry (DIST 1995b).

Table L.1: Cost and sales shares for the Australian human-use pharmaceutical industry 1991–92, per cent

	OTC pharmaceuticals	*Ethical pharmaceuticals*	*Human-use pharmaceutical R&D*
Cost shares			
Purchased inputs			
intra-industry	38	35	0
inter-industry	33	32	58
Labour	16	15	31
Capital	13	18	11
Total	**100**	**100**	**100**
Distribution of production (ex-factory values)			
Purchased by industry			
intra-industry	21	19	0
inter-industry[a]	33	4	0
Private consumption	38	51	0
Exports	8	16	100
Total	**100**	**100**	**100**
Share of product in total production of the pharmaceutical sector [b]	18	77	5
Share of imports in local market	30	31	0

a Inter-industry sales largely represent sales to the health industry.
b Row adds up to 100 per cent.
Source: Adapted from the MONASH database

As mentioned above, each pharmaceutical activity is viewed as very exposed to international competition. In particular, world demand for Australian exports of ethicals, non-ethicals and R&D is assumed to be very price sensitive and imports of ethicals and non-ethicals are assumed to be close to perfect substitutes for domestic products. These characteristics generally imply that an industry will be geographically mobile. Small changes in production costs (and subsidies) may induce large changes in the Australian industry in the long run.

In the short run, however, it is assumed that, once installed, capital is sunk and the industry continues to produce until the plant is depreciated and closed.[5]

In light of this characterisation (which corresponds to scenario B) of the pharmaceutical industry, Phase II of the Factor f scheme may be expected to have a significant impact on activity levels in the industry.

L.3 Phase II of the Factor f scheme[6]

In Phase II of the Factor f scheme, participants receive payments at a maximum rate of 25 per cent for additional value adding (local content) on PBS-type pharmaceuticals destined for domestic or export markets and for additional R&D directed towards pharmaceuticals, relative to a base year.[7] The expected time profile of Factor f payments and commitments is presented in Figure L.1.

To put Figure L.1 into perspective, the Australian Pharmaceutical Manufacturers Association survey (APMA 1995a) reports production value added (PVA)[8] for the Australian pharmaceutical industry of $2022 million in 1993–94, and this is forecast to grow to $3381 million by 1997–98.[9] Industry expenditure on R&D (on own behalf) is reported at $135 million in 1993–94,

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5 The MONASH model explicitly recognises the supply-side constraints that exist in the Australian economy. This represents a key difference between the results of MONASH simulations and multiplier analysis with input–output models. This is because multiplier calculations generally recognise few if any supply-side constraints, assuming that the economy has large (or even infinite) slack capacities of capital and labour which allow firms to respond to increased demand.

6 This section is largely based on recent work by the BIE (1995), APMA (1995b) and unpublished data.

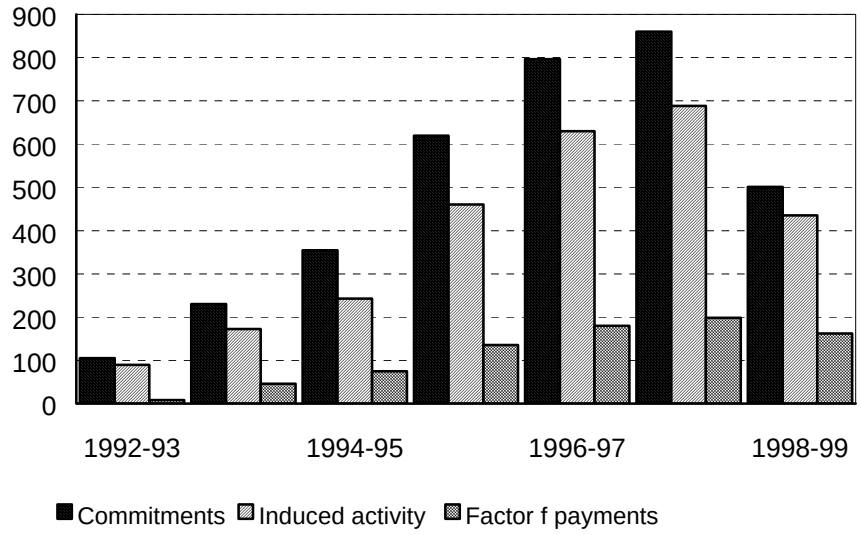
7 As PBS-type pharmaceuticals include both ethicals and non-ethicals, Factor f affects each of the three activities identified above. There are, however, relatively few non-ethicals listed on the PBS (although significant examples include paracetamol, ventolin and insulin). For modelling purposes, it is assumed that Factor f applies only to the ethical and R&D activities.

8 The concept of PVA differs from the standard economic concept of value added which is used in the MONASH model. PVA is defined by the APMA (1995a) as turnover less imports. It is also the sum of 'domestic value added' (DVA) and 'export value added' (EVA). These concepts are used in the Factor f pricing guidelines (PBPA 1992). They are different to the standard definition of value added which is defined as returns to primary inputs (land, labour and capital). However, PVA may be a reasonable approximation of value added *if* the main purchased input in the production process is imported active ingredients.

9 The APMA survey covers approximately 90 per cent of the pharmaceutical industry's turnover (APMA 1995a).

and is expected to increase to $191 million in 1997–98 (APMA 1995a, Appendix C, p. 5).[10] Added together, R&D and PVA total $2157 million in 1993–94 and are forecast to total $3572 million in 1997–98.

Figure L.1: Factor f Phase II commitments, induced activity and payments, 1992–93 to 1998–99, $ million [a,b]



a The figures for Factor f commitments are adjusted to conform to a standard financial year and are calculated as the sum of the commitments for domestic value added, export value added and R&D.

b The method for calculating induced activity is described in BIE 1995.

Source: BIE unpublished data

PVA and R&D commitments represent 10 per cent of total PVA and R&D for 1993–94 and 24 per cent of the total for 1997–98. By comparison, the Factor f payments for these years represent respectively 3 per cent and 6 per cent of total PVA and R&D. Over the life of Phase II, R&D accounts for approximately 10 per cent of total commitments (BIE 1995).

Commitments by pharmaceutical firms under the Factor f scheme therefore account for a significant amount of activity in the pharmaceutical sector. However, as reported by the BIE (1995), not all the commitments to additional activity can be attributed to the Factor f scheme.[11] The BIE estimated that

[10] These figures account only for the R&D undertaken 'on own behalf', which is the concept relevant for Factor f payments.

[11] In fact, it is possible to argue that at least some of the levels of production claimed to be induced by the Factor f program would have occurred even without the incentives offered by the program. Such an argument would assume that firms' reports of commitments

between 10 per cent and 40 per cent of this additional activity would have occurred without Factor f funding. The remainder, which represents the estimated amount of activity induced by the scheme, is interpreted as a lower bound for the impact of Factor f on activity in the pharmaceutical industry. This estimation of the level of induced activity forms the basis for scenario A. The level of commitments, and hence the estimated level of induced activity, rises steadily in the first few years (as firms install more capacity) and then drops markedly in the final year (see Figure L.1). This time profile is explicitly accounted for in the modelling.

In addition to its effect on activity levels, Factor f may affect the input mix of pharmaceutical producers. That is, payments for PVA may bias the production process towards the use of Australian inputs. However, active ingredients are a large component of imported inputs into production (representing 47 per cent of all pharmaceutical imports by value—inputs and finished products—in 1993–94 (APMA 1995a)) and there is probably little scope for switching to the production of active ingredients in Australia. In addition, as most production in Australia already involves the stages in the production chain from formulation through to final packaging, the scope for expanding activity in one of these stages over and above the others may also be limited. The Factor f scheme is therefore assumed not to affect the way in which production is carried out. Rather it is assumed only to affect the level of production.

L.4 Results

The response to the Factor f scheme by the pharmaceutical industry is uncertain. The scheme could be responsible for promoting a significant proportion of current activity, or a relatively small increase in activity. The MONASH model was used to project activity in the Australian economy at an aggregate and industry-specific level. In neither of the alternative scenarios is the model used to estimate the response of the industry to Factor f. Rather, it is used to estimate the effects that different assumed impacts of Factor f on the pharmaceutical industry would have on the rest of the economy. Thus, a base case and two scenarios for the period 1992–93 to 1998–99 are considered.

- In the base case, the economy is projected with Phase II of the Factor f scheme in place.

reflect strategic behaviour in trying to portray themselves as requiring Factor f payments to expand their production levels.

- In scenario A, the economy is projected assuming that Phase II had not been implemented. The direct effect of this on activity in the pharmaceutical industry is *assumed* to be limited to the amount of induced activity under Factor f estimated by BIE (1995).
- In scenario B, like scenario A, the economy is projected without Phase II. However, in this scenario the existence of the ethical and R&D activities in the long run are *assumed* to be dependent on Factor f payments. In the context of strong international competition, removing Factor f will then force these activities to decline in Australia. The results of this scenario represent an upper bound on the industry and economy-wide effects of Factor f.

Model projections are presented in Table L.2 for macroeconomic variables and Table L.3 for broad industry groups and disaggregated pharmaceutical industry groups. Column 1 refers to the base case, and columns 2 and 4 to scenarios A and B respectively. Results are expressed as average annual growth rates over the period 1992–93 to 1998–99. The third and fifth columns show the difference between the base case and scenarios A and B. These are interpreted as the contribution of Factor f to the industry and economy-wide effects.

L.4.1 Base case

The base case projections incorporate forecasts from a range of sources for the movement of key economic variables over the period (see Box L.1). Also included is the assumed effect of Factor f on activity in the pharmaceutical industry.

The economy is projected to grow at about 3 per cent annually over the period, with moderate growth in wages and employment (between 1 per cent and 2 per cent annually). Trade is projected to grow between 8 per cent and 9 per cent annually. Different components of exports are projected to grow at quite different rates; agricultural and mining exports are projected to grow much less rapidly—at about 4 per cent per year—than exports of other Australian products, which are projected to grow at average annual rates exceeding 10 per cent.

In the base case, activity in the pharmaceutical R&D industry was modelled to grow at an average annual rate of 16 per cent in real terms, and the production of ethicals was modelled to grow by 9 per cent annually while Factor f Phase II was assumed to be in force.

Table L.2: Projections for macroeconomic variables, 1992–93 to 1998–99, average annual growth rates, per cent

	Base case	*Scenario A*		*Scenario B*	
	Proj. (1)	*Proj. (2)*	*Difference (3)* [a]	*Proj. (4)*	*Difference (5)* [a]
National expenditure					
Real aggregate consumption	3.02	3.02	..	3.01	0.01
Real aggregate investment	4.20	4.21	-0.01	4.20	..
Real aggregate government spending	2.77	2.77	..	2.77	..
Real GDP	3.21	3.20	..	3.20	0.01
Trade aggregates					
Aggregate export volumes	8.25	8.25	-0.01	8.29	-0.05
Aggregate import volumes	8.87	8.88	-0.02	8.91	-0.05
Terms of trade	0.37	0.37	..	0.35	0.02
Export volumes - traditional[b]	4.32	4.39	-0.07	4.55	-0.23
Export volumes - pharmaceuticals	15.78	12.61	3.17	-11.19	26.97
Export volumes - tourism	11.85	11.91	-0.06	12.13	-0.27
Export volumes - other	11.80	11.80	..	11.94	-0.14
Primary inputs					
Real wage rate (cost)	1.50	1.49	..	1.47	0.03
Aggregate employment	1.72	1.72	..	1.72	..
Aggregate capital stock	3.92	3.92	0.01	3.91	0.01

a (3)=(1)–(2), (5)=(1)–(4).
b Agriculture, mining and selected manufacturing.
.. between -0.005 and 0.005 per cent
Source: MONASH simulations

Table L.3: Projections for domestic production by aggregated industry group, 1992–93 to 1998–99, average annual growth rates

Industry	*Base case*	*Scenario A*		*Scenario B*	
	Proj. (1)	*Proj. (2)*	*Difference (3)*[a]	*Proj. (4)*	*Difference (5)*[a]
1 Agriculture, forestry and fishing	2.64	2.66	-0.02	2.73	-0.09
2 Mining	5.14	5.19	-0.04	5.29	-0.14
3 Food, beverages and tobacco	2.60	2.63	-0.02	2.70	-0.09
4 Textiles, clothing and footwear	-0.31	-0.31	-0.01	-0.28	-0.03
5 Wood, wood products & furniture	3.39	3.39	...	3.41	-0.02
6 Paper, paper products & printing	4.67	4.66	0.01	4.65	0.02
Commercial printing	6.05	6.04	0.01	6.02	0.04
7 Chemicals (excl. pharm. etc)	3.57	3.57	...	3.60	-0.03
8 Pharm. products and pesticides	8.07	5.89	2.18	-1.79	9.86
OTC pharm.	3.15	3.15	...	3.17	-0.02
Ethical pharm.	9.42	6.60 [b]	2.81	-6.95 [b]	16.37
Human-use pharm. R&D	16.00	12.62 [b]	3.37	-2.02 [b]	18.01
9 Non-metallic construction mat.	1.76	1.76	...	1.75	0.01
Glass products	2.68	2.65	0.03	2.60	0.08
10 Basic metal products	2.98	3.00	-0.02	3.05	-0.07
11 Cars and other transport equip.	2.50	2.51	-0.01	2.57	-0.07
12 Electronic, & specialist equip.	4.71	4.72	-0.01	4.75	-0.04
13 Leather, rubber, plastic etc.	1.99	1.98	0.01	1.97	0.03
Plastic products	1.85	1.82	0.03	1.76	0.09
14 Electricity, gas and water	3.04	3.04	...	3.05	-0.01
15 Construction	2.37	2.38	-0.01	2.37	..
16 Wholesale and retail trade	4.50	4.49	0.01	4.47	0.04
17 Transport and storage	3.04	3.06	-0.01	3.09	-0.04
18 Communications	6.77	6.77	...	6.76	0.01
19 Finance, property & bus. serv.	4.12	4.12	...	4.12	0.01
20 Dwelling ownership and rental	2.21	2.21	...	2.21	...
21 Public admin. and defence	2.47	2.47	...	2.47	...
22 Health, education and welfare	2.84	2.84	...	2.84	...
23 Hospitality, leisure etc.	3.77	3.77	-0.01	3.80	-0.03

a (3)=(1)–(2), (5)=(1)–(4)
b exogenous
.. between -0.005 and 0.005 per cent
Source: MONASH simulations

L.4.2 Alternative scenarios

The differences between the alternative projections and the base case (columns 3 and 5 in Tables L.2 and L.3) are interpreted as the effects of Factor f under each scenario. The pattern of effects is the same under each scenario, however the effects are larger in scenario B than in scenario A. This is because of the different assumptions made concerning the direct effects of Factor f on the pharmaceutical industry.

At the macroeconomic level, Factor f has little impact, as indicated by the small numbers in the first and last parts of columns 3 and 5 in Table L.2. This is because the pharmaceutical industry accounts for a relatively small proportion of Australian activity (with value added accounting for between 0.1 per cent and 0.2 per cent of GDP over the period 1992–93 to 1998–99 in the base case, or approximately $745 million in 1993–94).

In the base case, with Factor f, the pharmaceutical industry's output is projected to grow at about 8 per cent. The effect of withdrawing Factor f depends on the scenario. In scenario A, output of the pharmaceutical industry is projected to grow a little more slowly than in the base case (6 per cent annually); it is projected to *decline* at an annual rate of 2 per cent in scenario B. Again, the difference in these projections reflects the differing assumptions underlying the scenarios.

The direct effects of the scheme also have an impact on the rest of the economy. These effects are linked to the way in which the rest of the economy is linked to the stimulated pharmaceutical industry through:

- industries competing for resources used in the production process; and
- inter-industry linkages with supplying industries.

In the results reported in Tables L.2 and L.3, the Factor f scheme is assumed (implicitly) to be financed by an increase in income tax rates and workers are assumed (implicitly) to secure a compensating increase in their pre-tax wage rates. Under this assumption, stimulating activity in the pharmaceuticals sector crowds out other activities which are sensitive to wage costs.

Increased activity in the pharmaceutical industry also leads to some pressure on wages as the industry must attract workers (and other inputs) from the rest of the economy. Under scenario A, pharmaceutical activity increases less than under scenario B, resulting in lower wage pressures, and hence a negligible increase in

real wage growth. Under scenario B, increased activity in the industry is associated with a real wage increase of 0.03 per cent.[12]

The flow-on effects of increased wages and other input prices arising from increased pharmaceutical activity, slightly increase the production costs of all industries in Australia. This makes Australian products more expensive relative to foreign products, which reduces domestic and foreign demand for Australian products and increases domestic demand for imports. Although exports of pharmaceuticals increase (by 3 per cent under scenario A and 27 per cent under scenario B), exports in other sectors of the economy are depressed slightly.

Table L.3 indicates the industry effects associated with Factor f. In scenario A, Factor f is modelled to have stimulated the growth of the pharmaceutical industry by about 2 per cent in addition to the growth the sector would have been expected to display without Factor f. In scenario B, this extra growth is projected to be about 10 per cent per year. Output in other sectors that are competing for resources is projected to grow more slowly as a result of the extra demand for inputs made by the pharmaceutical industry. The output of industries that supply the pharmaceutical industry follows its expansion. Thus, the growth in output of the commercial printing, glass products and plastic products industries used in packaging pharmaceutical products increases between 0.03 per cent and 0.08 per cent when using the assumptions underlying scenario B (less in scenario A).

In summary, the simulations show that increased output by the pharmaceutical industry has minor flow-on effects to other industries. However, it is important to bear in mind the assumptions used in this exercise in order to interpret the results in terms of the actual impact of Factor f. Given the relatively small size of the pharmaceutical industry, impacts on the rest of the economy are limited.

L.5 What can we learn from the simulations?

Overall, the simulations indicate that the economy-wide effects of Phase II of the Factor f scheme are minor. The pharmaceutical industry is relatively small in comparison with the rest of the economy and higher growth in the pharmaceutical industry associated with Factor f payments is partly offset by lower growth in other industries that are disadvantaged by the effects of higher real wages and increased competition for resources.

[12] The financial cost of Factor f is small relative to the size of the wage bill and the tax effect resulting from the assumption mentioned above does not appear in the wage increases reported in Table L.2.

Modelling the Factor f Phase II scheme indicates that under two sets of plausible assumptions (scenarios A and B), the scheme:

- is associated with growth in the pharmaceutical industry (but there is some doubt about the level of this growth);
- is associated with effects on other sectors of the economy, in particular on suppliers of inputs to the pharmaceutical industry; and
- has small economy-wide effects for two reasons. First, increased pharmaceutical activity due to Factor f raises input prices hampers growth in other sectors of the economy. Second, the pharmaceutical industry comprises a relatively small part of the Australian economy.

Given the small economy-wide impacts estimated here, another scheme that had similar impacts on the pharmaceutical industry would also have a relatively small impact on the economy as a whole.

M FACTOR F—ADDITIONAL INFORMATION

This Appendix contains additional tables from the Report of the 1995 Bureau of Industry Economics' survey of the pharmaceutical industry and the Australian Pharmaceutical Manufacturers Association 1995 survey of its members. This information is in addition to that contained in Chapter 11.

Table M.1: Comparison of activity levels with and without Factor f—current participants in Phase II (n=11)

Activity	*Number of companies indicating how activity levels in 1999 are expected to differ from those in 1993:*					
	With Factor f			*Without Factor f*		
	No significant change [a]	*Higher*	*Lower*	*No significant change* [a]	*Higher*	*Lower*
Value added on domestic sales	-	11	-	3	2	6
Value added on export sales	-	11	-	3	2	6
Formulation	2	9	-	1	3	7
Packaging	2	9	-	2	3	6
Production of actives	9	2	-	9	-	2
Overall manufacturing capacity	1	10	-	3	2	6
Research into NCEs	5	6	-	6	1	4
Research to enhance existing chemical entities	6	5	-	5	2	4
Clinical trials	2	9	-	3	2	6

a The no significant change category includes not relevant.

Source: BIE 1995, p. 42

Table M.2: Comparison of activity levels with and without Factor f— unsuccessful applicants for Phase II (n=6)

Activity	*Number of companies indicating change over period 1993 to 1999:*					
	With Factor f			*Without Factor f*		
	No significant change [a]	*Higher*	*Lower*	*No significant change* [a]	*Higher*	*Lower*
Value added on domestic sales	-	6	-	2	4	-
Value added on export sales	-	6	-	3	3	-
Formulation	1	5	-	4	2	-
Packaging	1	5	-	3	3	-
Production of actives	6	-	-	6	-	-
Overall manufacturing capacity	-	6	-	3	3	-
Research into NCEs	4	2	-	5	1	-
Research to enhance existing chemical entities	3	3	-	5	1	-
Clinical trials	1	5	-	2	3	1

a The no significant change category includes not relevant. The group of six unsuccessful applicants included three companies that participated in Phase I of Factor f . The Pharmaceutical Benefits Pricing Authority (PBPA) submission lists seven unsuccessful applicants for Phase II (sub. 74, p.11), of whom six responded to the BIE survey, but one of these did not describe itself as an unsuccessful applicant. Another BIE respondent reported that it had been developing an application for submission to the PBPA when the decision to cap funding was announced, and therefore abandoned its application— it is included in the table.

Source: BIE 1995, p. 44

Table M.3: Human use pharmaceutical sales by market type 1993–94 $ million [a]

	PBS Type [b]	*Non-PBS Type* [c]	*Total*	*% PBS type*
Factor f participants				
Phase I only participants	343	58	401	86
Continuing participants	581	28	609	95
Phase II only participants	461	50	511	90
Total	**1 385**	**136**	**1 521**	**91**
Non-Factor f	866	477	1343	64
Total industry	**2 251**	**613**	**2 864**	**78**

a Ex-factory prices.
b All Pharmaceutical Benefits Scheme (PBS) sales plus other prescription sales through Government price controlled mechanisms, eg Repatriation Benefits Pharmaceutical Scheme, hospital, Government tenders.
c Mainly over the counter sales.
Source: APMA, sub. 119, Attachment 1, p. 4

Table M.4: Comparison of activity levels with Factor f and deregulated pricing—current Phase II Factor f participants (n=11)

	Number of companies indicating change over period 1993 to 1999:					
	With Factor f			*Deregulated pricing*		
Activity	*No significant change* [a]	*Higher*	*Lower*	*No significant change* [a]	*Higher*	*Lower*
Value added on domestic sales	-	11	-	3	8	-
Value added on exports	-	11	-	5	5	1
Formulation	2	9	-	5	3	3
Packaging	2	9	-	4	5	2
Production of actives	9	2	-	10	1	-
Overall manufacturing capacity	1	10	-	6	3	2
Research into new chemical entities	5	6	-	7	2	2
Research to enhance existing chemical entities	6	5	-	8	3	-
Clinical trials	3	8	-	3	6	2

a The no significant change category includes not relevant.
Source: BIE 1995, p. 49

Table M.5: BIE estimates of inducement ratios, per cent [a]

	Inducement ratio	*Share of activity*	*Weighted average inducement ratio*
Export value added			
Foreign owned participants			68
Continuing	54	61	
New	90	39	
Australian owned participants			62
Continuing	60	92	
New	90	8	
R&D			
Foreign owned participants			61
Continuing	43	61	
New	90	39	
Australian owned participants			71
Continuing	67	83	
New	90	17	
Domestic value added			
Foreign owned participants			90
Australian owned participants			90

a The inducement ratios indicate the percentage of activity eligible for Factor f actually induced by the Factor f scheme.

Source: BIE 1995, p. 73

Table M.6: Views of Phase I participants—qualitative benefits (n=8)

Potential benefit of Factor f	*Number of companies reporting importance as:*				
	No importance [a]	*Marginal importance*	*Some importance*	*Important*	*Very important*
Enhanced profile for your company's products abroad	1	-	4	3	-
Enhanced credibility of your company as an internationally competitive unit within the overall corporate structure	1	1	-	1	5
Acquisition of new product and process technologies and skills	-	-	2	3	3
Development of key competitive competencies (manufacturing, marketing etc)	-	-	2	3	3
Fostering of collaborative links with Australian research institutions	-	1	1	4	2
Fostering collaborative links with other pharmaceutical companies	3	2	1	1	1

a No importance also includes not relevant.

Source: BIE 1995, p. 80

Table M.7: Views of Phase II participants—qualitative benefits (n=11)

Potential benefit of Factor f	*Number of companies reporting importance as:*				
	No importance [a]	*Marginal importance*	*Some importance*	*Important*	*Very important*
Enhanced profile for your company's products abroad	2	1	3	2	2
Enhanced credibility of your company as an internationally competitive unit within the overall corporate structure	1	-	-	1	9
Acquisition of new product and process technologies and skills	-	-	-	4	7
Development of key competitive competencies (manufacturing, marketing etc)	-	-	-	3	8
Fostering of collaborative links with Australian research institutions	-	-	2	4	5
Fostering collaborative links with other pharmaceutical companies	1	2	1	5	2

a Not important also includes not relevant.
Source: BIE 1995, p. 81

N REVISED FACTOR F SCHEME

This Appendix describes in more detail the structural issues to be addressed in any future Factor f scheme, as well as upper and lower cost estimates. It also briefly describes another possible method of increasing pharmaceutical industry activity—tax concessions.

N.1 A revised Factor f scheme

Several participants agreed with the Draft Report recommendation that the current Factor f scheme should not be continued in its current form. For example, Faulding stated:

> It seems to me that just to continue the current plan would not address the very valid needs of all the players in the Australian pharmaceutical market, so I would find it difficult to see how just a mindless continuation of the Factor f plan without a very major re-scoping of the ground rules would make much sense for the total Australian environment (roundtable, p. 262).

The Commission's Draft Report outlined a preferred model for a new Factor f type scheme. This attracted numerous comments from participants. The Commission has subsequently modified this scheme in a number of respects to increase the likelihood that it will bring net benefits to the community. The Commission's revised scheme is described in Section N.3.

N.2 The Commission's Draft Report model

The Commission's Draft Report outlined an option for a replacement Factor f scheme. It offered wider coverage of companies at lower rates of payment than are currently granted under the Factor f scheme in an administratively simple manner, with as few decision distorting characteristics as possible.

The key features of the scheme are described in Box N.1.

Box N.1: Key features of the Draft Report option

- Price increases applied to patented products on the PBS only.
- The base year was a three year moving average.
- Funding was open ended, but payment rates were lower than in the current scheme.
- Entry was non-competitive.
- Quantitative eligibility criteria were limited to administrative thresholds to prevent processing minor claims.
- It was suggested, although not recommended, that price increases could be actual rather than notional.
- It commenced when the current Factor f program ceased in 1999.

N.3 Structural issues

In response to the comments received from participants regarding this scheme, the Commission reassessed the Draft Report option. This section discusses the Commission's revised model. Structural issues include:

- whether price increases should be actual or notional;
- the products to which price increases may be applied;
- changing the eligibility criteria;
- the appropriate base year;
- whether entry should be automatic or competitive;
- entry hurdles;
- the appropriate level of assistance;
- the appropriate timeframe for assistance;
- program review; and
- administration.

Issue 1: Actual or notional price increases?

The Commission's Draft Report raised the question of whether price increases should be paid as actual or notional prices.

The Commission has accepted that the threat of country of origin pricing can have a real impact on company activity (see Chapter 12). Actual prices are more likely to be of assistance to a company facing such concerns. Also, actual prices, rather than notional prices, would be more likely to send positive signals to head offices regarding Australia's desirability as an investment location.

The main practical problems with actual price increases are:

- goods may become uncompetitive on the domestic market;
- pharmacists and wholesalers may take advantage of the price increase through higher margins; and
- the quantum of money delivered through actual price increases might exceed the amount for which the company is eligible, requiring monitoring and clawback provisions.

Regarding goods becoming uncompetitive on the domestic market, this could be the case if the price of the competing product was less than the maximum copayment paid by the consumer, or if the Factor f payment was construed as a brand premium, also to be paid by the consumer. Any other price rise would not be noticed by the consumer. However, some participants have argued that doctors are becoming increasingly aware of cost pressures on the Pharmaceutical Benefits Scheme (PBS) budget, and may prefer to prescribe a cheaper treatment where they are convinced that this is not against their patients' interests.

One potential mechanism for dealing with this problem was suggested by Merck, Sharp & Dohme (roundtable, p. 277, sub. 88). This suggestion was to grant an actual price increase to all producers of that type of product but ensure that companies not carrying out Factor f type activity reimburse the Government for any windfall gain. Merck, Sharp & Dohme believes the main advantages of the approach to be:

- it eliminates the issue of Australia being seen to have low prices—it will therefore address such issues as reduced export opportunities because of country of origin pricing etc;
- no company could claim to be excluded from participating—the extent of the benefit received from increased prices is directly related to the extent to which a company undertakes specified activity;

- it enables the government to establish the true cost of its social welfare objectives through the PBS;
- it enables the Government to change its health/industry development objectives periodically to reflect the demands of a new environment;
- it better reflects the objective of compensating the pharmaceutical industry for low prices—it is more difficult to portray such a scheme as a 'handout' to pharmaceutical companies;
- it is more accountable than the current scheme;
- as the scheme is directed to patented products, its long term effect is to reward those pharmaceutical companies who have a good research pipeline, and recognises that—provided that the patent term is adequate—generic price competition is appropriate after patent expiry;
- it rewards existing activity as well as new activity (sub. 88, pp. 1–2).

However, the major potential disadvantage of this approach are that it may be administratively costly. It may be difficult for the Government to retrieve the money it has given to some companies which have not undertaken sufficient activity in Australia.

In the context of actual price increases generally, higher margins to wholesalers and retailers is a significant issue. However, it is within the control of the Minister for Health and Family Services via the Pharmacy Guild/Minister Agreements to control the flow-on effects of higher actual prices to wholesalers' and pharmacists' margins. These are currently calculated as a percentage of the price of the drug. It would be possible to ensure that the calculation did not include any Factor f price increase.

The National Pharmaceutical Distributors' Association (NPDA) noted that notional price increases prevented flow-on price effects to both wholesalers and pharmacies. The NPDA claimed that it would support the continuation of a Factor f type scheme, 'providing it is not funded out of the wholesaler margin' (sub. 9, p. 11). Since the Factor f scheme is designed to compensate pharmaceutical manufacturers for price suppression, rather than any possible under-pricing of wholesaling or retailing services, the Commission can see no reason for allowing these groups to experience a windfall gain.

The final difficulty with actual price increases is that companies might receive more money through unexpectedly high sales of their product than to which they were entitled. For example, say a company undertook activity in period one which entitled it to price increases worth a total of $5 million. At the start of period two, price increases could be applied to products which, based on predicted sales volumes, would pay the company $5 million in period two. However, if demand unexpectedly increased for those products, the company

might experience a windfall gain. In this case, the Pharmaceutical Benefits Pricing Authority (PBPA) could monitor the total amount of extra money paid to the company through price increases and could either:

- lower prices once the total amount had been paid; or
- maintain the higher price, but require that the company pay back any extra amount paid at the end of the time period.

Alternatively, companies could keep 'bank accounts' with the PBPA, keeping a running tally of amounts owed and received through actual prices. Companies could choose to accrue money in these accounts until they require the funds to launch a new product at an acceptable price.

Due to the importance of prices for benchmarking and country of origin purposes, the Commission considers the latter option to be preferable.

While the Commission acknowledges that there may be difficulties associated with an actual price increase scheme, it considers that companies themselves are in the best position to judge whether the problems will outweigh the benefits. Therefore, the Commission considers that companies should have the option of receiving their payments in the form of actual price increases.

Issue 2: Price increases for which products?

The Commission's Draft Report preferred model stated that payments should only apply to patented products on the PBS.

Price increases should make up for the price differential between PBS and European Union prices, or at least partially make up for this difference. For patented products, the price differential represents the use of monopsony bargaining power by the government. For off patent products, however, price differentials often represent a choice by companies not to increase the price relative to those of competitors. Under the rules of the PBS, companies may voluntarily place a brand premium on off patent products where there is a cheaper brand listed. This brand premium represents an out of pocket expense to consumers. As noted in Chapter 4, brand premiums are at present low and not all companies have taken the opportunity to increase their prices. This would suggest that the price differentials between Australian and European prices in the case of off patent drugs may often be either the result of competition with generic manufacturers, or of the companies' own choosing. Either way, they should not be the subject of a compensation scheme.

CSL stated that :

> ... I have been of the view ... that generics, just simple, straight generics ... have difficulty demonstrating much harm in the current system. They may disagree with that, so I'm open to some persuasion, but I think the prices for generics here are reasonable. ... If you can't demonstrate harm you don't deserve compensation (transcript, p. 1172).

Merck, Sharp & Dohme's initial submission said that any future Factor f payments should apply to patented products only (sub. 88, p. 2). Bristol-Myers Squibb's suggestions for change also emphasised PBS, patented products (sub. 78, p. 4).

The Commission's Draft Report recommendation that Factor f price increases should only apply to patented products attracted considerable comment.

Several companies disagreed with this recommendation. For example, Institute of Drug Technology (IDT) claimed that it would exclude many Australian companies (sub. 156, p. 1). Eli Lilly (sub. 142, p. 14) and Glaxo Wellcome (sub. 144, p. 15) claimed that since both patented and non-patented products are affected by low PBS prices, both should attract payments. CSL (sub. 118, p. 5), Astra (sub. 141, p. 17), Faulding (sub. 129, p. 5) and Glaxo Wellcome (sub. 144, p. 15) disagreed with this recommendation on the basis that it excluded innovative versions of old products and innovative devices. CSL suggested that:

> The test of what constitutes an innovative product is that it cannot be registered via the Australian equivalent of an FDA Abbreviated New Drug Application (ANDA), not can it be substituted by pharmacists in the market place (sub. 118, p. 6).

Parke Davis (sub. 121, p. 4) and Schering-Plough (sub. 128, p. 4) both disagreed that only products on the PBS should be included for compensation payments. These companies suggested that over-the-counter (OTC) products be included in any new scheme. However, the Commission considers that the impediment of low PBS prices does not apply to OTC products and that therefore there is no justification to include such products.

CSL and Faulding claimed that hospital products and vaccines should also be included in the scheme. For example, CSL stated that because vaccines are purchased under a nationally coordinated tender, the price suppression effect was exactly the same as under the PBS:

> It's the same hammer; it's just in a different person's hand (transcript, pp. 1181–1182).

Faulding, however, stated that 'competition would be the major reason' why the prices for some of their hospital out-of-patent products are low (transcript, p. 1325). If this is the case, then it is difficult to see why such products should receive price increases under any new Factor f scheme.

Several other companies, such as Pfizer (sub. 133, p. 16) and Merck, Sharp & Dohme (sub. 122, p. 12) agreed with the Commission's recommendation to limit compensation to patented products on the PBS.

The Commission has concluded that compensation should only apply to products where a clear case of price suppression exists. In the case of unpatented products, this seems only to apply in the case of innovative versions of old drugs or innovative devices for delivering old products. Other products, such as straight generics or out-of-patent innovator brand drugs, appear not to be substantially harmed by the PBS because of the ability to include a brand-premium if desired. Moreover, discussions with the head offices of several multinational companies suggested that the prices for new products were integral to their perceptions of Australia as an investment location, rather than prices for older products. Therefore, the Commission considers that price increases should only apply to patented products or else products that cannot be patented but still incorporate a significant degree of innovation.

Issue 3: Changing the eligibility criteria

Participants suggested several changes to the eligibility criteria. This section describes the following possible changes:

- including health promotion activities;
- breaking the link between research and development (R&D) and production activity;
- targeting R&D;
- targeting Australian companies;
- targeting industry development more broadly; and
- subsidising existing as well as incremental activity.

Health promotion activities

One suggestion was to expand the list of eligible activities to include health promotion activities.

As Merck, Sharp & Dohme noted:

> ... there was not enough flexibility in the range of activities which could be undertaken by companies who wished to participate in the scheme (for example, activities which contribute to the quality use of medicines or assist the Government in meeting its health objectives could have been considered) (sub. 27, p. 18).

Bristol-Myers Squibb expressed a similar view, suggesting that the government could target health issues such as Aboriginal health, drug compliance, programs in community care and preventative activities. Set criteria could be used to avoid overt product oriented promotional activities, and a sliding scale of payments could apply (sub. 78, p. 4).

Several participants considered managed care to be the way of the future (see Chapter 6). There could be benefits arising from pharmaceutical companies taking a broader role in health care, due to their knowledge of their own products, as well as their contact with doctors in all countries.

Contributing to health promotion goals could be recognised under qualitative criteria in any new scheme. Under the current Factor f scheme, the qualitative criteria are used as an entry into the scheme. However, activities approved under the qualitative criteria may not necessarily be subject to Factor f payments. For example, new investments, commitment to best manufacturing practice and establishing Australia as a centre for operations in the Asia/Pacific region are all mentioned in the qualitative criteria, but none of these activities in itself is eligible for payments. Similarly, the promotion of health goals could become a factor to be viewed favourably when assessing entrants to any new scheme, without directly subsidising such activity. However, since the Commission's preferred Factor f type scheme does not have large quantitative entry hurdles, the role of any qualitative criteria diminishes.

Alternatively, the health promotion activity could be a paid activity under the scheme. It may be the case that companies are more likely to work cooperatively with health authorities where they feel that their environment is not 'hostile', or when local subsidiaries are more profitable.

For example, the Australian Pharmaceutical Manufacturers Association suggested that eligible activities should include:

> ... activities relating to the Quality Use of Medicines, including educational and other projects of public benefit, eg initiatives in support of improvements in Aboriginal health, school education and the like (sub. 119, p. 22).

In either case, the activity would need to be measured and assessed. This presents administrative difficulties since spending on such activity is only an

intermediate goal. The contribution towards the real goal of better health may be very difficult to assess. Also, it may be difficult at times to distinguish between companies' marketing activities and any broader educational activities.

Moreover, the Commission considers that the major impediments to such changes are institutional rather than related to low prices under the PBS. While the industry has a good deal to offer Australia in terms of achieving health outcomes, this would be better dealt with through institutions responsible for the promotion of the rational use of medicines, such as the Australian Pharmaceutical Advisory Council and the Rational Use of Medicines Sub-Committee.

The Commission considers that health promotion activity should not be included as an eligible activity in any new scheme.

Breaking the link between production and R&D

As discussed in Chapter 11, the fact that companies must undertake both R&D and extra value added in production may be a source of undercompensation. SmithKline Beecham suggested that the link between export growth and R&D should not be a prerequisite to any industry development program established (sub. 13, p. 3). Some companies appear to be doing R&D that they would not have done in a deregulated pricing environment simply to be eligible for the much larger production payments. The Commission considers this to be an unnecessary complication of the scheme.

Targeting R&D

A scheme targeting R&D and clinical trials would build upon what many participants described as one of Australia's strengths. While the direct links are not obvious between domestic prices and R&D, it may be that the perception of a hostile environment which low prices have created has suppressed such activity. In the absence of low PBS prices, such activity might increase, with associated benefits for Australia.

A scheme targeting R&D would also encourage linkages between pharmaceutical companies and the Australian medical research community. As discussed in Chapter 11, such linkages could be the source of considerable spillover benefits.

As the CSIRO noted, targeting R&D would build upon the significant public investment made in medical research through the Commonwealth Scientific and Industrial Research Organisation, Cooperative Research Centres and the National Health and Medical Research Council (transcript, pp. 271–272).

There is a difference between targeting R&D *per se* and targeting linkages. Some participants have emphasised R&D, for example the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists recommended government support for the establishment of a number of new training positions for clinical pharmacologists, and that government support for medical research be increased to maintain expertise (sub. 6, pp. 4, 7).

Other participants have concentrated on the linkages formed between pharmaceutical companies and Australian research institutions. For example, the Association of Australian Medical Research Institutes noted that:

> There is a synergistic relationship between the pharmaceutical industry and medical research in universities and research institutes. A strong medical research community, including medical research institutes, is essential if there is to be vigorous industry research; likewise, a strong pharmaceutical industry is important as a research partner for institutes and universities, and also serves as an essential vehicle for commercialising discoveries (sub. 18, p. 1).

CSL also emphasised linkages:

> ... CSL considers such a scheme may need to be more carefully targeted to ensure that the long term development of the Australian pharmaceutical industry capitalises on the strengths of Australian science and innovation, while facilitating its development and commercialisation in Australia and its access to international markets whether by Australian or foreign owned pharmaceutical companies.
>
> Accordingly, CSL believes that the Government's industry development program will need to be targeted at those companies which have demonstrated that they have established effective links with the Australian research community and have the capacity to take the resulting products through to the international market place (sub. 39, p. 2).

The Commonwealth Government already has schemes specifically targeting R&D and the creation of linkages (see Chapter 7 and Appendix F). These include the 150 per cent tax concession for R&D, the Competitive Grants scheme, the Cooperative Research Centres Program, the Collaborative Research Grants Scheme and the Australian Postgraduate Awards (Industry) program. The Commission does not consider there to be a case for any extra funding targeted specifically at R&D or linkages in the pharmaceutical industry. Rather, any industry specific assistance should only be given on the grounds that it is restoring efficient activity that has been lost due to the impact of low PBS prices. Since it is very difficult to know what this activity is, any scheme offering offsetting payments should be broad based and should include but not favour R&D activity *per se*.

Some participants interpreted the Commission's Draft Report recommendation that R&D should be included but not favoured in any future scheme to mean that R&D would receive less favourable treatment than other activities. For example, AMRAD stated that:

> ... the conclusions and recommendations of the BIE and the Industry Commission to downgrade the priority of R&D in any future scheme is completely overlooking the basis on which a pharmaceutical industry is established and is a short term measure to encourage rapid growth through manufacture and export, ignoring the requirements for the long-term future of the industry. AMRAD requests the Commission to give further consideration to the fundamental role of R&D in the industry and the vital importance of including R&D support as a major plank in the policy for the next stage of the Industry development plan (sub. 117, p. 3).

However, the Commission's intention was that any future scheme should not try to engineer its outcomes. By making the payment rate the same for all activities, firms can respond with maximum flexibility.

Target Australian companies?

Some participants have argued that the Factor f scheme should favour Australian owned companies. For example, Sigma stated that:

> We wish to see a recognition that similar degrees of support provided to different companies in the same industry result in varying degrees of benefit to the Australian economy. Australia's pharmaceutical manufacturing base has been seriously and unnecessarily eroded by the determination of the government to ensure that no preference is placed on locally owned companies that conduct their entire manufacturing operations in Australia. We believe that to sacrifice Australian industry for an ideological goal does not make commercial sense (sub. 19, p. 5).

Pharmaction stated that:

> It should be borne in mind that the Factor f scheme to date has primarily benefited multinational companies who still remit a significant proportion of their profits to overseas investors. Support and assistance to Australian owned companies and research establishments is vitally important to ensure that the value and ownership of the intellectual property remains in Australia (sub. 3, p. 1).

Faulding argued that:

> ... it may not be politically correct to stress this point too much but every country is protective and chauvinist with respect to its own publicly-funded institutions. I have no hesitation whatsoever in saying that if taxpayers' money in this country—and I guess if I was in Belgium or the US I would be saying the same thing—that there have to be some *a priori* rights to the fruits of taxpayer-funded

> medical research and that citizens in a country have are reasonable expectation to benefit from that (transcript, pp. 1311–1312).

While it is true that the direct gains to Australia from supporting foreign companies are lower than for domestic companies (as pointed out by the Bureau of Industry Economics (BIE), see Chapter 11) there are several reasons for not excluding the multinationals from the scheme:

- they forge profitable linkages with Australian researchers and smaller companies;
- they have greater experience in taking products to market all over the world than Australian companies do, making them valuable partners in commercialising Australian discoveries;
- there is potential for relatively large spillover gains from multinational companies employing the latest technology and management styles in Australia brought in from overseas; and
- they are large in comparison to the indigenous companies and so there is potential for their tax contribution to be significant.

Australian companies themselves noted the value of multinational companies to their own operations. For example, Faulding noted:

> It seems to me that for Australian pharmaceutical companies to reach anything like their potential in the local environment, their linkages with the great multinational companies with whom we interact is absolutely essential and that those linkages should be rewarded from both parties' points of view (roundtable, p. 263).

CSL argued that it would not support a scheme which linked government support to the ownership structure of the company (roundtable transcript, p. 267).

The Commission considers that the spillover benefits for Australia associated with the presence of multinational companies may be larger than for indigenous companies, but not large enough to make the current Factor f scheme welfare enhancing for the foreign-owned companies (see Chapter 11).

However, even if the Government wanted to target Australian companies, it might be administratively very difficult to do so. The BIE's conclusion that Factor f was more likely to have been welfare enhancing for domestic companies than for foreign owned companies relies on the domestic companies being owned by shareholders who reside in Australia. Ensuring that no Factor f money leaked overseas would require information about the country of residence of all shareholders.

Even if the Government could ensure that no foreign shareholders benefited from the scheme, it is likely that companies would organise their affairs in order to become eligible, for example through holding companies.

Targeting industry development rather than the effects of price suppression

Some participants have argued that eligibility for accessing the scheme ought to be broadened to include non-PBS suppliers. For example, RP Scherer commented that companies which were involved in outsourcing were ignored under the Factor f scheme and recommended that the Government:

> Eliminate Factor f and replace it with a scheme of investment incentives applicable to the entire industry and not just companies manufacturing and marketing PBS items (sub. 29, p. 9).

However, these proposals ignore the fundamental rationale of the Factor f scheme. The scheme has already been broadened to 'PBS-like products' (mainly hospital products) because it was accepted by government that such prices were indirectly suppressed by the PBS. To broaden the scheme further would go beyond any sort of compensating mechanism and would become purely a preferential industry development program.

Incremental or existing activity

Some of the larger companies have expressed the view that maintaining existing activity levels is as important as encouraging new activity (see Chapter 11). The Pharmaceutical Industry Discussion Group (Glaxo Wellcome, Eli Lilly, CSL and Merck, Sharp & Dohme) stated that:

> the compensation arrangements for participants in Phases I and II of the scheme need to take into account those companies' existing levels of activity, as well as new and incremental activity undertaken by those companies (sub. 198, p. 2).

However, if payments were made on existing activity, this might protect inefficient levels of production. Where payments are made on incremental activity, companies have an incentive to achieve the economies of scale that are prevalent in this industry. Payments on existing activity might serve to slow the trend towards rationalisation that must continue in Australia, as in the rest of the world, if the industry is to produce efficiently. Such payments would also require very low payment rates to avoid budgetary difficulties.

The Commission considers that payments should be made on incremental rather than existing activity.

Eligible activities should be value added production (for both the domestic and export markets) as well as R&D. All activities should be paid at the same rate.

Issue 4: The appropriate base year

Companies which participated in Phase I as well as Phase II were permitted to keep their Phase I base year. The effect of this was to significantly increase the entitlements of continuing participants. This led to potential overcompensation, as well as potential efficiency losses (see Chapter 11).

Alphapharm noted that:

> Any new scheme must be conscious to take into account grants already received. The new proposal must guard against 'double-dipping' whereby a company might receive further grants based on investment that was fully funded by past grants. In this way the government must be careful to be even-handed in its approach to the industry. To see further grants being extended to successful applicants from past Factor f schemes would be a travesty unless it could be fully justified when compared to the quality of other applications (sub. 14, p. 5).

It would seem fairer and a more cost effective use of funds to ensure that the base year for any new scheme would be the starting date for activity done under that scheme. This would eliminate the potential for double compensation which could occur if older base years are kept.

A more appropriate base year arrangement might be a moving average of, say, three years, to reduce the scope for overcompensation. This would automatically update the base year and associated base values.

Issue 5: Allocating benefits: competitive or automatic entitlement?

Another decision which needs to be made regarding a new scheme is whether everyone who is eligible is admitted into the scheme, as in Phase I, or whether a competitive approach is adopted.

Some participants argued that a competitive process was more appropriate for a Factor f scheme, because it avoided the available funds being spread too thinly. For example, the Pharmaceutical Industry Discussion Group (CSL, Eli Lilly, Glaxo Wellcome and Merck, Sharp & Dohme) stated that:

> ... the criteria for participation ... should encourage and reward the introduction, expansion and retention of highly valuable contributions with implications for ongoing viability and international competitiveness, even if this means that not all companies can participate in Factor f (sub. 198, p. 2).

There are several points which should be kept in mind regarding a competitive arrangement.

First, all applicants must know that this will be the process before they apply. This feature was absent from the Phase II selection process.

Second, governments would also have difficulty in deciding *ex ante* which proposed activities would bring the greatest net benefits to the Australian community. As discussed in Chapter 11, measuring welfare gains associated with increased activity is complex, even on an *ex post* basis.

Third, competitive entry may create incentives for unduly optimistic bids. As governments would not be easily able to know which companies were inflating their bids and which were not, choosing the 'best bids' is a risky approach. Penalties for not meeting agreed targets could be introduced to deal with this problem, although this may be inappropriate where companies fail to complete their programs through no fault of their own.

Fourth, a good deal of time and effort may be used in preparing an impressive bid and lobbying government to try to increase the chances of being admitted to the scheme. These resources may have been better employed in other uses.

On the other hand, allowing every company which meets the criteria to be admitted to the scheme may create other difficulties for government relating to the uncertainty of future budgetary outlays and the lack of control over these outlays.

Any future scheme should be non-competitive, subject to adequate methods of dealing with budgetary issues. These issues are discussed below in the context of the level of assistance of any future scheme.

Issue 6: Entry hurdles

The current Factor f scheme contains quantitative criteria which, in a practical sense, serve to limit the number of companies that will be eligible to enter the scheme (see Chapter 5). Changing the quantitative criteria could have the effect of changing the number of companies which might be eligible to enter the scheme, or changing the mix of activities companies might choose to pursue. Alternatively, threshold criteria could be used simply to avoid the administrative burden of monitoring and processing small claims.

The Commission considers that any new Factor f scheme should be as non-distortionary as possible. For this reason, the Commission sees only administrative threshold criteria as being justified. These criteria should be developed to be similar to those in other assistance schemes.

Issue 7: The appropriate level of assistance

A further question to be answered is to what extent eligible activities should be rewarded. This must be answered at three levels: the size of the total compensation package, the rates of payment for each eligible activity and the level of compensation to individual companies.

Total funding

Funding for a future Factor f scheme could be capped or uncapped.

If funding is uncapped, there is the disadvantage of outlays being unpredictable. However, governments face these problems on a daily basis for much larger programs than Factor f. For example, governments face uncertainty over outlays on unemployment benefits, Medicare outlays, PBS outlays and so on. Tax receipts are also affected unpredictably by schemes such as the 150 per cent R&D tax concession. More importantly, capping funding is likely to lead to rationing, which in turn could lead to unfair treatment of some companies and 'picking winners' at the expense of other companies.

However, overall program costs should represent a relatively small proportion of the overall level of price disability faced by companies.

At a more fundamental level, unless there is evidence of diminishing returns to Factor f dollars, those who fulfil the criteria should not be turned away because there is a chance that these applicants could also contribute net benefits to the Australian community. As long as the benefits outweigh the costs of the scheme, funding should not be restricted. If benefits are less than known costs, then it is likely that the criteria have been improperly specified, a problem which should be tackled directly.

Given that Factor f was designed to promote internationally competitive activity, there may be scope for payments to decline over time. According to CSL:

> ... I always felt that the scheme was quite generous. There was always an issue of whether or not there should have been an issue of diminishing returns, whether after a while, given that you had been given a reasonable degree of encouragement, the percentage of value added or in fact the total dollars per annum should have in fact been managed. That sort of never got dealt with and I guess that was never on the table. But that partly caused I think some of the anomalies that have been created by the bucket getting empty faster than it should have been (roundtable, p. 274).

If the government decides that funding is to be capped, then this could occur by way of a pool of funds which is distributed among all of the participants, according to their level of eligible activity, with a lower rate of assistance for

all. The advantage of this approach is that no one who is eligible is turned away. The disadvantage is that there is considerable uncertainty attached to the eventual benefits of entering the scheme.

Capped funding could also be dealt with by making access to the scheme competitive, as discussed earlier. This has the advantage that rates of assistance could be specified before activity was undertaken, reducing the costs of uncertainty.

Rate of assistance

Since the current scheme appears to have overcompensated some participants and since it appears much more likely that the scheme would have been welfare enhancing if the rate of payment had been lower, the Commission considers that a lower rate of payment would be appropriate in any future scheme. Based on this evidence plus calculations of the benefits required of a scheme to break even in a welfare sense at lower payment rates, the Commission suggests a payment rate of 15 per cent.

Capping payments

The Draft Report contained a suggestion that payments could be reduced by limiting price increases to 80 per cent of the EU price, in recognition of the fact that the PBS provides an expanded market to companies through the consumer subsidy.

This suggestion received considerable criticism from participants, who claimed that this was unjustified and would only intensify negative perceptions about Australia. For example, Merck, Sharp & Dohme cited evidence that Australian per capita expenditure on pharmaceuticals is lower than the OECD norm (sub. 122, p. 9). The Commission has also received considerable evidence that the PBS also operates as a rationing system for newer, expensive drugs and actually results in a smaller market than in comparable countries.

For these reasons, the Commission agrees that price increases should only be limited by 100 per cent of the EU price.

Issue 8: The appropriate timeframe

Several participants noted the long-term nature of pharmaceutical industry investments. The uncertainty resulting from the stop-start nature of funding over a relatively short time has been criticised by many participants.

For example, the Association of Australian Medical Research Institutes noted that the Factor f program had succeeded in dramatically increasing R&D in Australia, but that funding under Phase II was erratic with:

> ... dire consequences for the recipient research institutes. The reality is that pharmaceutical R&D takes substantially longer than three years and any program which provides incentives to pharmaceutical R&D must be structured with that clearly in mind.
>
> ... the continuity of funding must be assured so that an individual company can continue a specific research program for 5–10 years—the minimum interval for really important discoveries to be made. This could be achieved by redistribution of funds, rather than increasing the total size of the program (sub. 18, p. 2).

Eli Lilly stated that:

> The overriding concern of ELA [Eli Lilly Australia] and its corporate networks about present policy is the degree of uncertainty created for the company in its investment process. It is difficult, we accept, to legislate uncertainty out of the future. Nevertheless, ELC [Eli Lilly Corporation] would suggest that policy certainty is a major determinant (if not the major determinant) for investment location decisions. Risk management processes are obviously part of any global enterprise's planning but *ad hoc* or fortuitous decisions are major deterrents to long term investment decisions (sub. 67, p. 13).

Astra recommended that Australia should:

> Establish a long term bi-partisan approach, recognising that the development of a world class pharmaceutical industry is a long term strategy which requires certainty and continuity of investment if pharmaceutical R&D is to flow (sub. 20, p. 25).

Many research organisations were concerned that the current Factor f timeframe was too short. For example, Prince Henry's Institute of Medical Research stated that the Factor f scheme should be extended for 15 years with reviews at five year intervals (sub. 4, p. 4).

The Commission accepts that uncertainty is costly. However, it is impossible to remove uncertainty altogether. Government schemes need to be reviewed periodically to ensure that they are fulfilling their aims in a cost effective manner. For example, the evaluation of the current Factor f scheme in Chapter 11 has uncovered some serious flaws in the design of the scheme.

Another factor to be taken into account is that the PBS itself may change. Any future scheme needs to be looked at in the context of what is happening to PBS prices. As discussed in Chapter 8, it is possible that in the future Australia's prices will converge with European prices as other countries pursue cost-

containment strategies such as benchmark pricing. Under these circumstances, there would be no justification for a Factor f type scheme.

Issue 9: Review

As for any Government program, any new Factor f scheme should be reviewed regularly. The Commission considers that any new scheme should be reviewed after five years.

Issue 10: Administration

In Chapter 11, the Commission described numerous problems with the administration of the Factor f scheme. Many of these problems related to a lack of transparency in the operation of the scheme and the selection process, from both the industry's and the community's point of view.

Selection process

It has already been concluded that:

- the quantitative criteria that were designed with industry development goals in mind should be replaced by administrative thresholds, which allow companies to respond as flexibly as possible;
- eligible activities should be R&D and value added production, with the same payment rate for both; and
- entry to the scheme should be non-competitive.

The combination of these elements ensures that the current selection process is essentially eliminated. Companies would know in advance what activity was eligible (and could check with the administrators in advance to make sure). Information should also be distributed to companies outlining any evidence of increased activity they needed to collect to receive payments. They would also know what the administrative thresholds for the minimum quantity of payments would be. Companies could undertake activity with certainty that they would receive payments, since there would be no process of choosing between applicants. The Commission considers that this approach is much more transparent and simple than the arrangements for the current Factor f scheme.

The Draft Report contained a recommendation that the details and amounts paid to individual companies, any performance targets and monitoring reports should be publicly available for Phases I and II of the Factor f scheme, and for any new scheme unless there were commercial or legal reasons for maintaining

confidentiality. This elicited numerous responses from participants. Merck, Sharp & Dohme epitomised the theme of these responses:

> MSD [Merck, Sharp & Dohme]accepts this recommendation in relation to any new scheme. However, MSD opposes the retrospective elements of this recommendation, as this represents unilaterally changing the rules of the game. This will merely fuel the negative perceptions of parent companies. It may also be inappropriate at this time, as it may prejudice legal proceedings which are underway. ...
>
> MSD has no difficulty with the concept of public disclosure. As the Commission noted, MSD was the only company to detail its Factor f payments to date (sub. 122, p. 5).

The Commission accepts that the retrospective elements of its Draft recommendation may increase perceptions of sovereign risk. Since these perceptions can be costly and particularly difficult to overcome, the Commission considers that existing scheme payments and other details not be required to be made public.

Nonetheless, the Commission strongly supports the notion that taxpayers are entitled to know where their money is being spent and what they have received in return for their money. Therefore, in any new scheme, these details ought to be made public. Since all payments are made in arrears of activity in the Commission's preferred Factor f type option, there are no apparent difficulties with confidentiality of company plans.

N.4 Likely cost to Government

The Commission has undertaken some preliminary estimates of the likely cost of such a scheme. The most likely scenario is presented in Chapter 13.

An upper estimate for the costs of such a scheme would be around $280 million over five years, and $830 million over ten years. This assumes that:

- eight additional 'average' sized companies enter the scheme;
- companies grow at 75 per cent of their current growth rates; and
- a 15 per cent payment rate is used.

A lower estimate is that the scheme will cost around $85 million over five years, and $220 million over 10 years. This assumes:

- six additional 'average' companies enter the scheme;
- companies grow at 50 per cent of their current growth rates; and

- a 10 per cent payment rate is used.

N.5 Another method—tax concessions

Any Government attempt to remove impediments to the growth of the pharmaceutical industry is not necessarily confined to an approach directly related to prices. Other possibilities, such as tax concessions, could also improve the growth prospects of the industry. Since they do not directly address the price impediment, the Commission has not recommended that such schemes be adopted.

SmithKline Beecham focussed its suggestions for a future scheme on what it considered to be Australia's uncompetitive company tax rate. This scheme was designed to:

> ... compensate industry participants for the high tax rates applied on export growth which act as a significant disincentive to Corporations in selecting Australia as a centre for regional activities. This could take the form of some form of grant/rebate etc calculated to reduce the effective tax rate on export growth, but not necessarily a reduced tax rate for the industry specifically (sub. 115, p. 6).

SmithKline Beecham considered that the promotion of value added exports should be the focus of industry expansion and that:

> R&D is not considered critical to local industry survival or prosperity. This is due to the predominance of multinational enterprises in the industry, who adopt centralised R&D activities (sub. 13, p. 3).

By lowering the effective tax rate on exports (either directly, or via reimbursement) to 20 per cent to 25 per cent, multinational companies would be more likely to use Australia as an export base:

> This is a clear win–win result for both industry participants and the economy. It would enable the industry to become more attractive for growth via the delivery of regional supply, which would enable it to access the economies of scale required to compete in the global market, whilst the economy would obtain growth and a considerable reduction in the current account deficit, gain in employment and benefit via the multiplier effect on domestic suppliers of goods and services. Most importantly, this incentive will be self-funding and indeed cash flow positive from the government's viewpoint. The Federal Government will receive additional taxation revenue on export profits, albeit at a concessional level, which in the absence of such an incentive would not have been derived at all. In addition, Government revenue would benefit further via the impact on suppliers to the industry (sub. 13, p. 37).

The Commission's Draft Report stated that the question of the most appropriate level of the company tax rate is a matter for broad consideration, with no particular issues facing the pharmaceutical industry more than any other type of company. A lower tax rate also does not attack what the industry generally considers to be the key industry specific impediment to the development to the industry—low PBS prices for patented products.

SmithKline Beecham disagreed with this conclusion however. The company stated that:

> Such a scheme does not address the key industry impediment of PBS, but it does address the second key impediment—tax.
>
> We also maintain that it is not correct to say that '... there are no particular issues facing the pharmaceutical industry more than any other type of company'. The justification for why such a scheme is of particular relevance to the pharmaceutical industry is due to the globalisation of the industry currently taking place, which will lead to regional suppliers. Selection of the country for regional supply will be based on a wide range of criteria, including the after tax return. A high tax rate on export sales will obviously impact this criteria (sub. 115, p. 6).

Nevertheless, the Commission concludes that global rationalisation is not a valid reason for government intervention. There are many industries which have already gone through such a process, or are currently involved in such a process.

Alternatively, the Government could increase the current 150 per cent tax concession on R&D to, say, 200 per cent for the pharmaceutical industry, as suggested by AMRAD (sub. 24, p. 18). The 150 per cent tax concession is a scheme which is designed to compensate for the fact that organisations pursuing R&D cannot appropriate all of the benefits flowing from their work (see IC 1995b). These benefits which accrue to other members of the community are called 'spillover' benefits. Extending the 150 per cent tax concession for the pharmaceutical industry would rely on there being greater spillover benefits flowing from pharmaceutical R&D than from other sorts of R&D. This may not be the case.

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