Evaluation of the Pharmaceutical Industry Investment Program

PRODUCTIVITY COMMISSION

Research Report

January 2003

Foreword

With the expiry of the Pharmaceutical Industry Investment Program (PIIP) in 2004, the Government asked the Commission to conduct an evaluation of the program's rationale, effectiveness and efficiency.

The Commission's report has drawn on information from consultations with pharmaceutical companies participating in the PIIP, non-participating companies, the pharmaceutical and biotechnology industry associations, as well as a range of research organisations and academics. The review has benefited from two roundtable discussions held to discuss the findings and recommendations of a draft report, as well as submissions from interested parties. The Commission wishes to thank the many people who have contributed.

This evaluation of the PIIP was overseen by Commissioner Tony Hinton and undertaken within the Program Evaluation Branch.

Gary Banks
Chairman
January 2003

Terms of reference

Evaluation of the Pharmaceutical Industry Investment Program

PRODUCTIVITY COMMISSION ACT 1998

The Productivity Commission is requested to undertake an evaluation of the Pharmaceuticals Industry Investment Program (PIIP). For the purposes of this study, the Commission's evaluation should:

1. Examine the appropriateness of PIIP by: determining whether there is economic justification for intervention in the pharmaceutical industry; and articulating and assessing the arguments for an against PIIP. In particular, the Commission should determine whether the economic rationale for counteracting price outcomes under the Pharmaceutical Benefits Scheme (PBS) remains credible.

2. Examine the effectiveness of PIIP, by establishing whether PIIP is:

   (a) Meeting its policy objectives, including whether it is levering additional investment, production and research and development on top of what would have happened in the absence of the program; and

   (b) Producing net benefits for the Australian economy as a whole.

3. Examine the efficiency of the PIIP, taking into account all the costs involved with the program's administration and compliance.

4. Examine, if it is found that intervention in the pharmaceutical industry is justified, whether PIIP is an effective form of intervention, or whether alternative interventions would be more efficient and effective. In particular, if a continuing need to counteract price outcomes under the PBS is established for post 2004, identify possible policy and program measures to do this, with an assessment of each option.

In making assessments in relation to the effectiveness of the program (and without limiting the methods the Commission may wish to determine these questions) the Commission is to:

1. Define the pharmaceuticals industry as all those who contribute to the discovery, development, manufacture and supply of pharmaceutical products and services in Australia, thus including the bio-medical sector;

2. Compare the economic activity of the program participants, both pre- and post-participation in the program, with the activity of non-participants across the

Australian pharmaceutical industry, taking into account residual effects of the earlier Factor (f) Scheme;

3. Compare activity undertaken with that foreseen by both successful and unsuccessful PIIP applicants;

4. Where data are available, compare the activity of Australian subsidiaries of multinational firms with subsidiaries in other countries;

5. Consider the factors both internal and external to the program, that have enhanced or limited the program's effectiveness;

6. provide an indication of the robustness of any conclusions, particularly given that data exist only for the first three years of the PIIP; and

7. Consider whether the program is meeting the current requirement that the Pharmaceutical Benefits Pricing Authority take into account the level of activity being undertaken by the company in Australia, including new investment, production, research and development (Factor (f)).

The Commission will produce an interim report by November 2002 and a final report by January 2003. The final report is to be published.

IAN CAMPBELL

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Contents

Abbreviations

ANAO	Australian National Audit Office
APMA	Australian Pharmaceutical Manufacturers Association
ATO	Australian Taxation Office
BIE	Bureau of Industry Economics
CJD	Creutzfeldt-Jakob Disease
DHFS	Department of Health and Family services
DIST	Department of Industry Science and Tourism
FDI	Foreign Direct Investment
IAC	Industries Assistance Commission
IC	Industry Commission
IDP	Industry Development Plan
IP	Intellectual Property
IR&D	Industrial Research and Development
IRD	Induced Research and Development
ITR	Department of Industry Tourism and Resources
IVA	Induced Value Added
MEB	Marginal Excess Burden
MNE	Multinational Enterprise
NME	New Molecular Entity
NSB	Net Social Benefit
OECD	Organisation for Economic Cooperation and Development
OTA	Office of Technology Assessment
OTC	Over the Counter
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme

PC	Productivity Commission
PhRMA	Pharmaceutical Research and Manufacturers of America
PIIP	Pharmaceutical Industry Investment Program
PVA	Production Value Added
R&D	Research and Development
RPBS	Repatriation Pharmaceutical Benefits Scheme
TGA	Therapeutic Goods Administration
TOR	Terms of Reference
VA	Value Added
WTO	World Trade Organisation

Glossary

Additionality	the extent to which a program (such as the PIIP) increases activity above what it would have been in the absence of the program.
Formulary	Refers to a book containing a list of pharmaceutical substances along with their formulas, uses, and methods of preparation that are available at subsidised prices to patients.
Generics	Drugs that are not / no longer under patent and manufactured by non-originator firms.
Inducement	See Additionality.
Me-too	A branded drug that targets the same disease as a new innovative drug but which has been developed later.
New innovative	A new drug that addresses substantially new disease targets.
Off-patent	A product for which the patent has expired.

OVERVIEW

Key points

- The Australian pharmaceutical industry is a major and innovative contributor to the economy, with a high R&D intensity, a skilled workforce and high wages. However, pharmaceutical firms perceive the low prices they receive under the Pharmaceutical Benefits Scheme as a deterrent to activity in Australia.

- The Pharmaceutical Industry Investment Program (PIIP) is intended to induce domestic activity lost as a result of such price suppression.

- The PIIP has been effective in stimulating R&D and, to a lesser extent, value added in production. It has also had broader benefits for the capabilities of the industry, for example, by shifting R&D to more complex areas.

- Despite this effectiveness, the program is not likely to make Australia better off overall.
    - Its major rationale — to help counter the effects of low PBS prices on pharmaceutical activity — is, by itself, insufficiently strong to justify a tax-funded program, with the costs that this entails.
    - Notwithstanding some benefits, particularly from spillovers associated with R&D activity, it is likely that the program generates net costs for Australians. This mainly reflects the distorting costs of raising taxes and the difficulties in targeting the program that lead to significant transfers abroad.
    - It has some inflexibilities in its design that reduce its benefits.

- There are, nevertheless, some policy impediments to the industry — particularly the inability of many pharmaceutical firms to effectively access the R&D Tax Concession, as well as the persistence of some PBS-related effects — which provide grounds for policy action. A replacement program — significantly modified from the current PIIP — is warranted. Given the prospects of high additionality and significant spillover benefits, a modified program, re-oriented to only R&D, is likely to generate net benefits for Australia as a whole.
    - Other design changes would also produce dividends, such as providing more scope for high calibre applications after program commencement.

- There are grounds for changing patent law to permit Australian producers of generic drugs to export to countries where patents have expired during the period of the Australian patent extension.

Overview

The Australian pharmaceuticals industry is often seen as emblematic of 'new economy' manufacturing. It exhibits high skill levels with associated high wage rates. Knowledge generation is a core activity, with the industry having a substantial R&D intensity by Australian manufacturing standards. It also has a strong global orientation through ownership links to multinational enterprises (MNEs) and through increasing exports, especially to the Asia-Pacific region.

Australia has some key advantages for the location of pharmaceutical activity, such as excellence in its public and university medical research infrastructure, a high quality clinical research capability, relatively low R&D costs, good access to the region and low sovereign risk. Innovative biotechnology companies, which are growing strongly in Australia, are providing a valuable source of new therapeutic substances and more efficient research technologies for the pharmaceutical industry.

Against these advantages, many in the industry perceive that the Commonwealth's purchasing arrangements for drugs through the Pharmaceutical Benefits Scheme (PBS) act as a constraint on the development of the local industry. In essence, this is attributed to low prices resulting from the operation of the PBS, designed to benefit Australian consumers and taxpayers.

Subsidies for drug purchases by patients apply only to the drugs listed on the PBS. This provides the Commonwealth with strong bargaining power when determining prices for drugs to be listed. Combined with a requirement that new drugs meet demanding cost-effectiveness standards, this has resulted in Australian drug prices being lower than in most developed countries. The industry claims that these low prices — termed 'price suppression' — and problems in listing new drugs, adversely affect production and R&D activity in Australia.

The Pharmaceutical Industry Investment Program (PIIP) is the most recent of a set of Commonwealth industry support arrangements aimed at offsetting the perceived influences of the PBS on the activity of Australian pharmaceutical firms (box 1). The PIIP, introduced in 1999 to replace the Factor f scheme, is due to expire in 2004. This review — requested by the Government — considers whether the program:

- has a credible rationale;

- is effective in achieving its objectives of increasing value added and R&D activity, and assisting in the development of a sustainable pharmaceutical capability in Australia;

- generates overall benefits for Australians (the efficiency test); and

- should be continued or modified.

Box 1   **The Pharmaceutical Industry Investment Program (PIIP)**

The PIIP commenced on 1 July 1999 and will run to 30 June 2004. Acceptance into the program was competitive, based on assessment of the relative merits of the production and R&D activity commitments proposed by each company.

Participating firms are paid subsidies for eligible R&D and production value added that exceeds prescribed base levels — the program is designed to reward only incremental activity. A fixed base applies to R&D and a moving base is used for value added. The subsidy rate is 20 per cent.

Subsidies are only available to the extent that a firm faces prices for its PBS-listed drugs that are below those in the European Union. Accordingly, only firms that supply the PBS are eligible to participate.

There are nine firms participating in the program (from among 22 original applicants in 1998). Three of these are domestically-owned firms and six are Australian subsidiaries of large multinational pharmaceutical companies.

Over the three years from 1999-00 to 2001-02, the program has paid subsidies of around $140 million to participants (of which the majority, $113 million, was for value added). Over its full five year term, participating pharmaceutical companies will receive approximately $300 million.

What are the rationales?

Do Australia's PBS arrangements justify the PIIP?

The main stated rationale for the PIIP is that price suppression has an adverse impact on pharmaceutical activity in Australia. It is argued that this justifies offsetting subsidies for firms facing price suppression.

For the price suppression argument to have merit, it must be demonstrated that:

- price suppression exists;

- price suppression damages pharmaceutical profits;

- low profits or other facets of price suppression lower domestic activity; and

- such lower activity has adverse allocative efficiency effects relative to a benchmark in which prices are higher.

It appears likely that the first two conditions are met to some degree:

- A recent survey by the Commission (PC 2001) confirmed that Australian prices are indeed lower than in many other developed countries, though less so for 'innovative' pharmaceuticals. While several factors contribute to international price differences, it is likely that the Australian Government's purchasing arrangements for drugs have reduced domestic drug prices, particularly through the use of reference pricing.

- It is probable that the operation of the PBS has reduced profits in the industry, although the effect of price suppression on pharmaceutical firm profits is partly offset by higher volumes of sales. (This reflects the large subsidies to consumers for drugs listed on the PBS.)

However, it is less clear that the remaining two conditions relating to lower activity are satisfied to the extent needed to form a strong rationale for government intervention.

For those (typically globally operating) firms that derive only a small proportion of their income from Australian sales, lower profits arising from price suppression need not mean reduced activity in Australia. Once a firm has decided to list a drug at its suppressed price, it no longer faces a question of *how much* to supply (that is now demand-determined), but *where* to supply it from. It can do so through imports or through varying degrees of local manufacture. Whether it makes the drugs locally or not will depend primarily on production considerations — such as relative costs, quality, sovereign risk, preservation of intellectual property and supply reliability — and not on realised prices. All other things being equal, if these criteria are best met by Australia, then it is likely that production will take place in Australia.

The story may be different for any pharmaceutical firms that primarily depend on the Australian market. Such firms (in all likelihood Australian-owned) may be more highly exposed to the Australian market because they seek to list their product in Australia first or find it hard to get access to global markets quickly. Where they are exposed in this way, low prices for in-patent drugs would reduce the overall return to innovation and dampen incentives for future innovation.

There may also be other subtle links between price suppression and adverse effects on pharmaceutical activity in Australia. In particular:

- Listing and volume constraints under the PBS may reduce options for R&D and production. For example, if a drug is not listed in Australia, it would be less likely to be manufactured locally for export markets, because economies of scale

are reduced in the absence of local production. Many new drugs are not listed in Australia. However, no country comes close to listing all new molecular entities. Moreover, the evidence suggests that new drugs that are listed in Australia account for a bigger share of pharmaceutical expenditure than in many other countries.

- – However, there is some evidence that, over the last two years, drugs with the potential for large budgetary impacts for government have faced longer delays in listing on the PBS than in the past. To the extent that the problem is severe, the appropriate response would be to reform PBS listing processes, rather than have an industry support program.

- Price suppression could also result in the head offices of some pharmaceutical firms forming the view that the Government is not supportive of the development of the industry in Australia. In turn, this may be interpreted by MNE headquarters as signalling that the Government may not be prepared to work with industry to address other barriers to investment locally, such as those arising from taxation or regulation. Such uncertainty might inhibit investment in Australia.

The above factors could have adverse effects on pharmaceutical activity in Australia, but their overall impact is likely to be small. This is supported by empirical evidence suggesting that, while prices vary greatly around the world, these price variations do not seem to be related to the distribution of pharmaceutical activity among countries. (Moreover, any deficiencies in PBS listing processes would need to be addressed directly, rather than through an industry assistance program — reflecting the fact that the major impacts of such deficiencies would be felt by Australian consumers.)

Nor is it clear, from an economic perspective, that any effects of price suppression on activity generate inefficiencies. This is because the pharmaceutical 'market' is riven with distortions and regulatory features that sometimes over-encourage production (such as 'leakage', when a drug is prescribed for conditions where that treatment is not justified on cost-effectiveness grounds) and sometimes discourage production. Even were these other effects not present, the inefficiencies associated with weak activity effects are likely to be small.

Overall, the rationale for assistance to the pharmaceutical industry based on price suppression is much less persuasive than conventionally claimed. Nonetheless, some adverse effects on activity are likely. While these effects may not themselves justify a program, they should be taken into account if there are additional grounds for an industry-specific program.

Are there other features of the pharmaceutical industry that provide a rationale for the PIIP?

A commonly held perception is that pharmaceutical industry development provides an additional rationale for the PIIP. As one participant contended, the 'PIIP is an industry development program masquerading as an antidote to the PBS'. The question therefore arises as to whether features of the industry could justify assistance of this kind.

It is likely that the Australian pharmaceutical industry produces indirect benefits for Australia beyond its direct contribution, particularly in relation to spillover and agglomeration effects from investments by pharmaceutical firms.

- The industry conducts a large amount of R&D and is an important source of collaboration and expertise to the biotechnology sector. This is likely to produce significant knowledge spillovers for other firms. But overall there is no evidence to suggest that spillover rates in the pharmaceutical industry are greater than in other industries. For example, large components of what is regarded as R&D in the industry — regulatory compliance with toxicology requirements and phase III and IV clinical trials — are not likely to be major sources of spillovers.

- There may be agglomeration benefits from attracting particular foreign firms with particular capabilities that can be diffused more widely. However, through Invest Australia there already exists a general mechanism for encouraging MNE investment to Australia. Under these arrangements, it is possible to assess the relative merit (benefits and costs) of attracting investment across all industries.

The point to emphasise is that the pharmaceutical industry is one of a variety of industries in which spillover and agglomeration issues arise. This explains why governments have crafted generic policies to deal with them, rather than develop policies for harnessing such benefits on an industry by industry basis.

One important policy consideration here is that R&D undertaken by a foreign MNE is not eligible for the R&D Tax Concession unless the intellectual property (IP) is Australian-owned. This is not consistent with the major rationale for the concession, which is to support R&D for its accompanying spillovers, not for the private benefits it generates for the firms that own the IP. The restriction effectively cuts off access to the concession by foreign pharmaceutical MNEs since they generally hold their IP in their head office country. The present restriction provides a prima facie case for either modifying the R&D Tax Concession or, if that is not appropriate or practicable, using some other instrument to support R&D by such firms in the pharmaceutical industry.

How effective has PIIP been?

The main targets of the PIIP are increased value added in production and R&D activity in the local pharmaceutical industry. The design of the program increases the likelihood of inducing activity because only incremental activity is eligible for subsidies.

Using survey and administrative data, the effectiveness of the program was estimated by examining differences between:

- the pre and post PIIP performance of participants and non-participants; and

- levels of activity forecast under the PIIP by applicants and the actual levels achieved. This is a good test of whether the program is effective at stimulating activity since, if it were, unsuccessful applicants should not achieve the targets set down in their applications without the program subsidies. This 'forecast errors' approach is a relatively robust technique, since it controls for unobserved differences between firms.

Other factors, such as past participation in the Factor f program, differences between applicants and non-applicants and firm size, that may have obscured the real effects of the PIIP, were controlled for in the empirical analysis. Case studies provided useful indications of the program's effectiveness for some participants.

The evidence provides mixed signals about the program's effectiveness in stimulating production:

- comparisons of production levels between participants and non-participants from 1998–99 to 2001–02 suggest that value added has been strongly stimulated by the program, as does evidence on the changing structure of production (for example, the import share of sales would have been higher amongst program participants in the absence of the program);

- against this, analysis using the 'forecast errors' approach suggests only a modest inducement rate;

- comparisons of the production activity in the three years of the PIIP with the activity in the three preceding years suggest no effect at all; and

- comparisons of the employment, investment and export trends suggest weak overall effects of the PIIP so far on productive capability. (Confounding factors such as outliers in the data and the prevalence of outsourcing may result in some underestimation of the real short-run response of firms in these areas.) Longer-run responses — especially for investment — could be expected as capacity utilisation rises.

On the other hand, stronger and more consistent evidence of positive effects on R&D were found using all methodologies (although, as with the production results, large variability between firms means that the point estimates have wide confidence bounds). The estimates of the amount of additional R&D generated by the program per dollar of subsidy — the 'bang for a buck' — are much higher than have been found for other R&D incentives in Australia and internationally.

In addition to its effects on R&D expenditure, the program also appears to have increased the relative importance of phase I and II clinical trials and to have increased R&D employment. Its effect on collaborative R&D is uncertain.

Overall, the empirical analysis, bolstered by case studies, suggests that the PIIP has induced a significant amount of new R&D and, to a lesser extent, value added activity among participants. It also appears to have strengthened the capabilities of PIIP participants in diverse ways, such as by increasing the complexity of the research they undertake.

Efficiency

The Commission used a benefit-cost framework to assess the net benefit to Australia as a whole (or efficiency) of the program. Under this framework, the benefits of the PIIP include:

- any benefits from R&D spillovers;

- the benefits from particular broad activity commitments, such as health education programs, fellowships, training and sponsorships, that were facilitated through the program;

- consumer health benefits arising from drugs that were only listed because their price was supplemented by PIIP funds; and

- the possible benefits from shifting resources to higher value uses in the pharmaceutical industry.

The main costs are those that inevitably arise from tax-funded policy interventions. These are:

- the distorting costs of raising taxation revenue to fund the program; and

- the costs of leakages to foreign shareholders of subsidy payments that do not induce new R&D or value added. These costs reflect the difficulties in targeting subsidies on only additional activity.

It is highly likely that, under the *current* design, the costs of the PIIP have exceeded the benefits and would continue to do so. This is a robust result that could only be overturned with highly optimistic scenarios for key parameters.

At a more detailed level, payments for R&D are likely to have generated benefits that exceed the costs, but with the program's current emphasis on production subsidies, these have not been sufficient to generate an overall net benefit for the PIIP as a whole. Were the scheme to be re-oriented to R&D only, there is a strong likelihood of net gains with an expected return to subsidies of about 70 per cent. In such a scheme, the net benefits to Australia from R&D activities by both domestic and foreign firms are likely to be positive (unlike under the present PIIP design that has an estimated net cost for payments to foreign firms).

Conclusions

The future of the PIIP

The existing PIIP has several limitations that suggest change is warranted:

- its principal rationale — the effects of price suppression on activity — is not as strong as commonly supposed;
- the program is unlikely to generate net benefits; and
- it has several design limitations that inhibit desirable flexibility.

Despite these limitations in the current program, there remains a case for action to address the effective inability of foreign pharmaceutical MNEs to access the R&D Tax Concession and, where the costs of intervention permit, the adverse effects of the PBS on pharmaceutical activity in Australia.

The R&D Tax Concession could be modified, either by relaxing the provisions relating to IP ownership for all MNEs or developing a 'ring-fenced' concession for the pharmaceutical industry alone. However, the initial analysis suggests that a broad change to the R&D Tax Concession could, among other things, risk tax revenue on royalty streams and could be open to abuse. These implications would warrant substantive and detailed consideration before any implementation. The Commission's inquiry into automotive assistance (PC 2002, pp. 84–86) indicated the desirability of an independent review of Australia's general support measures for R&D around 2005. Part of any such review could reconsider whether general changes in the beneficial owner requirements would be warranted, taking account of the issues raised above.

The ring-fencing proposal also has some major limitations that suggest it is not a practicable route for providing an incentive to R&D in the pharmaceutical industry. It would complicate the existing R&D Tax Concession and introduce some definitional complexities. It largely fails to address the impacts of the PBS on the pharmaceutical industry.

In that context, a modified PIIP, re-oriented to R&D, is a superior policy option. Other changes to the program would resolve some of its other design limitations. Overall, a new PIIP should have the following features:

- *be refocussed towards subsidising only R&D*. This reflects the rationale for action. Given the prospects of high additionality and significant spillovers, a program focusing only on R&D would be likely to generate net benefits for Australia as a whole. The omission of production value added reflects the fact that, while some activity may have been lost as a result of the PBS, the costs of policy intervention overwhelm the benefits of offsetting these losses. Concentrating on R&D could also make a 'bigger splash in a smaller pond', which may better help make an impression on multinationals' perceptions of the Australian environment;

- *be open only to pharmaceutical firms with products listed on the PBS*. This eligibility condition best targets those firms that cannot effectively access the R&D Tax Concession, and domestic firms and foreign MNEs affected by the PBS. The domestic biotechnology industry, while outside the scope of the program, would still benefit through collaborations and other interactions with the pharmaceutical industry;

- *have multiple entry and exit points for participants*. For example, a six year program would allow three entry tranches. This design change would overcome the present problem that entry can only occur at the program start — with the choices of gaining entry to the program dependent on the vicissitudes of drug breakthroughs and supply pipelines at that single date;

- *have competitive entry criteria* that emphasise undertaking beneficial activity that would not otherwise occur; and

- *maintain capped total funding*.

Other measures relevant to the pharmaceutical industry

In addition to the recommended modifications to the PIIP outlined above, there are several other measures that deserve further consideration with respect to the pharmaceutical industry.

Clause (f)

When setting prices, clause (f) requires the Pharmaceutical Benefits Pricing Authority (PBPA) to take account of 'the level of activity being undertaken in Australia, including new investment, production, research and development.'

One view is that, by subsidising Australian activity where firms face suppressed prices, the PIIP meets the objectives of clause (f). However, there is some unease within the Pharmaceutical Benefits Pricing Authority (PBPA) whether this is the case. In particular, many pharmaceutical firms facing apparent price suppression are unable to access the program because of its competitive entry requirements and capping. Given that the structure of the PIIP militates against it effectively fulfilling clause (f), it is unclear how to interpret and act on the clause in a fashion that is likely to be beneficial to Australia.

Indeed, the only way to fulfil the clause effectively would be to raise PBS prices (which could be achieved in several ways, such as tying prices of Australian-manufactured drugs to 'world' prices, or using rate of return regulations, as used in the UK). Price hikes, especially at the level sought by the industry, would have substantial effects on the Government's budget and/or costs to patients, and would not generate sufficient offsetting benefits. Were the price hikes to be limited to Australian manufactured drugs, they would also have the potential to severely distort resource allocation and conflict with WTO obligations.

Clause (f) is redundant. This is one Gordian knot that can be cut safely. Clause (f) should be deleted from the guidelines issued to the PBPA by the Government.

The operation of the PBS

Pharmaceutical companies have raised a number of concerns about the recent operations of the pharmaceutical regulatory bodies, the Pharmaceutical Benefits Advisory Committee (PBAC) and the PBPA, as well as the approval process for listing new drugs on the PBS. These include claims:

- of excessive recent delays in approving drugs, as in the case of Avandia;

- that cost-effectiveness methodology is being vitiated by an increased emphasis on cost containment; and

- that the PBAC does not adequately recognise some clear and quantifiable benefits (such as enabling the patient to return to work sooner) when assessing cost-effectiveness.

The Commission has not been in a position to assess such claims in this review. To the extent that the problems are serious and sustained, they raise concerns that listing processes could damage perceptions of Australia as a location for pharmaceutical activity, apart from the implications for timely patient access to new drugs. There were widespread calls by participants in this evaluation for a review of the current PBS arrangements.

Exporting generics

Under Australia's patent law, Australian producers of generic drugs are unable to manufacture and export to countries where patents have expired while the extended Australian patent is still in force. This is an unintended impact of Australia's patent extension arrangements. It acts as an impediment to the growth of generic manufacturers, as their competitiveness depends on reaching markets as soon as possible after the original patent expires. Changing the existing provisions to enable generic manufacturers to export during the patent extension period to markets where the patent has expired would have no effect on branded manufacturers. It would allow Australian generic manufacturers to compete in overseas markets with foreign generic manufacturers.

Recommendations and findings

Recommendations

Dealing with deficiencies of the PIIP

<div align="right">RECOMMENDATION 7.1</div>

Upon the expiry of the PIIP in 2004 the Government should put in place an R&D-only subsidy program for the pharmaceutical sector. The program should:

- *provide subsidies for R&D;*
- *be open only to pharmaceutical companies with products on the PBS;*
- *have its total funding capped;*
- *have entry based on competitive criteria that emphasise undertaking beneficial activity that would not otherwise occur;*
- *include more than one entry point; and*
- *have a duration of five to six years (six years would allow three entry tranches). (page 7.23)*

Other measures

<div align="right">RECOMMENDATION 8.1</div>

Clause (f) should be deleted from the guidelines issued to the Pharmaceutical Benefits Pricing Authority by the Commonwealth Government. (page 8.4)

<div align="right">RECOMMENDATION 8.2</div>

There are strong economic grounds for Australia's intellectual property legislation to be amended to allow generic drug manufacturers in Australia to export to countries where patents have expired during the period of the Australian patent extension. (page 8.13)

Findings

Compensating for the Pharmaceutical Benefits Scheme

FINDING 3.1

Bargaining power arising from Australia's PBS arrangements almost certainly lead to lower prices, but the exact price effect is unknown given other influences. (page 3.13)

FINDING 3.2

While volume effects partly counteract the effects of price suppression, it is still likely that the overall impact of price suppression on net revenue remains negative. (page 3.18)

FINDING 3.3

Once a decision has been made to supply the Australian market, price is likely to be much less relevant to global location decisions by pharmaceutical MNEs than other factors such as costs and quality. (page 3.22)

FINDING 3.4

Low PBS prices for drugs may adversely affect incentives for future investment in innovation by any pharmaceutical firms that draw a significant share of their global revenue from Australian demand. (page 3.24)

FINDING 3.5

To the extent that it affects profits, the operation of the PBS could affect pharmaceutical activity by exacerbating liquidity constraints, particularly for domestically owned firms not able to access global capital. However, given that there are better ways of overcoming liquidity constraints, they provide a weak rationale for compensation to pharmaceutical firms. (page 3.26)

FINDING 3.6

Price suppression and PBS listing problems may create a wider adverse perception by head offices of the suitability of Australia for pharmaceutical activity. This may have possible effects on investment decisions in some cases. In general, however, it appears that large MNEs are deliberative and hardheaded in their investment allocation decisions, using decision-making processes based on business fundamentals. (page 3.28)

Country of origin pricing by other countries does not provide a credible rationale for compensation for PBS pricing in Australia. (page 3.30)

Problems in PBS listing could have some effects on activity. However, these would best be countered by targeting them directly. (page 3.35)

While MNEs may possess some additional bargaining power associated with the perceived desirability of pharmaceutical activities, this power is not likely to be very substantial. (page 3.37)

The empirical evidence that pharmaceutical pricing significantly influences production activities is not strong. However, this does not rule out weak effects, which would be hard to detect using the data that are available. (page 3.41)

Overall, while the activity of some individual firms may be affected by PBS-related factors, it is likely that the aggregate effects are relatively small. (page 3.41)

The rationale for assistance to the pharmaceutical industry based on price suppression is much less persuasive than conventionally claimed. Nonetheless, some effects on activity are likely. While the magnitude of these effects may not justify a program by themselves they should be taken into account if there are additional grounds for an industry-specific program. (page 3.46)

Other rationales

There is no persuasive evidence to suggest that pharmaceutical activity leads to higher spillover rates than other industries, though they are still likely to be appreciable. (page 4.6)

FINDING 4.2

Intellectual property ownership requirements effectively reduce access by the Australian subsidiaries of foreign multinational enterprises to the R&D Tax Concession. Unless countered by other initiatives, this may lead to lower levels of pharmaceutical R&D in Australia than ideal. (page 4.17)

FINDING 4.3

The PIIP is not well geared to attract FDI. Promoting FDI should be done by getting the broad policy settings right, not through an industry specific program. (page 4.20)

FINDING 4.4

It is implausible that mis-perceptions by head offices about Australian capabilities are widespread. Multinational pharmaceutical firms have had an involvement in Australia over several decades — many with production and research facilities. In any case, there are more efficient direct ways of dealing with mis-perceptions than subsidising activity. (page 4.23)

FINDING 4.5

A desire to secure access to drugs in times of crisis is not a compelling rationale for assistance to the pharmaceutical industry. Where a need of domestic access to drugs can be made — on the basis of sound risk management analysis — other options appear more realistic. (page 4.23)

Effectiveness of the PIIP

FINDING 5.1

While the empirical results are mixed, on balance the analysis suggests that the PIIP has induced a significant amount of new R&D and, to a lesser extent, value added activity among participants, and has strengthened the capabilities of participants in diverse ways. (page 5.31)

Efficiency of the PIIP

While there are some benefits from the PIIP, inefficiencies in raising funds for PIIP subsidies and the inability to perfectly target the scheme make it more likely than not that the program produces net costs for the Australian economy as a whole. However, the R&D component of the scheme appears to generate net benefits. (page 6.24)

1   Introduction

The pharmaceutical sector is a major and innovative industry. It is a critical part of the health care sector. Its products are the source of major benefits for Australians. It is a major employer and pays high wages relative to most other sectors. This reflects the high skill intensity of the industry and the importance of R&D — it is one of the most R&D intensive industries in Australia. Increasingly, the industry has forged alliances with the growing biotechnology industry, whose boundaries with the pharmaceutical industry are blurring.

Australia imports most of the active ingredients used to manufacture pharmaceuticals. However, it is an important regional hub for the formulation and packaging of drugs, mainly by the subsidiaries of globally operating firms. Exports of human-use pharmaceuticals were around $1.4 billion in 1999-00 and increased in real terms by about 17 per cent per annum over the last 4 years.

The industry is concerned that the Commonwealth Government's purchasing arrangements for drugs, the Pharmaceutical Benefits Scheme (PBS), is a major deterrent to the development of the industry. The PBS, which accounts for the lion's share of prescription medicines sold in Australia, sets drug prices that are lower in Australia than most other developed countries. The processes for listing drugs on the PBS are also demanding and often lengthy. The industry claims that low prices associated with these purchasing arrangements — termed 'price suppression' — are a disincentive for head offices of multinational enterprises to locate activity in Australia.

Responding to these concerns, since 1988, the Australian Government has provided industry assistance to partially compensate some, but not all, pharmaceutical firms for price suppression. The Pharmaceutical Industry Investment Program (PIIP) is the most recent of a series of arrangements aimed at stimulating Australian pharmaceutical activity. It provides firms with notional PBS price increases for drugs in exchange for undertakings by firms to increase value added, R&D and other eligible activities in Australia. Entry to the program is competitive, based on a comparative assessment of firms' applications, with nine firms currently receiving assistance.

As the PIIP is due to expire in 2004, the Government needs to determine whether it should be replaced with a new program. It requested the Commission to undertake

an evaluation of the PIIP to inform that decision. The main focus of the terms of reference is on the appropriateness, effectiveness and efficiency of the program.

1.1   Overview of the Pharmaceutical Industry

The Australian pharmaceutical industry is an integrated part of the global industry. Subsidiaries of MNEs undertake a significant proportion of pharmaceutical activity in Australia, although there are also some large Australian owned companies within the industry (particularly producers of out of patent drugs).

Under the terms of reference, the definition of the pharmaceutical industry is all those who contribute to the discovery, development, manufacture and supply of human-use pharmaceutical products and services in Australia, including the bio-medical sector.

At different points in the evaluation, the definition used can be wider or more narrow than this. For example, in assessing the impacts of the PBS on pharmaceutical activity — the underpinning for the PIIP — the focus is on firms that supply the PBS. At other times — for example, when discussing industry trends — the industry includes all human-use drugs, both those available through prescription or over-the-counter. Key features of pharmaceutical R&D and manufacturing in Australia are discussed below, followed by a brief discussion of the biotechnology sector.

Pharmaceutical Research and Development

R&D is the lifeblood of the pharmaceutical industry, which relies on developing safe and effective new products to maintain and sustain growth.

Pharmaceutical R&D involves drug discovery, pre-clinical testing and clinical trials (which test new drugs for efficacy and safety). In addition, discovery research depends upon basic research, which seeks to understand human biology and disease processes. The majority of basic medical research in Australia is undertaken by public institutions — over half of all human health-related biological research in Australia is funded by the Commonwealth Government and undertaken by universities, medical research institutes, the Commonwealth Scientific and Research Organisation (CSIRO) and in conjunction with industry via Cooperative Research Centres (table 1.1).

Table 1.1 Human health related biological sciences[a] and pharmaceutical industry R&D[b], 1996-97 to 2000-01

	1996-97	1998-99	2000-01	Real growth 1996-97 to 2000-01[c]
Human health related biological sciences	$m	$m	$m	%
Public and non-profit R&D	606	637	748	3.2
Business R&D	126	146	278	19.4
Total	732	783	1026	6.6
Pharmaceutical industry R&D	122	158	199	10.7

a Includes business, non-profit and public sector research into: Biochemistry and cell biology; Genetics; Microbiology; Physiology; Biotechnology; Other biological sciences; Immunology; Medical biochemistry and clinical chemistry; Medical microbiology; Pharmacology & pharmaceutical sciences; Medical physiology; and Neurosciences. All expenditures are nominal values, although the growth rate is based on real values. **b** R&D expenditures undertaken by ABS ANZSIC code 2543. This will include some R&D that would not be categorised as R&D in the human biological sciences (for example, process R&D). In that context, the ratio of pharmaceutical R&D to total R&D in the human biological sciences provides a good, but not perfect indicator of the importance of pharmaceutical industry R&D to this area of research. **c** This is the real compound growth rate over this period, using the GDP deflator for converting nominal to real values.

Data source: ABS 2002b, ABS 2002c.

Total R&D spending by pharmaceutical companies in Australia is around $200 million annually. Recent data on the proportion of expenditure on each component are not available, however, clinical trials have been growing and comprise the largest component. Medicines Australia (APMA 1996) report that in 1994, clinical trials comprised 42 per cent, pre-clinical research 22 per cent, process research 18 per cent and basic research 13 per cent of the total expenditure by pharmaceutical companies.[1] The human-use pharmaceutical industry accounts for a significant share of total business expenditure on R&D (with a 4.1 per cent share in 2000-01). It also has a much higher R&D intensity than manufacturing as a whole (with R&D accounting for around 4.9 per cent of turnover in the pharmaceutical industry in 1999-00, compared with 0.9 per cent for manufacturing as a whole).

The growth in clinical trials is a major contributor to rising industry R&D expenditures. The number of Australian clinical trials rose from around 530 in 1992-93 to around 2000 in 2000-01 (ITR 2002a, p. 14).

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[1] In 1991-92, APMA reported basic and pre-clinical accounted for 19.3 per cent of the total.

Pharmaceutical Manufacturing

Pharmaceutical production is an integrated process that often involves several intermediate stages undertaken within different production facilities. The major stages are:

- manufacturing the 'active' ingredient (primary manufacture);

- formulation, where the active ingredient is 'mixed' and combined with non-active ingredients (fillers, etc) and then compounded into dosages (tablets, liquids, or other delivery mechanisms); and

- packaging and labelling of bulk formulations according to specific country requirements.

Most innovative drugs under patent will be manufactured by one multinational firm. Typically, these firms will maintain one to two large scale actives plants and multiple secondary manufacturing facilities worldwide.

Other than alkaloid production by GlaxoSmithKline and Janssen-Cilag, based around the Tasmanian poppy industry, there is little large-scale manufacturing of active ingredients undertaken in Australia. IDT, a Victorian-based company performs niche manufacturing of actives on a contract basis for a range of companies, including pharmaceutical MNEs, while CSL maintains a biopharmaceutical manufacturing operation in Melbourne. The Australian Nuclear Science and Technology Organisation manufactures and supplies radiopharmaceuticals and radioisotopes for use in nuclear medicine and for research purposes (sub. 18).

Thus, manufacturing industry in Australia mainly comprises secondary manufacturing — formulation and packaging and labelling activity. Table 1.2 shows sales of drugs in Australia by degree of manufacture. At least 10 companies operate at least one secondary manufacturing facility supplying the domestic and export markets (ITR 2002a).

Reflecting the rationalisation and consolidation of the industry globally, there have been several mergers and acquisitions involving the subsidiaries of MNEs in Australia. The merger and acquisition activity of companies involved in the PIIP is described in chapter 2.

Another important distinction between manufacturers is between producers of drugs that are under patent (often termed research-based producers) and those that manufacture drugs when the patent has expired (often known as generic producers). In Australia, while the bulk of pharmaceutical manufacturing is undertaken by research-based companies, there are also several generics producers. In Australia,

sales of generics account for ten per cent of total PBS sales (Stevens 2000) and a somewhat greater share of Australian-based production of pharmaceuticals. The generics share of PBS sales doubled in the eight years to 1998-99.

Table 1.2   **Sales by degree of Australian manufacturing, 2001-02**

Extent of manufacture	Share of total pharmaceutical sales
	per cent
Fully imported products	43.6
Products imported fully finished in bulk and packaged locally	18.1
Products formulated and packaged locally from brought-in active ingredients	33.6
Other goods and services[a]	4.7
Total	100.0

a Includes actives manufacture.

Source: Productivity Commission survey.

Gaining a perspective on the size of, and trends within, the pharmaceutical industry, is dependent on defining the boundaries of the industry, which vary significantly across different information sources.

The Pharmaceutical Industry Action Agenda presented data from the ANZSIC class 'Medicinal and pharmaceutical product manufacturing' (ABS 4-digit industry classification 2543). This classification includes veterinary, vitamin and face cream products, in addition to human-use pharmaceuticals. In order to obtain figures for just human-use pharmaceuticals — which is what the PBS and thus the PIIP apply to — a special data request was made to the ABS for more detailed manufacturing and R&D data. Human-use trade figures were obtained from ITR.

The ANZSIC and human-use classifications of the ABS manufacturing data only include information for establishments that generated the majority of their turnover from the sale of Australian manufactured products (these sales can be partially or fully manufactured in Australia). As such, these figures under-report the size of the pharmaceutical industry by omitting the activity of establishments that predominantly generate sales from imported pharmaceuticals (these establishment are instead classified as pharmaceutical wholesalers, ANZSIC 4796).[2]

Nevertheless, the manufacturing data are the most detailed and complete source for trends in value added, turnover, employment and wages in the Australian industry over the late 1990s. In addition, the contribution of the manufacturing sector is of

[2] Medicines Australia (APMA 2002) estimated that the turnover of the pharmaceutical industry, including wholesaling, was $6.99 billion in 1999-00.

particular interest, because one of the focuses of the PIIP is on encouraging domestic manufacturing activities.

Table 1.3 shows key industry statistics for the ANZSIC and human-use classifications.

Table 1.3 **Pharmaceutical manufacturing industry, key statistics**

	Human-use pharmaceutical Manufacturing			ANZSIC 2543 from the Action Agenda [a]		
	1995-96	1999-00	Real compound annual growth	1995-96[a]	1999-00	Real compound annual growth
	$m	$m	%	$m	$m	%
Turnover [b]	2 905	3 742	5.2	3 757	5 360	7.9
Value added	944	1 157	3.9	1 280	1 625	4.8
R&D [c,d,e]	123	182.5	9.0			
Profit	363	436	3.4			
Capital expenditure	162	298	14.9			
Employment	8 650	8 393	-0.8	11 500	13 700[d]	3.1
Wages and salaries	344	473	6.9	468	667	7.9
Exports [e]	720	1423	17.0	940	1 769	15.6
Imports [e]	1 486	3 099	18.6	2 017	3 829	15.9
Net imports	766	1 676	20.1	1 077	2 060	16.1
Establishments (No.)	70	95	7.9	187	212	1.9

[a] The IBIS figures quoted in the Action Agenda (ITR 2002) are broadly comparable, but differ slightly from the ABS 1999-00 Manufacturing Census and Merchandise Trade figures for ANZSIC 2543 (Medicinal and Pharmaceutical Product Manufacturing). Figures are nominal, except those used in the calculation of the growth rate. The real growth rates were calculated by deflating the nominal values by the GDP deflator and then computing the compound growth rate. The comparable ABS figures for nominal values in 1995-96 and 1999-00, and for compound real annual average growth rates are respectively: turnover ($3858m, $5360m, 10.1 per cent); value added ($1112m, $1625m, 9.9 per cent); employment (12 097, 12 722, 1.3 per cent), wages and salaries ($489m, $667m, 6.7 per cent); exports ($894, $1715m, 22.6 per cent); imports ($1831m, $3520m, 21.3 per cent); and net imports ($937m, $1805m, 20.0 per cent). [b] Turnover equals Australian based domestic and export production (valued at the amount of ex-manufacturer sales). [c] Medicines Australia survey data show larger R&D expenditure figures than the ABS. Medicines Australia's figures include Australian-based R&D expenditures funded by multinational headquarters in addition to the R&D expenditures funded by local subsidiaries. They record $254 million in R&D in 1995-96 and around $300 million in 1999-00 (an average real growth rate of 4.2 per cent). [d] R&D calculated on an ANZSIC basis. [e] R&D, import and export figures are for the Australian human-use pharmaceutical industry (excluding biotechnology), including establishments that predominantly generate sales from imported pharmaceuticals.

Source: ABS 2001, ABS 2002a ABS 2002b, ABS 2002f, ITR 2002a, ITR 2002b.

The table reveals that the industry has grown considerably since 1995. In particular imports and exports grew strongly, both at over 15 per cent per annum, illustrating the increased integration of the Australian industry with the global industry. Capital expenditure estimates for human-use pharmaceutical manufacturing show strong

levels of investment. The ANZSIC classification shows employment increasing, although the human-use classification shows a marginal decline between 1995-96 and 1999-00.

In 1999-00, the human-use pharmaceutical manufacturing industry's value added was 1.7 per cent of total manufacturing value added and was 0.2 per cent of GDP. Comparisons can also be made with other industries in the economy — the human-use pharmaceutical industry is around one third the size of the Motor Vehicle and Parts manufacturing industry and around one third the size of the Electrical and Appliance manufacturing industry.[3]

The industry also includes sales and marketing, primarily to promote sales to general practitioners and hospitals. Although data are not available for Australia — globally, pharmaceutical companies typically spend 25 per cent of turnover on marketing.

The biotechnology sector

Advances in the biological sciences are enabling an increase in the rate of development of novel human therapeutics. A large part of this work is being undertaken within private biotechnology firms. In Australia up to 70 per cent of these are spin-offs from public research. Some biotechnology/pharmaceutical research firms are also developing technologies that improve the efficiency of pharmaceutical research.

Partnerships are a feature of the biotechnology industry. Ausbiotech (sub. 14, p. 5) reports that:

> Because of the cost of developing pharmaceutical products, partnerships with MNCs are necessary to complete product development and to ensure the marketing and distribution strategies for the biotechnology company's products are maximised globally. Partnerships can include, but are not limited to, licence agreements, strategic alliances, contract research agreements and joint ventures.

According to Hopper and Thorburn's (2002) Bio-Industry Review, there were around 315 biotechnology firms in Australia in 2002. Around 65 per cent of products being developed by Australian biotechnology companies relate to human health, including pharmaceuticals, medical diagnostics and medical devices (Ausbiotech sub. 14, p. 5).

Between 1994-95 and 2001-02 the number of biotechnology firms has trebled. In 2001, the number of firms grew by 29 per cent and in 2002 by 9.5 per cent.

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[3] Industry size measured as value added.

In 1999-00, there were 35 core biotechnology firms listed on the share market. These firms had a turnover of around $900 million, and R&D expenditures of around $110 million (Ernst and Young 2001).

The listed companies in the Australian biotechnology sector grew strongly in the year to 1999-00 in terms of the numbers of new businesses, turnover and employment. While the sector made a loss in 1999-00, this reflects high R&D spending programs and firms that are in the start-up/investment phase of their operations.

1.2   Key issues and methodology

In line with its Act, the Commission must assess the PIIP from the perspective of the welfare of the community as a whole, not just the pharmaceutical industry or consumers of PBS drugs.

It should be emphasised that this report is an evaluation of the PIIP and whether it improves Australia's wellbeing, not an assessment of the pharmaceutical industry itself or its contribution to the Australian economy. For example, it is quite possible for an industry to be dynamic and productive, but for government interventions that support activity in that industry to be inefficient and/or ineffective.

The tests for a successful program are demanding. The conditions for a successful program are somewhat akin to that of a new drug: there must be an identified need, the intervention must work better than alternatives, it must be delivered appropriately and it must not have adverse side-effects that outweigh its advantages. Figure 1.1 sets out the key questions to determine whether the program should continue as is, be modified to improve its effectiveness, or be discontinued.

Clear and credible rationale

Any government business program or regulation must have a sound rationale. A government intervention may achieve all of its objectives, be well designed and implemented efficiently, and yet not be justified because it is founded on an inappropriate rationale. Indeed, the greater the effectiveness of an intervention with an inadequate rationale, the worse are its welfare implications. For example, governments have at times put in place controls that limited shop opening hours very effectively, but their removal has produced net benefits. Accordingly, a sound evidence-based rationale is a pre-requisite for any intervention.

The PIIP is premised on the notion that price suppression under the PBS adversely affects activity in the Australian pharmaceutical industry to the detriment of the economy as a whole. For that to be true, it is important to establish that:

- there is price suppression associated with the Government's bargaining arrangements under the PBS;

- any price suppression adversely affects pharmaceutical firms' profit;

- low prices for listed products threatens activity (or that the processes that lead to price suppression also lead to non-listing or other consequences that may be inimical to activity in Australia); and

- any lost activity results in an efficiency loss.

Figure 1.1   **Evaluation framework**
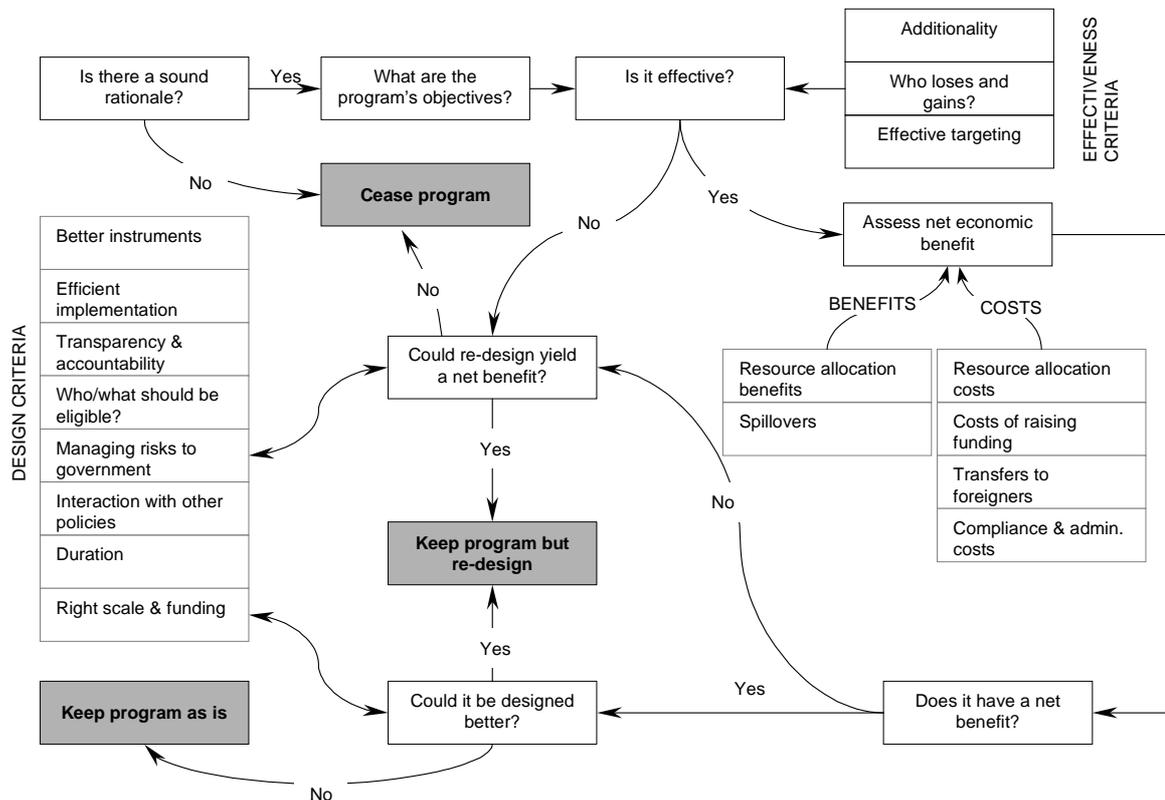
For a PIIP-type program to be warranted it also needs to be demonstrated that an industry assistance program is the correct remedy for the problems associated with the PBS — rather than more direct (ie PBS) solutions.

The pharmaceutical industry has also been viewed by government and industry members as a strategically important industry, embodying many of the characteristics of so-called 'knowledge economy' industries — high R&D

intensities, significant skilled labour demands, the prospect of securing niche global advantages for Australian firms and sustained strong growth rates. This view of the industry underlies policy interest in developing domestic capabilities in pharmaceutical production and R&D — and the associated biotechnology and biomedical industries.

Given the potential relevance of industry development in its own right, this evaluation also considers whether there may be rationales for assistance to the pharmaceutical industry based on factors other than price suppression — for example, whether it gives rise to substantial technological spillovers or succeeds in attracting 'footloose' capital that is of benefit to Australia. One industry participant considered that the PIIP was an 'industry development program masquerading as an antidote to the PBS'.

As has been noted in past reviews (for example, the IC 1996, pp. 95–102), these perspectives have partly influenced the design and nature of assistance arrangements to the pharmaceutical industry. For example, most firms facing price suppression cannot get any compensation under the PIIP because of the competitive entry requirements of the program — suggesting that price suppression is not the only issue of interest. It is also notable that past reviews' assessments of the Factor f program (BIE 1991, 1995 and IC 1996) — the predecessor to the PIIP — hinged on technological spillovers generated by the industry, rather than efficiency gains from counteracting any distortions resulting from the PBS.

However, sound rationales are only the first of a series of tests that must be met for a positive assessment of a program.

Effectiveness

The program must also be effective in achieving its objectives. The main test of the effectiveness of the PIIP is that it makes a significant difference to pharmaceutical value-added and R&D beyond what would have occurred in the absence of the program — so-called 'additionality'. Additionality is often elusive because it is difficult to design a program that does not also assist activity that would have occurred any way. The Commission examines the issue based on survey and other evidence of activity by participants and non-participants — as well as considering evidence from the Factor f program, which had a similar design to the PIIP.

Efficiency

Efficiency has many dimensions. The central measure in an economic program evaluation is the net benefit associated with the program. To generate benefits, the

PIIP must shift resources in the economy to higher value uses — by either increasing returns to factors employed in the pharmaceutical industry (such as labour and capital) or by creating additional 'spillover' benefits elsewhere in the economy.

The benefits must be sufficient to outweigh all of the costs of achieving this shift, such as compliance and administrative burdens, transfers to foreign shareholders, the distortions from raising taxes to pay for subsidies, and any unintended inefficiencies.

These gains and losses can be dynamic as well as well as short run. For example, on the negative side, a program may elicit strategic behaviour by participants that, through rent seeking or loopholes in the program design, lead to future costs (the abuse of the now abolished Syndicated R&D program is an instance where such behaviour arose).[4] On the positive side, an intervention might achieve longer run benefits if it exploits agglomeration benefits that only arise when the critical mass of activity in an industry reaches a certain threshold. These dynamic effects are, by their nature, very hard to predict.

For many programs — and especially ones involving relatively small subsidy rates as in the PIIP — it is very difficult to assess net benefits with precision. Indeed, in recognition of its endemic uncertainties, cost-benefit analysis is open to what one economist has called 'cooking the books without heat'. Choice of assumptions can determine the outcome of the analysis. For example, by throwing in a large spillover rate, almost any intervention can appear to be justified. That said, cost-benefit analysis is a useful framework that forces evaluators to make assessments of the likely value of the relevant parameters. In this study, the Commission seeks to overcome the weaknesses identified above by testing the robustness of its investigations and setting out clearly the nature and reasoning behind the assumptions.

Design issues

There is often scope to improve the design of a program, and indeed, sometimes, doing so can make the difference between a program with likely net costs and one with likely net benefits. Accordingly, regardless of the review's findings with respect to the appropriateness, effectiveness and efficiency of the PIIP, the existing design of the program is examined for possible improvements.

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[4] Lattimore 1996.

The key design features examined are:

- the extent to which entry should be on a competitive basis or open to all firms that meet some minimum eligibility requirements;

- what firms should be eligible;

- the subsidy rates;

- whether expenditure under the scheme should be capped;

- whether participating firms are determined at the commencement of the program or whether there is scope for letting additional parties participate during the program's life;

- whether value added and R&D should be treated equally as eligible activities; and

- the appropriate time span for the program.

1.3   Guide to the report

The report is structured as follows.

- Chapter 2 describes the PIIP and how it operates. It also provides information on participants and the extent to which they have met their undertakings.

- Chapter 3 examines the rationale for the PIIP stemming from the government's purchasing arrangements for drugs. It explores each of the questions posed in section 1.2 about the effects of the PBS on efficient activity in the pharmaceutical industry.

- Chapter 4 is associated with chapter 3 and looks at whether there are any special characteristics of the pharmaceutical industry — quite separate from its nexus with the PBS — that could provide a cogent rationale for government assistance.

- Chapter 5 evaluates the effectiveness of the PIIP by measuring the impacts of the PIIP on outcomes — such as R&D and value added.

- Chapter 6 applies a cost-benefit framework to the PIIP to consider whether the program, as it is currently structured, is likely to improve or retard overall economic efficiency.

- Chapter 7 examines appropriate design modifications for the PIIP.

- Chapter 8 examines some other policy issues that affect pharmaceutical activity in Australia (Clause f of the Pharmaceutical Benefits Pricing Authority's guidelines, PBS processes and some patent issues).

1.4 Participation

To facilitate participation in the review, the Commission:

- undertook visits with 25 pharmaceutical firms and 6 other interested parties;

- invited written submissions — 6 were received prior to the release of the draft report and a further 12 in response to the draft report;

- held two roundtable discussions in Sydney and Melbourne to seek the views of pharmaceutical firms and other interested parties; and

- undertook a survey of firms that have participated in the PIIP, applicants to the PIIP that were not successful and non-applicants. 27 firms of the 43 requests sent out responded to the survey, with 90 per cent of PIIP applicants responding (further details of the survey are in chapter 5).

Appendix A lists organisations and individuals who have participated in the inquiry.

2 The Pharmaceutical Industry Investment Program

The Commonwealth Government's Pharmaceutical Industry Investment Program (PIIP) commenced on 1 July 1999 and will run to 30 June 2004. Under the PIIP, participating companies will receive approximately $300 million over the five years. Eligibility is based on increasing production, research and development (R&D), and industry activity in Australia.

2.1 Objectives and guiding principles of the program

The rationale for the PIIP is that the Government's pharmaceutical purchasing arrangements have an adverse effect on pharmaceutical industry activity in Australia (chapter 3):

> In developing the PIIP, the Government has recognised that its position as sole buyer of pharmaceutical products under the Pharmaceuticals Benefits Scheme reduces returns to suppliers. This, in turn, has an adverse impact on the level of pharmaceutical activity undertaken in Australia and the growth of the pharmaceutical industry. (DIST 1998, p. 1)

Thus, as stated in its Program Guidelines, the PIIP is designed to 'compensate the pharmaceutical industry, in part' for low prices under the Pharmaceutical Benefits Scheme (PBS) (DIST 1998, p.1). It does this by paying higher prices on nominated products supplied by participating companies in return for those companies meeting commitments to undertake certain (additional) activities in Australia, including manufacturing and R&D.

The PIIP's rationale is reflected in the program's four guiding principles (box 2.1). The principles are intended to provide guidance to participants on the broad characteristics of activities that the program is intended to encourage.

Box 2.1   **Guiding principles of the PIIP**

Principle 1

The Pharmaceutical Industry Investment Program is intended to increase the total level of research and development activity undertaken in Australia which has a direct link to or, is of direct relevance to, the pharmaceutical industry. It is not, however, intended to influence the direction of that research and development activity.

Principle 2

The Pharmaceutical Industry Investment Program is intended to increase the total level of pharmaceutical production value added activity undertaken in Australia, In particular, it seeks to encourage high value adding per unit activity over lower value adding per unit.

Principle 3

The Pharmaceutical Industry Investment Program is intended to encourage pharmaceutical companies to achieve not only growth in existing activity, but also to undertake additional activity which is different in scope from existing activity, or is otherwise new to the company and of 'significance' to its operations and/or its position in the global environment.

Principle 4

The Pharmaceutical Industry Investment Program is intended to encourage a sustainable pharmaceutical industry in Australia, undertaking activity which is internationally competitive and of benefit to Australia.

Source: DIST 1998.

2.2   Entry to the PIIP

Prospective participants were invited to apply for entry to the program in April 1998. In order to be considered for entry, applicants needed to be a company incorporated under Australian law.

Acceptance into the program was competitive, based on assessment of the relative merits of the activity commitments proposed by each company. Proposals were assessed by a panel comprising government officials and non-government representatives with pharmaceutical industry or research expertise. The assessment process for PIIP applicants is outlined in box 2.2.

Box 2.2   Assessment process for PIIP applications

Assessment Panel comprising the chair of PBPA, experts in the pharmaceutical industry field and representatives of ITR and DHFS convened. Panel supported by Secretariat within ITR.

↓

Panel determines whether applicants are companies incorporated under Australian corporations law and whether applicants are related bodies corporate. Applicants failing these criteria are not considered further.

↓

Applicants make presentation to panel outlining the strengths of their program commitments.

↓

Panel assesses whether PVA and R&D activity are consistent with PIIP guidelines and meet eligibility criteria.

↓

Panel assesses merit of applicants having regard to whether individual elements of program commitments contribute to goals outlined in PIIP principles, broad arguments for participation and any other relevant issues.

↓

Applicants ranked according to relative merits and the panel makes a recommendation to the Minister regarding the rank of each applicant and the level of funding. (The Minister is not bound to accept the recommendation.)

↓

The Minister contacts applicants with an offer of participation. Applicants that accept the offer enter into an agreement with the Commonwealth.

↓

When all companies have responded, the Panel considers whether there are sufficient funds to make another round of offers. If there are sufficient funds the Panel makes further recommendations to the Minister based on the ranking of relative merit.

Source: DIST 1998.

Program commitments are classified into two broad streams:

- *Production Value Added (PVA) and/or R&D activity targets* — these comprise commitments to achieve activity targets for total production value added and/or R&D activity, encompassing both existing and additional activity (applicants were not required to include both PVA and R&D activities in their program commitments, even if they are engaged in both activities); and

- *Broad Activity Commitments* — commitments to undertake broad activities which are of strategic importance to the company and of benefit to Australia, including those which contribute to PVA and/or R&D activity. This includes investment in plant and/or equipment, collaborative links with Australian research or medical institutions, development of R&D infrastructure, improvements in productivity, increases in employment, workplace reforms or the location of regional headquarters in Australia.

In making their case for entry, applicants were required to outline how each element of their program commitments (that is PVA and/or R&D activity as well as their

broad activity) would contribute to meeting the guiding principles. For example, in addressing the first two principles, companies needed to demonstrate that, all other things being equal, the overall value of PVA and/or R&D undertaken in Australia would increase.

Successful applicants entered into a contract with the Commonwealth Government specifying, among other obligations, conditions of participation, agreed activity targets and entitlements (expected payments based on forecast activity). The Pharmaceutical Benefits Pricing Authority (PBPA) administers the program.

Twenty two companies applied to enter the PIIP. The original nine contracted companies were: AMRAD, Bristol-Myers Squibb, CSL, Eli Lilly Australia, FH Faulding (now Mayne Pharma), Glaxo Wellcome Australia (now GlaxoSmithKline), Janssen-Cilag, Pfizer and Pharmacia & Upjohn (now Pharmacia) — section 2.7 provides information on each firm's performance under the PIIP to date.

2.3   Eligible activity

Production Value Added

For the purposes of the PIIP, PVA is defined as the difference between the ex-factory selling price of pharmaceutical products and the cost of ingredients, materials, royalties and other similar payments. Value added can also include income from royalties and other similar payments.

All PVA related to innovative and generic products listed on the PBS is eligible to generate entitlements under the PIIP. This includes sales of such products to hospitals and under tender or contract to government. Companies can also claim PVA on 'PBS like' pharmaceutical products (eg vaccines) when agreed to by the PBPA. Generally, over the counter (OTC) products were not be eligible to generate entitlements.[1]

To be eligible for the PIIP, PVA activity must be wholly undertaken in Australia, either directly by the applicant or by a third party under contract. Further, the pharmaceutical product produced as a result of any contract PVA activity needed to

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[1] OTC products under the PBS can be included in activity targets, subject to approval by the Assessment Body (the Minster, through his delegate decides, on the advice of the PBPA). Non-PBS OTC products can be included where a similar product is available on the PBS and companies consider that there is a very clear link to PBS price suppression.

be registered or listed with the Therapeutic Goods Administration in the name of the applicant.

PVA activity that was deemed eligible to generate entitlements at the close of applications for the PIIP continues to remain eligible during the course of the program, irrespective of scheduling or PBS listing changes.

Research and Development

For the purposes of the program, R&D is defined as the systematic investigation or experimentation of activities:

- that involve innovation, technology transfer into Australia or technical risk;

- that are carried out in Australia;

- the object of which is new knowledge, or new or improved materials, products, processes, services, or devices associated with the delivery of pharmaceutical products; and

- which have a direct link to, or are of direct relevance to, the pharmaceutical industry as demonstrated to the satisfaction of the PBPA (DIST 1998, p. 5).

R&D expenditure is measured as before-tax expenditure net of any benefits for R&D activities provided by the Government. Only R&D expenditure related to domestic activity constitutes eligible expenditure, although R&D activities undertaken overseas could be included in a company's program commitments. Provision is also made for R&D undertaken by third parties under contract to be included in program commitments.

As with PVA, activities which are deemed eligible as R&D at the commencement of the program remain eligible for the life of the program.

2.4   Entitlements

Companies generate annual entitlements based on their PVA and/or R&D activity targets. A payment rate of 20 per cent is applied in determining entitlements for both PVA and R&D. The maximum entitlement for any participating company is $60 million over 5 years. However, within that constraint, there is no cap on the entitlement for any individual year, or the proportion of entitlement that can be earned from PVA or R&D when both are included in the program commitments.

Calculation of entitlements

Entitlements were calculated at the start for the program, as the difference between forecast activity in a each year and a defined base level of activity (box 2.3). The PVA base is calculated using a three year moving average. This means that companies had to submit forecasts of increasing PVA in each year of the program to continue to earn a subsidy. The fixed base for R&D means that firms generated an entitlement whenever their forecast level of activity exceeded the based established in 1998-99.

Box 2.3   **Calculation of the base year for PVA and R&D**

PVA entitlements for any given year are determined using a moving average base. The base comprises activity in the previous three years such that:

- Base applying in year 1 (1999-00)= average ($1996\text{-}97_A$, $1997\text{-}98_A$, $1998\text{-}99_A$)

- Base applying in year 2 (2000-01) = average ($1997\text{-}98_A$, $1998\text{-}99_A$, $1999\text{-}00_F$)

- Base applying in year 3 (2001-02) = average ($1998\text{-}99_A$, $1999\text{-}00_F$, $2000\text{-}01_F$)

Where $_A$ denotes actual activity (consistent with activity targets) and $_F$ denotes forecast activity.

R&D entitlements for any given year are determined using a fixed three year average base. The base comprises activity in the three years prior to the company's participation in the program.

The base is not adjusted to take into account actual activity during the course of the PIIP.

Source: DIST 1998.

2.5   Payments

Payments are calculated on the difference between the actual level of activity and the base in a given year (up to the maximum entitlement). These payments are made to companies either as *actual* or *notional* price increases, up to the average European Union (EU) price for the nominated product. Participating companies are free to select the payment method that best suits their needs.

Notional price increases are allocated to sales on nominated PBS products, but paid as a lump sum annually. The allocation is done at the end of each year of participation. Nominated products can vary from year to year.

PIIP payments claimed as actual price increases are negotiated by participants and the PBPA. Under this option the company receives a higher price from the Government on nominated drugs. However, to ensure that the PIIP component of the price does not create further costs to the Government or consumers further down the supply chain, companies must bear certain costs in receiving payments as actual price increases. These include wholesaler and pharmacist margins associated with higher prices. Further, if the PIIP does not continue, prices return to base levels at the conclusion of the program in 2004. To date, all nine companies participating in the program have opted for notional price increases.

Payments from the PIIP constitute assessable income for company tax.

Products on which increases can be paid

Participants are able to claim PIIP entitlements against PBS sales of innovative, generic and OTC products listed on the PBS where they can demonstrate that PBS prices are being suppressed below the EU average as a consequence of the Government exercising its purchasing power under the PBS.[2]

Participants can also claim price increases on some pharmaceutical products sold to hospitals or through other arrangements to government. In these instances, in addition to demonstrating that prices are below the EU average, companies also need to show that the same or a similar product is listed in the PBS or that exceptional circumstances exist to preclude PBS listing. In the case of OTC products, price increases will be limited to PBS sales.

2.6   Administration of the program

As noted, the PIIP is administered by the PBPA, an independent non-statutory authority established in 1988. (The PBPA is also responsible for reviewing the prices of products under the PBS and recommending prices for new products listed on the PBS.) In relation to the PIIP, the PBPA is served by a secretariat located within the Department of Industry, Tourism and Resources.

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[2] The EU average price is determined from the ex manufacturer prices of the same product from a range of countries which must include any six of the following: Austria, Belgium, Sweden, France, Germany, Ireland, Italy, Netherlands, Spain and the United Kingdom. Companies are required to supply data from Inter-Continental Medical Statistics to demonstrate that the product, or its equivalent is available in the nominated market and the price of the product in each market. Where prices are not available from six of the ten nominated countries, a price is negotiated between the Administering Body and the company concerned.

Each company's performance is assessed against all program commitments by the PBPA on an annual basis. To facilitate this assessment, companies are required to provide:

- audited data for PVA and or R&D activity;

- an outline of progress towards meeting program commitments; and

- a general commentary on activity undertaken over the year (such as activity or investment not included in companies' program commitments).

A subsequent review six months later may be conducted where the participant:

- has failed to undertake activity that represents 75 per cent of total forecast PVA and R&D activity;

- where a company has achieved 75 per cent targets, but failed to undertake additional activity to which it committed;

- has consistently under-performed; or

- the PBPA has serious reservations regarding progress.

Where the PBPA decides to undertake a review, the first payment for the following financial year is withheld until the review is completed.

If, following the review, concerns still remain regarding the progress of participants, then payments are reduced for the last quarter of the year and the first quarter of the following year. The extent of the reduction is at the discretion of the Minister.

Following a review of performance the Minister has the power to reduce payments or terminate participation in the program. Alternatively, the PBPA can continue to monitor performance. If the company continues to fail to meet commitments, the PBPA can recommend to the Minister that participation be terminated.

Where practicable, any funds freed up are to be reallocated to new participants.

Performance compliance

Both under and over-performance (in actual activity relative to forecast activity) can be carried forward through the PIIP. As any over-performance can be used to offset under-performance in a given year, participants are provided with some flexibility in terms of the timing of activity without incurring penalty.

Over-performance is carried forward in full throughout the course of the program. In contrast, under-performance is carried forward year to year according to a sliding scale (figure 2.1).

Figure 2.1   Sliding scale for carryover of under performance
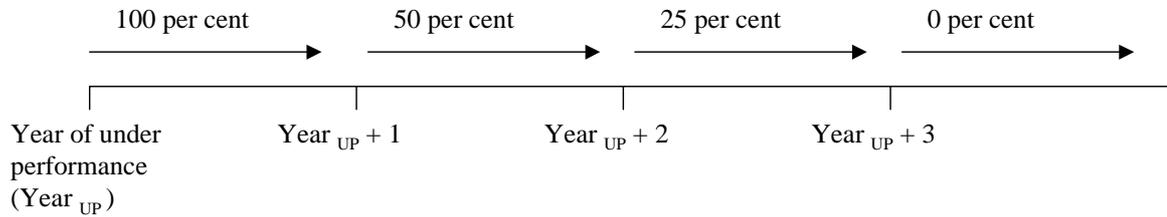
Under the sliding scale, participants are not penalised for under-performance if they are able to fully offset that under-performance in the following year. Carrying under-performance forward for more than on year results in a reduction in entitlement. For example in year $_{UP}$+3, 75 per cent of the activity associated with the under-performance is lost.

Since participants cannot be paid any more than their total entitlement determined at the beginning of the program, any over-performance outstanding at the end of the program is lost to the company.

While carryover provisions apply to both PVA and R&D, carryover is not interchangeable between activities. For example, over performance in PVA can not be used to offset under-performance in R&D and vice versa.

Substitution of activities

In addition to the *ex post* flexibility afforded by carry forward provisions, scope for substitution of activities provides participants with *ex ante* flexibility. Where it is clear that a company is unable to meet its commitments in relation to a project or activity, they are able to apply to the PBPA to replace that project or activity, including substituting PVA with R&D (but generally not vice versa), provided that the company can demonstrate that the replacement activity:

- is of a similar quality and quantity to that being replaced;

- meets the program's principles and eligibility requirements; and

- retains the overall 'flavour' of the company's program commitments.

2.7   Use of the PIIP

As noted, nine companies were successful in obtaining PIIP funding. However, to remain within the $300 million total funding cap for the program, entitlements for Pfizer and GlaxoSmithKline were reduced from the levels contained within their applications for the program.

The successful companies' maximum entitlements — based on their forecast level of PVA and R&D activity relative to their base levels — are shown in table 2.1. Overall, around 75 per cent of the contracted entitlements have been awarded for PVA and 25 per cent for R&D commitments.

The successful firms made commitments to undertake PVA of around $5.7 billion and R&D of around $1 billion over the five years of the scheme.

Table 2.1   **Total entitlements under the PIIP**
Original contracted figures at June 1999

	PVA entitlement	R&D entitlemement	Total
	$m	$m	$m
AMRAD	12.73	7.46	20.19
Bristol-Myers Squibb	31.05	8.34	39.39
CSL	47.61	12.20	59.81
Eli Lilly	0.00	19.88	19.88
Mayne Pharma	34.11	6.24	40.35
GlaxoSmithKline	23.13	4.29	27.42
Janssen-Cilag	14.22	3.35	17.57
Pfizer	28.60	10.30	38.91
Pharmacia	30.62	3.29	33.90
Total	222.07	75.35	297.39

Source: ITR data.

Performance to date

The PIIP has now operated for three full years. Overall, activity levels are close to the company targets. The aggregate PVA is 7 per cent above the forecasts made by the companies in their contracts with the Government, while R&D is 1 per cent below the targeted level. However, there is greater variation between participating firms. Table 2.2 shows the PVA and R&D activity relative to the target for each company for the first three years of the scheme. In relation to PVA, seven out of the nine firms are above their targets, while AMRAD and CSL are below their forecast levels of activity. In relation to R&D, a number of companies are below their forecast, with only Janssen-Cilag and Eli Lilly significantly above their forecast.

Table 2.2 Company activity compared to targets under PIIP

Activity as a percentage of targets from 1999-00 to 2001-02

Company	Production Value Added	Research and Development
	%	%
AMRAD	63	76
Bristol-Myers Squibb	107	89
CSL	90	99
Eli Lilly	na	116
GlaxoSmithKline	122	103
Mayne Pharma	112	93
Janssen-Cilag	129	151
Pfizer	113	96
Pharmacia	112	73
Total	**107**	**99**

na is not applicable.

Source: PBPA 2000b, PBPA 2001b. Advice from PBPA secretariat.

Owing to the structure of the scheme, over-performance does not increase entitlements. On the other hand, when there is under-performance relative to the target, the reduction in entitlements may be greater than the percentages shown in table 2.2. As noted above, there are two reasons why this can occur:

- Entitlements are paid for activity above a base level. A relatively small under-performance in activity relative to the target level for particular year will represent a much larger under-performance relative to the base. For example, assume a company has a base in a particular year of $150 million and an activity target of $200 million. This would generate an entitlement of $10 million ((200-150)*0.2). If actual performance was at 90 per cent of the target ($180 million), the entitlement would be reduced to 60 per cent of the initial entitlement.

- Under the carryover arrangements, if under-performance in a given year is not fully offset by over-performance in the following year, there is a loss of some entitlement. This can lead to a situation where a company achieves the sum of its annual targets, but because of variability in the timing of activity, it can lose some of its entitlement.

The estimated payments made to each company for the first three years of the scheme as a percentage of their maximum entitlement for that period are provided in table 2.3. The table shows that, with the exceptions of AMRAD and CSL, all companies have received their maximum PVA entitlement. Payments for R&D show more variation, with only three of the nine companies receiving their full R&D entitlement.

Table 2.3   **Estimated PIIP payments 1999-00 to 2001-02**

Company	Payment for PVA	Percent of max entitlement *a*	Payment for R&D	Percent of max entitlement *a*
	$m	%	$m	%
AMRAD **b**	1.57	20	0.11	4
Bristol-Myers Squibb	16.92	100	3.64	78
CSL	14.95	54	5.44	96
Eli Lilly	na	na	8.10	100
GlaxoSmithKline	12.38	100	1.31	100
Mayne Pharma	18.97	100	2.26	84
Janssen-Cilag	10.34	100	1.44	100
Pfizer	13.42	100	3.80	91
Pharmacia	24.63	100	0.68	41
Total	**113.17**	**84**	**26.79**	**82**

a It is possible that under-performance may be recouped later in the scheme under the carryover arrangements. **b** Excludes payment data for AMRAD for 2001-02 which was not available. **na** is not applicable

Source: PBPA 2000b, PBPA 2001b, Advice from PBPA secretariat.

The variation in actual performance from that predicted by companies in their application reflects commercial dynamics within the industry as some products and R&D projects perform better or worse than envisaged in 1998.

AMRAD's payments under the program have also been affected by the sale of its non-core businesses. PBPA (2001b, p. 7) commented that:

> As noted in the PIIP supplement for 1999-2000, the Authority had formally sought reassurance from AMRAD Corporation that the divestment of AMRAD's non-core businesses would not detract from AMRAD's capacity to comply with established activity commitments. The Authority is continuing to monitor the performance of AMRAD in the light of slower than expected growth in R&D expenditure.

Merger and acquisition activity

According to the PBPA:

> Each companies contract with the Commonwealth stipulates that the Commonwealth may, should a participating PIIP company merge with or be taken over by another Company, review the implications of the merger for that Company's continued participation in the Program. (PBPA 2001a, p. 6)

There have been a number of changes to the ownership structure of some of the PIIP participants during the program.[3]

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[3] Mergers involving companies receiving payments under the PIIP raise a number of complex issues in relation to redefining the base activity levels of the merged entity for the remainder of

- Pfizer merged with Warner Lambert world wide. In Australia, this involved the merger with Parke Davis, a subsidiary of Warner Lambert in 2000. Pfizer's entitlements were unchanged as a result of the Parke Davis merger, although its PVA base and target increased to reflect additional Parke Davis activity on its books.

- Pharmacia and UpJohn merged with Monsanto worldwide. In Australia, Pharmacia & Upjohn Australia merged with Monsanto's pharmaceutical business, Searle (a non PIIP participant), to form Pharmacia Australia (Pharmacia) on 1 September 2000. Pharmacia's entitlements were unchanged as a result of the Monsanto merger.

- GlaxoWellcome merged with SmithKlineBeecham (not a participant in the PIIP) to form GlaxoSmithKline (GSK). GSK's entitlement also remained unchanged as a result of the merger.

- In September 2001, Faulding was acquired by the Mayne Group. The PBPA has confirmed that Faulding will continue to participate in the PIIP at its original levels of entitlement.

- In 2002, Pfizer announced a world-wide merger with Pharmacia (both PIIP participants. If this merger were completed, the proposed activity to be undertaken by the merged entity would need to be considered by the Authority and approved by the Ministers delegate.

the program. The Commission has not examined the PBPA's methodology for recalculating the PVA and R&D base for each of the mergers.

3   Compensating for the Pharmaceutical Benefits Scheme

3.1   Introduction

This chapter examines whether there is a reasonable rationale for the PIIP based on the effects of the Government's drug purchasing arrangements under the Pharmaceutical Benefits Scheme (PBS).

The stated rationale for the PIIP is the effect of cost containment and bargaining arrangements under the PBS in lowering the (wholesale) prices of pharmaceuticals in Australia — so-called 'price suppression' — with potential distorting effects on domestic activity. For example, most recently, ITR (2002d) stated that:

> The Pharmaceuticals Industry Investment Program (PIIP) compensates participating companies for price suppression delivered through the Pharmaceuticals Benefits Scheme … PIIP aims to stimulate investment in pharmaceutical activity and to develop Australia as a regional centre of excellence in both R&D and manufacturing, by offering partial compensation for the impact on activity from the Government exercising its monopsony (sole purchaser) purchasing power under the Pharmaceutical Benefits Scheme.

As noted in the Industry Commission's inquiry into the Australian pharmaceutical industry (IC 1996, pp. 95–102), at times this compensation rationale has been confused with the goal of developing the local industry for other reasons. The issues are separable. Chapter 4 examines whether any special characteristics of the pharmaceutical industry warrant a sectoral industry development program.

Effects of the PBS

The argument that price suppression provides a rationale for a compensating industry assistance program has several logical requirements, all of which have to be met:

- price suppression must exist;

- price suppression must reduce pharmaceutical profits (while price suppression per se lowers revenue, it is also associated with access to consumer subsidies that, all other things being equal, have positive offsetting volume effects on revenue);

- price suppression must result in a lower level of domestic activity — such as R&D, production or investment — than would otherwise occur; and

- the resulting level of domestic activity under price suppression must have adverse allocative efficiency outcomes compared to a benchmark where prices are higher.

This chapter first examines the workings of the PBS (section 3.2), since understanding its functioning goes to the heart of a diagnosis of price suppression or other PBS effects on pharmaceutical firms operating in Australia. The four issues above are then considered consecutively (sections 3.3 to 3.6). Finally, section 3.7 draws together the evidence about the effects and implications of the PBS for pharmaceutical industry policy.

3.2   The Pharmaceutical Benefits Scheme

Most prescription medicines sold in Australia are listed in the PBS. The PBS subsidises users of pharmaceuticals by setting a retail price limit on listed drugs. Different limits apply to general beneficiaries and concessional patients.[1] These measures are supplemented by safety nets that further lower prices once consumption exceeds certain thresholds.[2] Benefit-paid pharmaceuticals (those PBS scripts that are at least partly subsidised by government) cost $5003 million in the year ended 30 June 2002 (this excludes those PBS-listed scripts whose price was below the relevant maximum co-payment levels for patients).[3] Overall, the subsidy rate for benefit-paid pharmaceuticals for concessional patients is 90.2 per cent,

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[1] From 1 January 2003, price limits were $23.10 for general beneficiaries and $3.70 for concessional patients. The 2002–03 Budget introduced increases to $28.60 and $4.60 for general and concessional patients, respectively (but these have not yet been approved by Parliament).

[2] When general patients (or their families) reach a safety net threshold of $708.40 they pay no more than the concessional rate for each additional script. Concessional patients obtain free scripts after reaching a threshold of $192.40. The 2002–03 Budget proposed that the thresholds be increased to $874.90 and $239.20 for general and concessional patients respectively, but these changes have not yet been approved by Parliament.

[3] Sourced from the Department of Health and Aged Care (from http://www.health.gov.au/pbs/pubs/pbbexp/pbjun02/index.htm).

while it is 65.4 per cent for general patients (both including safety net purchases, but excluding 'Doctors' Bag' drugs).[4]

Thus the bulk of the total cost of benefit-paid PBS pharmaceuticals — some $4197 million or 84 per cent in 2001–02 — is funded by the Commonwealth Government. Because patient co-payments are capped and, in the case of concessional patients, set quite low, the normal constraints exerted by prices on pharmaceutical demand *by patients* are diminished in Australia. Indeed, concessional patients (paying the lowest prices) accounted for 80 per cent of PBS funding in 2001–02. Consequently, even with inelastic demand at present subsidised prices, script volumes (at least for some products) can be expected to be significantly higher under these arrangements compared with unsubsidised demand.

Moreover, the existence of prescription subsidies will, unless countered by other regulations, typically push up the price set by manufacturers for specific drugs. For example, because of the ceilings on prices, a concessional patient is indifferent between two equivalent branded drugs costing $400 and $3.70 (as are unregulated prescribing physicians unless they actively care about burdens on taxpayers). Unless there are cheaper competing drugs below $3.70 — and for most drugs there are not — a pharmaceutical manufacturer has an incentive to add large premiums to drug prices if they have the market power to do so (and in cases where a drug is patented and has no close therapeutic substitute, it will have such power).

As in other parts of the publicly funded health sector, the government has attempted to contain the risks of cost blowouts due to volume and price responses to universal subsidies by rationing the supply of pharmaceuticals on the PBS and exercising its strong countervailing buyer bargaining power.

The government's bargaining power arises from two main features of the pharmaceutical market.

First, the government adopts a restrictive formulary for subsidised drugs — that is, only products that are listed on the PBS[5] are eligible for (the significant) government subsidies. Given the size of the subsidies and the impact that they have on the realised price to the patient, doctors tend to prescribe pharmaceuticals that are on the PBS. Failure to achieve a listing would significantly damage sales and overall revenues of pharmaceutical manufacturers. It is estimated that around 90 per

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[4] It should be noted that lower subsidy rates occur, particularly for non-concessional patients, if non-benefit paid PBS-listed prescriptions are included (as noted by Merck Sharp & Dohme sub. 11, p. 25).

[5] Or its counterpart for eligible war veterans — the Repatriation Pharmaceutical Benefits Scheme (RPBS).

cent of prescriptions are for pharmaceuticals that are listed on the PBS/RPBS and only 10 per cent are for drugs not listed (their purchase being directly funded by individuals). Consequently, pharmaceutical firms bargain with the government to gain listing and are willing to trade-off at least some lower prices for the volume benefits of listing. As Jelovac (2002) shows, the lower the co-payment by patients, the more important it is for pharmaceutical firms to acquire listing, the greater will be government bargaining, and the lower will be prices paid to producers.

Secondly, the technology used in pharmaceutical production and the existence of statutory protection of intellectual property through patents implies that prices for a particular drug need not be fixed, but will depend on the nature of demand.[6] While the average costs of patented pharmaceutical products are often high, their marginal cost — the costs borne by incrementally expanding output — are often 'very low' (Danzon 2000, p. 8).[7] This reflects the fact that many of the costs do not vary with the scale of production, such as R&D costs (which represent around one third of total costs), some marketing, and investment in production facilities. For example, the total cost of developing and approving a new drug is estimated to cost around US$500–800 million (OECD 2001, p. 30 and Glover 2002, p. 2), while a plant for manufacturing an active ingredient may cost more than US$100 million.

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[6] Sheehan (sub. 15, p. 5) argues that economic theory predicts that pharmaceutical prices would — in the absence of government buying practices — be equalised across countries. However, this would only apply in a competitive market and ignores the (necessary) market power bestowed by patents. This market power allows firms to set different prices in different markets.

[7] Unfortunately, while it is generally acknowledged that marginal costs of pharmaceutical products are very low, estimates of how low are very sparse. It should be noted that fixed costs do not just refer to R&D costs. Often there are large fixed costs in installing production capacity and in establishing a brand reputation among prescribers for a drug. Once a plant is in place (and most are apparently not operating at capacity), the additional costs of further production are likely to be a fraction of total average costs. Hughes et al. (2002) indicate an estimate of marginal cost of 17 per cent, but this is a rough measure that mainly removes the fixed costs of R&D from costs and so ignores other aspects that would generally imply lower marginal costs. Data on price differences between generics manufactured in India and those in the US also reveal very large price differences, which give some impression of the costs, stripped of large fixed marketing and R&D costs. Though the estimates are of questionable accuracy, these products are apparently selling between 3 and 10 per cent of the US price (Lybecker 2001 and Conway 2001). The PC used IMS data to examine the difference between originator brand and the cheapest generic brand of off-patent drugs in the US for a variety of popular drugs (Ranitidine, Salbutimol, Diazepam, Metoprolol, Ditliazem, Proxicam, Atenolol, Temazepam, Oxazepam and Betamethasone) where economies of scale would also be enjoyed by generic manufacturers. In the US, branded drugs are not substantially discounted after patent expiry, so the price differential provides a guide to markups required to meet upfront R&D expenses. For these seven drugs, the lowest generic prices were between 1.2 and 5.8 per cent of the originator brand price, with an unweighted average of 3.8 per cent. This suggests that marginal costs could be quite low relative to average costs.

A firm must anticipate being able to set prices that cover its aggregate long run average costs in order to, ex ante, have incentives for undertaking the typically huge irreversible investments in innovation and plant capacity. However, this is an aggregate pricing condition, not one that must be met for each customer. Faced with buyers with varying demand elasticities, pharmaceutical producers will tend to set prices so as to recover more of the fixed costs from buyers with relatively inelastic demand — so-called 'pricing to market'. In the case of pharmaceuticals, the market is a global one, and so firms tend to set different prices in different countries depending on their demand characteristics. It is profitable for the firm to set prices below average cost for buyers with sufficiently elastic demand, so long as:

- prices do not fall below marginal cost;

- there is capacity in the source plant;

- the buyer cannot on-sell to third parties; and

- the sale does not set a reference price for sales to other parties that are willing to pay more.

In general, these conditions are met in Australia's case. The government has adopted regulatory and institutional structures for the purchase of pharmaceuticals that increase the elasticity of demand (by government[8]) for each individual drug (through measures such as generic substitution and the application of economic evaluation when listing drugs — see below). Prices, while low, are clearly not below marginal cost — no one would supply at this price. Australian demand for particular active ingredients is usually low relative to the capacity of the plants that manufacture them.[9] Australia has good arrangements to prevent on-sale to others. A third party could not buy pharmaceuticals from MNEs in Australia at PBS-suppressed prices and supply them to other countries where prices are higher, such as the US. And so far, it does not appear that Australia's low prices regularly establish a benchmark for prices used by many other negotiating parties (though this matter is discussed at greater length in section 3.4).

There are several mechanisms through which the Australian Government contains costs in the PBS. An understanding of these sheds some light on the likely type and

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[8] Thus, this should not be confused with the elasticity of demand of consumers — who pay highly subsidised prices — and are therefore operating in the inelastic portion of consumer demand curves for pharmaceuticals (Jelovac 2002).

[9] Australian demand for pharmaceuticals is around 1 per cent of the world total. Active ingredient manufacture is usually located in only a few global plants.

extent of adverse effects on the prices, revenue and activity of pharmaceutical firms.[10]

Strict evaluation of new pharmaceuticals

As in other countries, prior to marketing approval, new pharmaceuticals must first be assessed for quality, safety and efficacy (in Australia, by the Therapeutic Goods Administration — TGA). Pharmaceuticals that have been approved are available for private sale immediately, but must go through further steps before they can be listed on the PBS. The TGA part of the process does not place any pressures on pricing or the incentives to undertake activity in Australia. In fact, the perception of many firms contacted by the Commission during the evaluation was that Australia's TGA processes were recognised world-wide as of high quality — and this facilitated the supply of drugs from Australia to regional markets.

Price containment is exerted in subsequent phases of the process, involving scrutiny by the Pharmaceutical Benefits Advisory Committee (PBAC), the Pharmaceutical Benefits Pricing Authority (PBPA), the Minister for Health and Aging, and if expenditure is expected to exceed a threshold, other departments and ministers. (Where spending is expected to exceed $5 million a year, the Department of Health and Aging must also get approval from the Department of Finance and Administration and when it is expected to exceed $10 million a year, the approval of the Cabinet must also be obtained (PBPA 2002, p. 8.))

The PBAC assesses the benefits of a new pharmaceutical against existing listed drugs, taking into account the need for the product and evidence that it leads to improved outcomes over alternative therapies at an acceptable cost. Since 1993, pharmaceutical producers wishing to have their product listed on the PBS must submit an economic evaluation to the PBAC that indicates the incremental costs and benefits of their product over existing ones. Australia is one of few countries requiring this (Productivity Commission 2001, p. 24). A drug with marginal benefits over existing listed products will only be listed if its price is similar to existing products, while new innovative drugs offering greater patient benefits can command higher premiums. In principle, the need to demonstrate cost effectiveness creates strong pressures for low prices for 'me-too' drugs (chemical entities that have therapeutic substitutes).[11] Roundtable participants in the Productivity

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[10] The treatment that follows is abridged. The full process for listing pharmaceuticals is complex and lengthy. The PBPA (2002, p. 18) illustrates the full set of decisions that are needed prior to listing.

[11] Strong competition between rival manufacturers for the supply of generic drugs (chemically equivalent items — including the original branded product — made by different manufacturers

Commission's research into international drug price differences (2001, p. 78) considered that this was a major factor behind low Australian prices for this class of pharmaceuticals.

Once approval for listing has been given by the PBAC, the PBPA recommends to the Commonwealth Government a maximum price that should be paid to pharmacists for the therapy — based on meeting some minimum cost effectiveness standard. The pricing recommendation may also include a price-volume agreement, in which prices will fall if actual consumption under the PBS exceeds the forecast value (say due to 'leakage' when a drug is used for a wider set of indications than initially established by the PBAC, or simply when the forecast by the manufacturer is wrong). The Department of Health and Ageing negotiates, on behalf of the Government, with the pharmaceutical suppliers the prices of new prescription medicines. The Government then makes a final decision whether to list new pharmaceuticals.

Prescribing guidelines and volume controls

In common with many other countries, the Australian Government issues prescribing guidelines that aim to achieve 'evidence-based' rational prescribing. Sanctions can be applied if these are breached. As well, many costly or high risk treatments cannot be prescribed freely by physicians. Rather, the Government specifies the conditions in which the subsidised pharmaceuticals may be used (restricted drugs) — or in some cases, requires the physician to seek authorisation from the Government prior to prescription. Such restrictions reduce the volume of the drug sold and pharmaceutical company revenues. Thus the threat of imposing volume controls on costly drugs provides government with further leveraging power for bargaining for lower prices.

Reference based pricing

The maximum price that the Government is willing to pay for some classes of pharmaceuticals in Australia is determined by reference pricing (a practice that also occurs in other countries, such as Germany, the Netherlands and New Zealand). Under this approach, pharmaceutical products that have the same chemical structure

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after expiry of the patent) lead to typically low prices. No economic evaluation is required for the listing of generics.

and/or are deemed to be therapeutic substitutes form a reference group and a single price is used as the reference price for all members of the group.[12]

While the international evidence on the effects of reference pricing on containing pharmaceutical expenditure is equivocal (Ioannides-Demos et al. 2002), the use of reference pricing in Australia is more likely to lead to greater price suppression in the local market than a number of other OECD countries due to two design features:

- unlike many other countries, Australia's adaptation of reference pricing includes off-patent as well as patented pharmaceuticals in the groups. Off-patent pharmaceuticals — which are subject to much greater competition in supply — are typically much lower priced than pharmaceuticals still under patent and are likely, in the Australian reference pricing system, to constrain patent drug prices; and

- whereas Australia uses the minimum price as the benchmark, some other countries use the average group price.

The impact of reference pricing and other cost containment measures on the ultimate returns to a pharmaceutical supplier is somewhat mitigated by the capacity under current regulatory arrangements for the supplier to charge a higher price than the reference price, but with the patient paying the difference between the reference and selling price. However, such mitigation is limited since many brands do not charge a patient premium. Merck Sharp & Dohme (sub. 11, p. 26) noted that at June 2000, 27 patented brands — 1 per cent of brands listed on the PBS — charged a premium.

Generic substitution

Generics are cheaper than brand name pharmaceuticals[13] so that policies that encourage their take up tend to reduce the overall costs of the PBS, and are also likely to affect the pricing of listed brand name products. In Australia, unlike some other countries, pharmacists are not required to substitute a generic drug for a branded drug. However, substitution is permitted if:

- the prescribing doctor has not explicitly specified that substitution is not to take place;

- the patient agrees;

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[12] Four therapeutic groups of pharmaceuticals are subject to reference pricing in Australia — the H2 receptor antagonists, calcium channel blockers, ACE inhibitors and the HMG CoA reductase inhibitors (statins).

[13] Though seemingly not by a large margin in Australia relative to some other countries, such as the US.

- a suitable generic substitute exists; and

- the doctor has prescribed a more expensive pharmaceutical.

Sheehan and Sweeny (2002, p. 8) estimated that generics accounted for around 18.9 per cent of scripts in 2000–01 and about 9.6 per cent of expenditure.[14] These shares are generally well below those in the US, Canada, UK and northern European countries (p. 9). This probably reflects weaker financial incentives for patients to select generic products, given the low price margin between branded and generic equivalents in Australia (and the fact that pharmacists appear to have flexibility as to whether they pass on the full price difference between the generic and branded drug to consumers).

3.3   Is there price suppression?

These mechanisms by which the PBS contains costs in Australia are well understood. But it is difficult to measure precisely the impact of the Government's drug purchasing arrangements on drug prices:

- while it is generally accepted that Australian prices are lower than many other developed countries, it is difficult to measure by how much they are lower; and

- it is difficult to determine how much of the price difference is due to price suppression under the PBS, and how much might reflect other factors.

Finding out how much prices vary internationally

It is hard to appraise the extent to which prices vary internationally because:

- comparisons are affected by variations in the specifications of ostensibly similar products sold in different markets. The active chemical ingredient may be the same, but it may be provided in different forms and package sizes. For example, Pfizer (2000, p. 8) has claimed that in the US (in contrast with other countries), drug prices often do not vary much by the dosage, so that price relativities based on smaller dosage sizes will tend to overestimate US prices.[15] There can also be

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[14] These figures are consistent with others from IMS Health (2000) and Lofgren (2002), who estimated that generic prescriptions accounted for around 20 per cent of Australian (non-hospital) prescriptions. The Productivity Commission (2001, p. 41) estimated that 'generics' accounted for a PBS expenditure share of around 44 per cent for the top 150 PBS-listed molecules (which translates to a higher share of actual scripts). However, the Productivity Commission data includes out-of-patent originator molecules.

[15] The IAC (1986) cites (obviously dated) evidence showing that price relativities are less marked when dosage is taken into account.

'basket' problems. Drug price comparisons typically define a fixed set of drugs and then look at price differences between countries for that basket. It is usual to choose one country's consumption patterns as the basis for this basket. However, different countries have different consumption patterns (for example, patients in some countries may prefer drugs in a different form, such as suppositories versus tablets, or for a given indication, prefer one drug over another). If basket compositions vary significantly between countries, then price comparisons can be misleading;

- negotiations between big buying blocs, such as health maintenance organisations, and pharmaceutical companies may lead to large discounts, but these are commercially sensitive and are not publicly disclosed. In particular, this tends to give an exaggerated impression of aggregate prices in the US; and

- it is important to examine price suppression for different classes of pharmaceutical products — new innovative pharmaceuticals (products with significant clinical benefits that have limited substitutes), 'me toos' (patented drugs that have close substitutes) and off-patent drugs (comprising generics and off-patent originator brands) — since the price differences may vary markedly by class.

The Productivity Commission (2001) compared pharmaceutical prices in Australia and seven other countries for the 150 top listed pharmaceuticals for mid–2000 (these account for about 80 per cent of spending under the PBS). Using the lower estimates as the benchmark (table 3.1), Australian prices were around 60 per cent lower than the US, still significantly cheaper than Canada, the UK and Sweden and roughly similar to those in France, Spain and New Zealand. The price discount achieved was lower for new innovative products (which account for around 10 per cent of PBS sales). Comparisons based on other benchmarks gave qualitatively similar results that confirm that Australian prescription pharmaceutical prices are low by EU and US standards. In general, the Productivity Commission's results replicate the findings of past pricing reviews (Industry Commission 1996, BIE 1991).

However, some recent work has raised questions about the findings in respect of off-patent drug prices. Most recently, Sweeny (2002) has found the same patterns for patented drugs, but found that Australian generic prices for some key molecules (such as Ranitidine) were actually higher than US prices, while still below the average of other countries. Sheehan and Sweeny (2002, p. 10) also looked at evidence about the pricing of generic drugs and consider that Australian generic prices are relatively highly priced by international standards.

Table 3.1   **Ratio of Australian price to foreign price**
Weighted results[a]

	All		New innovative		Me-too		Off-patent[b]	
	Low	High	Low	High	Low	High	Low	High
US	0.38	0.29	0.49	0.46	0.35	0.33	0.40	0.22
Canada	0.66	0.55	0.92	0.92	0.63	0.58	0.66	0.47
UK	0.68	0.61	0.80	0.79	0.64	0.61	0.71	0.56
Sweden	0.68	0.64	0.91	0.85	0.63	0.61	0.67	0.61
France	0.89	0.85	1.09	1.09	0.85	0.85	0.91	0.78
Spain	1.04	0.98	1.18	1.18	0.98	0.93	1.12	1.03
New Zealand	1.09	1.02	1.00	1.00	1.03	0.99	1.20	1.09

a The estimates are based on the lowest and highest list price of manufacturers supplying the matched molecules. The results use an Australian basket of most popular molecules and are weighted by Australian sales volumes. As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country comparison with Australia, the results do not provide a good guide to relative price levels across other countries. The Australian to US price ratio may be higher than reported here because of the practice of discounting, which is thought to be more widespread in the US than in Australia. **b** The Productivity Commission (2001) referred to this class as 'generic' (in line with IMS) — but note that it includes originator brands that are out of patent as well as copies.

Source: Productivity Commission 2001 (chapter 3).

In part, the difference stems from the coverage by the Productivity Commission study of both out-of-patent originator molecules and generics, while these latest studies only included generics. It is well known that originator molecules remain highly priced after patent expiry in the US (Productivity Commission 2001, p. 54), and this is reflected in the Productivity Commission's estimates of price levels for US off-patent drugs, but not in the studies based on non-originator off-patent drugs. However, the Commission also looked at price differences between different countries based on the lowest price of manufacturers producing the molecule. Such a comparison would usually exclude originator out-of-patent brands, yet large differences still remain between Australian and US prices (table 3.1). On the other hand, evidence on the distribution of price differences between Australian and UK off-patent drug prices (discussed in section 3.5) suggest that a significant share of Australian off-patent drug prices are higher than UK prices for comparable molecules, and this may reflect Australian generic prices. The implication of this for a price suppression rationale for this drug type is addressed in section 3.5.

Price differences versus price suppression

While the operation of the PBS is likely to lead to lower prices, it should not be inferred that the differences between Australian and overseas pharmaceutical prices reflect only these institutional features. Price suppression may be a significant part

of the story, but like many other traded goods and services, there are a variety of other demand and supply factors that underlie price variations.[16]

Pfizer (2000, p. 5) — in commenting on the large apparent differences between US and other world prices — noted:

> … price variation is an entirely normal phenomenon… It's true across countries for all manner of products. It's not surprising: local supply and demand conditions differ from place to place.

A participant in the review, Merck Sharp & Dohme (sub. 11, p. 5) considered that there are 'several factors contributing to price differentials', though it argued that PBS arrangements are the 'overriding factor'. It gave evidence from studies by Schankerman (1998) and Danzon and Chao (2000) about the importance of price regulation in reducing prices, especially for older molecules. But other factors may also play a role — such as international variations in income and costs (some of these other possible contributors to price variations are considered in appendix D).

The Productivity Commission's (2001) detailed assessment of international variations in pharmaceutical prices could not find robust specific explanations for the observed bilateral price differences between Australia and other countries. For example, prices in Sweden were higher than Australia despite similar cost containment and subsidisation arrangements. The Commission concluded that international price differences stem from a combination of influences, such as systemic differences in health systems, cost-containment approaches, production costs (including marketing and liability costs) and demand conditions. Nevertheless the Commission concluded that there is:

> … some evidence to support the view that Australia's cost-containment arrangements may have contributed to keeping prices relatively low. The application of reference pricing in particular, may have been significant, although to what extent remains unclear. (p. XXX)

Overall, the bargaining power arising from Australia's PBS arrangements almost certainly translate into lower prices, but the exact price effect is unknown given that other influences may also lead to price effects. Price suppression is not equivalent to

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[16] It might be tempting to gauge price suppression by comparing the prices of drugs at their launch price on the private prescription market (where there is no price suppression) with their subsequent PBS list price. For example, Paroxetine (Aropax) was launched in the private market at a price of $50.03 and listed on the PBS in August 1994 nine months later at $49.93 (Productivity Commission 2001, pp. F.4–7). However, while apparently promising as a measure, it ignores the fact that there are usually some substitutes for private scripts on the PBS. Since the PBS places a (relatively low) cap on co-payments, this inevitably forces firms to price newly launched products on the private market at lower prices than they would if the PBS drugs to consumers were not subsidised.

the absolute difference in prices between Australia and relevant comparator countries.

Bargaining power arising from Australia's PBS arrangements almost certainly lead to lower prices, but the exact price effect is unknown given other influences.

3.4 Does price suppression reduce drug profits?

For price suppression to have any adverse effects on the local pharmaceutical industry, it must also reduce profits below what they would have been otherwise. It may seem obvious that a decrease in prices below the level selected by the manufacturer as profit maximising must reduce profits. However, price suppression is in exchange for selective access to a subsidised formulary. The revenue effects on suppliers are not proportional to the extent of the price suppression because of volume gains that arise from substantial consumer subsidies. If marginal costs are sufficiently low and gross revenues increase, then profits may increase for those firms whose products are listed.

The question when gauging the effects on profits of price suppression is the appropriate counterfactual. One possible counterfactual is free pricing, with consumers meeting all of the costs of drugs. Consumers would face much steeper prices. While there are few studies, it is generally held that pharmaceutical demand does not respond much to price increases.[17] However, almost certainly part of the reason for this is that many countries provide significant subsidies or insurance cover so that prices to consumers are relatively low, and elasticities are being measured in the less elastic region of the (Marshallian) demand curve. That would not hold under the given counterfactual.

Were consumers to actually face the prices paid to producers for drugs, demand could be expected to fall significantly[18], if nothing else because of the income

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[17] For example, Gibson and McLaughlin (2001) found a long term elasticity of -0.06 (from data where the co-payment increased from $2 to $7). Harris et al. (1990) found an elasticity between -0.06 and -0.08 (based on relatively modest changes in the absolute values of co-payments). Smith (1993) found an elasticity of -0.10. A UK study by O'Brien (1989) found a significantly greater degree of price responsiveness with an estimated elasticity associated with a co-payment of -0.33, with similar results reported by Hughes and McGuire (1995). However, Lavers (1989) found a rather lower UK elasticity (between -0.15 and -0.20). Details on a wider range of studies are in Lexchen and Grootendorst (1999) and Ringel et al. (no date).

[18] Assuming linearity, as prices rise, demand shifts to increasingly elastic portions of the demand curve.

effects of such high prices.[19] Thus, firms might make more revenue and, given low marginal costs for drugs, greater profits, from being in a low price but subsidised formulary, than to have 'free' pricing and no consumer subsidies.[20] Were the latter an appropriate counterfactual to the present arrangements, then it would not be clear that price suppression really harmed firms (that get listing for their products) at all relative to the monopolistic pricing benchmark — and this would invalidate the present rationale for the PIIP.

However, while several studies have seen this as an appropriate benchmark (such as the BIE studies), it is not a realistic or appropriate one. First, in the absence of a government scheme, private insurers would provide risk-pooling services that reduced the exposure of individual patients to high annual costs of pharmaceuticals. Demand would be higher, and in order to control costs, such insurers would themselves use strategies such as restricted formularies and authorisations. Consequently, a non-PBS counterfactual would not necessarily involve volumes that would be depressed by as much as the free pricing monopoly model would imply, nor prices that are as high.

In that case, it is less certain how profits would be affected by a restricted publicly subsidised formulary relative to some private risk pooling arrangements. For example, suppose that marginal costs are 15 per cent of non-suppressed prices, and Australian prices are 20 per cent below the appropriate benchmark prices. In that case, profit neutrality would require quantities of drugs sold under the PBS to be 30 per cent higher than that under a non-price-suppressed system with insurance. Whether this would be feasible would depend on the magnitude of subsidised co-payments in a public insurance system relative to that which would apply in a private system.[21]

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[19] One pharmaceutical firm indicated to the Commission that it expects to sell four times as many drugs when they are listed on the PBS than when they are available privately at full cost. However, that is probably not a good guide to demand patterns that would prevail in a 'free' market for the reasons discussed by Merck Sharp & Dohme (sub. 11, p. 28).

[20] For example, suppose that contributions to patents are $R=(p-c)q$, where p is the price to the manufacturer, c is marginal cost and q is the quantity of scripts. There is a linear demand curve of $p=a-bq$ and (in a regulated environment) co-payments of $(1-g)p'$ and price suppression of $(1-r)p'$ where p' is the price that would hold in an unregulated market. In the regulated market, there is a wedge between prices paid by consumers and that received by producers. The differences between regulated and unregulated revenue is $p'/b\{p'[g+r(1-g)]-cg-ra\}$, which will be generally positive so long as g is sufficiently higher than r and c is sufficiently small.

[21] Using the approach of IAC (1986, p. 22), net revenue (before meeting fixed costs) with no price suppression is $R_1=(p_1-c)q_1$. With price suppression, prices to producers are $p_1(1-r)$ and quantities are q_2 so that $R_2= (p_1(1-r)-c)q_2$. Following the IAC (1986), expressing c as a share of pre-price-suppression prices, $c=\lambda p_1$, then the value of (q_2/q_1-1) that allows $R_1=R_2$ is $r/(1-r-\lambda)$ from which the result in the text may be obtained.

In consultations, some pharmaceutical firms noted that Australian script volumes were not higher than other countries and that this refuted the notion that the PBS led to volume effects over other reasonable counterfactuals. However, such an observation is not a convincing refutation. First, it is not clear that the particular regulatory arrangements holding in another country — where even more generous subsidies may be provided — is a reasonable one. In the context of other markets, perhaps the most plausible counterfactual would be one in which prices were set freely by pharmaceutical firms and unsubsidised, fully informed, private insurers and patients collectively met the full costs of scripts. The relevant question is whether high consumer subsidies under the PBS — made possible by lower pharmaceutical prices — are likely to stimulate demand compared to a counterfactual in which prices are higher and drugs purchases are fully funded by private insurers and patients. It seems likely that this would involve some volume offset.[22]

Secondly, international comparisons fail to control for a host of other factors that can influence drug demand — such as income, GP practices and institutional differences. This seems likely and is consistent with the US PhRMA's (2001) findings in respect of the inability of expenditure controls to manage overall expenditure.

Further evidence on the question of volume and price offsets have been explored in several international empirical studies. Danzon and Kim (2002) find that any automatic link between low prices and low profitability cannot be assumed. They argue that differences between countries in the discounted present value of expenditure per capita at launch is a more meaningful indicator of comparative drug returns than single-point-in-time drug prices. The life cycle measure picks up volume effects — and most importantly the speed of diffusion of a new drug[23] — which are important determinants of the present value of expenditure. The new measure can reverse country rankings based on point-in-time drug prices. For example, among the seven countries examined over the period from 1981-1992

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[22] Some participants argued that price-volume agreements nullified the effects of the subsidy (for example, Sheehan sub. 15, p. 7). There is strong evidence that price-volume agreements and other restrictions are an important feature of PBS arrangements. However, interpreting their impact on overall drug volumes depends on how the counterfactual is depicted. To some extent, price volume agreements are incentive arrangements that address prescribing outside the agreed indications. Private sector agencies, such as HMOs in the US, also attempt to control drug uses outside agreed indications. Moreover, in the absence of price-volume agreements, and in the presence of funding constraints, government would have to raise co-payment rates, with their own volume effects. A reasonable counterfactual should not assume that tax payers fund any relaxation of pricing or volume constraints.

[23] The diffusion rate for a new drug is the share of expenditure on all drugs accounted for by the new drug.

(Canada, France, West Germany, Italy, Japan, UK and the US), France had the lowest launch prices (some 30 to 58 per cent lower than the US depending on weights), while the US, Germany and the UK had the highest. However, in terms of 30 year per capita life cycle revenues, the US was highest, then France (at 94 per cent of the US), followed by Canada (91 per cent) and Italy (86 per cent). Germany and the UK were at the bottom. Unfortunately, it is beyond this report to undertake similar analysis for Australia. However, it is notable that current diffusion rates of new drugs in Australia appear to be relatively high (as discussed later). On the other hand, as pointed out in several submissions (for example, Sheehan sub. 15, p. 7), there are range of volume controls in Australia.

PhRMA (2001), the major US pharmaceutical manufacturers association, claim that price controls do not reduce pharmaceutical expenditure, citing studies by Redwood in 1993 and Gross in 1994 that lower prices lead to a sufficient increase in the volume of drug sales to maintain the same level of revenue.[24] Were these findings to be valid, they imply that the impacts of cost controls on the profits of pharmaceutical manufacturers can be relatively weak. This is because pharmaceutical companies receive the same level of gross revenue, while the incremental costs of supplying any additional volume of drugs sold are relatively low (once large upfront investments in R&D, the active plant and marketing have been made).

However, it seems more likely that volume responses provide only a partial offset for profits lost from price decreases. The view of Merck Sharp & Dohme for the Australian situation (sub. 11, p. 8) was that:

> While the effect on total return of lower prices paid for pharmaceuticals under the PBS is offset by higher volumes as a result of government subsidies to some degree, this has to date not been quantified with any accuracy.

Even if only exerting a partial offset, volume effects have to be considered when estimating the overall cost of price suppression to Australian pharmaceutical firms. It is common to calculate the savings to Australians generated by PBS price suppression based on equalising Australian and world prices at existing volumes. For example, even the Commission's previous study of the pharmaceutical industry undertook such an assessment (IC 1996, p. 352). However, such estimates are upwardly biased as measures of the costs of price suppression to pharmaceutical firms because they make unwarranted assumptions about the source of international price differences and ignore the effects of volume reductions that would emerge with higher prices (box 3.1).

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[24] While expenditure by Governments may not be reduced, lower prices enable greater consumption of effective new drugs for any given level of expenditure.

Box 3.1   **The value of price suppression**

In 2001, spending on benefit-paid pharmaceuticals by individuals and governments was $4820 million.[25] Assuming that Australian prices were 70 per cent of the world average and that there would be no volume responses to higher prices, then Australia benefits, on this basis, from its deviation from world prices by around $2.07 billion a year.

However, in practice, the real impact of price suppression is likely to be much less than this. First, pharmaceutical firms acknowledge that 'free' pricing would still result in Australian prices that were lower than the world average. Secondly, some volume effects could be expected if higher priced pharmaceuticals were, to some degree, funded through higher co-payments.

As noted in appendix D, the 1995 BIE study estimated that free pricing would generate a 22 per cent increase in Australian prices. Suppose that just one third of the additional burden of such costs were met by co-payments, and the demand elasticity were -0.3 (which may be reasonable given that the resulting changes in co-payments are large, especially for concessional patients). In that case, back-of-the-envelope calculations (that take into account demand effects for concessional and general prescriptions separately) suggest that total revenue for pharmaceutical firms would rise by around $300 million per year, or just over 6 per cent of existing revenue — which is a long way short of $2.07 billion.

These calculations are clearly illustrative, rather than a careful attempt to measure the revenue impacts of price suppression. Changes in assumptions about the extent to which prices would rise, how much of the additional cost burden is funded through co-payments, consideration of the distribution of prices and different elasticity assumptions would clearly generate other estimates.[26] For example, if co-payments were required to fund half the additional cost burden, the total revenue of pharmaceutical firms would rise by only $55 million. Equally, under a different set of assumptions, increases in pharmaceutical firms' revenue could be substantially greater than $300 million. The point to emphasise is that measuring the revenue impacts of price suppression needs to go well beyond calculating the difference in revenue at constant volumes that arises by equalising Australian and world prices. They also need to posit clear counterfactuals (of which there may be several contenders) and to select appropriate parameters.

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[25] An additional amount was spent on non-benefit-paid PBS-listed prescriptions by individuals (AIHW 2002, p. 48). While no exact estimates are available of this amount, Miller and Draper (2001, p. 26) estimate that altogether 26 per cent of (non-hospital) prescriptions do not attract a government benefit. Some of these will be for non-PBS-listed drugs. But it is expected that the bulk are listed on the PBS, but are priced under the co-payment threshold for general beneficiaries. While such drugs are not subject to government subsidies, they are still subject to potential price suppression. In that sense, the financial effects of any price suppression based on benefit-paid pharmaceuticals will be underestimated.

[26] Noting that the first factor — price increases — should not be seen as an exogenous variable, but as a factor that pharmaceutical firms would determine in the light of the expected demand responses by individuals.

In summary, while volume effects partly counteract the effects of price suppression, it is likely that profits are suppressed by Australia's bargaining arrangements compared to reasonable counterfactuals.

FINDING 3.2

While volume effects partly counteract the effects of price suppression, it is still likely that the overall impact of price suppression on net revenue remains negative.

3.5   Does price suppression reduce domestic activity?

Almost all pharmaceutical firms visited by the Commission were of the strong view that price suppression, price-volume agreements and other features of the PBS made Australia a 'hostile' location for new investment in pharmaceutical production or R&D.[27]

A survey undertaken by the Lewin Group (2001) on behalf of a working group for the Pharmaceutical Industry Action Agenda elicited similar responses by head offices.[28] Head offices suggested that pricing and reimbursement factors were the most important dynamic for locational decisions (table 3.2) and reported Australia as a poor location in terms of two out of the three factors (table 3.3).

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[27] It should be emphasised that the fact that Factor f and PIIP — which provide compensation for PBS price suppression — have induced new activity does not imply that PBS price suppression would, by itself, reduce activity. This is because the subsidies in Factor f and the PIIP are designed to induce activity; subsidies are not paid unconditionally as part compensation for low prices.

[28] Quite apart from the usual problems associated with qualitative surveys of perceptions (such as subjectivity and finding the appropriate decision-maker/s in the firm), a significant drawback of such surveys is that they are likely to elicit strategic answers. MNEs would clearly prefer greater freedom to set reimbursement prices in all markets and their answers presumably reflect this.

Table 3.2 **Perceptions of factors important in driving pharmaceutical R&D and manufacturing investment[a]**

Head offices, 2001

	Operational costs	Taxation environment and incentives	Human resources and infrastructure	Regulatory issues	Pricing/reim-bursement issues	Geographic distance and time zones
	% of firms	% of firms	% of firms	% of firms	% of firms	% of firms
R&D						
Very high	13.3	37.5	25.0	50.0	62.5	0.0
High	46.7	37.5	56.3	31.3	25.0	20.0
Average	33.3	18.8	18.8	18.8	12.5	20.0
Low/very low	6.7	6.3	0.0	0.0	0.0	60.0
Manufacturing						
Very high	37.5	62.5	18.8	25.0	53.3	0.0
High	56.3	31.3	56.3	56.3	20.0	31.3
Average	6.3	6.3	18.8	12.5	26.7	31.3
Low/very low	0.0	0.0	6.3	6.3	0.0	37.5

a The data are based on responses from 15 to 16 firms, depending on the area being rated.

Source: Lewin Group (2001).

And the issue is not unique to Australia. For example, in a recent review of the UK pricing arrangements it was asserted that free pricing was an important factor in making the UK environment attractive to pharmaceutical firms:

> Pharmaceutical companies have freedom to determine launch prices in the UK, within the constraint on the total profits they are permitted to earn from sales to the National Health Service under the terms of the Pharmaceutical Price Regulation Scheme. This makes the UK a more conducive environment for innovative pharmaceutical companies than many other countries which do not permit free pricing at launch (PICTF 2002, p. 9).

More generally, a report in *Scrip* Magazine — an international publication for the pharmaceutical industry — contends that four indicators of public policy are important in determining the corporate strategy of research-based drug companies towards particular countries. These are:

> the strength and durability of patent protection, pricing policy for new drugs; reimbursement policy for new drugs and the policy balance between industrial and health care priorities (Redwood 2002, p. 8).

Based on those four factors, Redwood (2002) suggests that the industrial climate for pharmaceutical innovation in Australia (along with countries such as France, Spain and Italy) is weak or negative. The climate is ranked more highly in several countries, including the US, Switzerland, Germany, Ireland, Canada, Japan and Sweden.

Table 3.3   **Rating of the effects of Australia's pricing and reimbursement system on investment in R&D and manufacturing[a]**

Head offices, 2001

	Domestic pricing of pharmaceuticals	Transparency and predictability of the reimbursement process	Broad market access to pharmaceuticals
	% of firms	% of firms	% of firms
R&D			
Excellent	0.0	0.0	6.3
Good	0.0	12.5	25.0
Average	20.0	12.5	37.5
Poor	33.3	31.3	18.8
Very poor	46.7	43.8	12.5
Manufacturing			
Excellent	0.0	0.0	0.0
Good	0.0	0.0	23.1
Average	14.3	14.3	46.2
Poor	21.4	35.7	15.4
Very poor	64.3	50.0	15.4

a The data are based on responses from 14 to 15 firms, depending on the area being rated.

Source: Lewin Group (2001).

Past reviews of the Australian pharmaceutical industry and the PBS have concluded that there is probably a link between price suppression and domestic activity, albeit generally indicating that the size of the effect was modest (box 3.2).

These reviews were based primarily on the views of pharmaceutical firms and some empirical evidence relating to price differences. But, with the exception of the Commission's 1996 inquiry (IC 1996, pp. 321–50), they did not undertake in-depth analysis of the potential economic links between price suppression and pharmaceutical activity.

Government buying-power and locational decisions by MNEs

It is often remarked that the PBS buying arrangements represent a monopsony — a monopoly buyer facing competitive suppliers. The welfare and pricing consequences of classical monopsony are straightforward (Layard and Walters 1978, p. 238). By constraining final outputs and buying less inputs than would occur in a competitive market, the monopsonist is able to purchase inputs at a lower price. This occurs because (under the assumption of an upward sloping supply curve) the costs of supplying additional units of inputs rise as the supply of inputs rise. Prices are inefficiently low, as is output.

Previous reviews of the effects of PBS pricing on domestic pharmaceutical activity

In its report on the pharmaceutical industry in 1986, the Industries Assistance Commission concluded that price suppression under the PBS had:

> … probably led to some reduction in local activity. The extent of this reduction is difficult to estimate, but in the Commission's view it has not been substantial (p. 124).

In its 1991 evaluation of the Factor f scheme, the BIE argued that:

> … it is clear that pricing policies have reduced the level of local activity (p. XIV).

> … the suppression of pharmaceutical prices through the PBS has led to some loss of pharmaceutical activity in Australia, with consequent welfare costs … However, the comparatively small size of the lost activity suggests that care needs to be taken, in providing any compensation, not to create second-order distortions leading to further welfare losses (p. 127).

In its 1991 evaluation of the Factor f scheme, the BIE asked Australian pharmaceutical companies to judge the effects on domestic activity were PBS prices to be deregulated (with no PBS pricing power *or* consumer subsidies). Clearly the answers to such questions may be exaggerated for strategic reasons, and the results should therefore probably be seen as upper bounds. Forty per cent of firms claimed that they would increase exports of formulated and packaged pharmaceuticals significantly, while 75 per cent said they would increase the level of clinical trial activity. Very few companies thought that increased prices would make a difference to investment decisions for the manufacture of active pharmaceuticals. The BIE estimated that, based on survey responses by firms, price deregulation would result in increased activity of between $32 million and $108 million — or between about 2 and 8 per cent of current turnover (pp. 22, 50–51).

In its 1995 follow-up examination of the Factor f program, the BIE found that only 1 of 29 respondent pharmaceutical firms considered that deregulated prices would increase the production of active ingredients, while 11 of 29 (38 per cent) considered that overall manufacturing capacity would be increased. Some 66 per cent of firms claimed that employment would be higher and 59 per cent that investment in clinical trials would rise. The BIE estimated that pricing deregulation could increase formulation by 16 per cent and packaging by 30 per cent (pp. 12–15).

In its 1996 inquiry, the Industry Commission identified PBS price suppression as one of the 'key weaknesses of the Australian operating environment', noting that it affected the attractiveness of Australia as an investment location (p. 185), although it also argued that the 'extent and significance of activity lost from price suppression and other restrictions imposed by the PBS is unclear' (p. XIV). The Commission emphasised that any industry assistance scheme should be targeted to deal with any inefficiencies posed by PBS pricing, so that 'the aim of the scheme should be to restore activity lost due to price suppression under the PBS' (p. 275).

However, the classical monopsony case is a poor model for the Government's PBS buying arrangements. The supply curve for pharmaceuticals is not (at least in the

relevant region of interest) rising and the impact of the PBS arrangements almost certainly results in increases in the total supply of pharmaceuticals. (A further quibble is that the input market is imperfectly competitive given patent protection.)

An alternative characterisation of the buying arrangements is given by Ellison and Snyder (2001), Johnston and Zeckhauser (1991) and the IAC (1986). While they have slight variations, in these models, pharmaceutical firms comprise an oligopoly and compete with each other to gain access to a subsidised restricted formulary, transferring significant oligopoly rents to the consumer. Volumes — but not prices — are higher in these models than in a counterfactual state. Nor do these models require that government be the monopoly purchaser — this role can equally be fulfilled by a health maintenance organisation (as shown in the empirical evidence presented by Ellison and Snyder).

In the context of these more realistic models of bargaining under the PBS it is not clear that there would necessarily be any direct effect on Australian activity from price suppression (though, as discussed later, indirect effects can occur when listing itself is affected). Once a firm has decided to list a drug at its suppressed price, it no longer faces a question of *how much* to supply (that is now demand-determined), but *where* to supply it from. It can do so through imports or through varying degrees of local manufacture. Other than when some more subtle factors are at work (see below), whether it makes the drugs locally or not depends on production considerations, such as relative costs, quality, low sovereign risk, preservation of intellectual property and supply reliability, and not on realised prices. All other things being equal, if these production criteria are best met by Australia, then it is likely that the facilities will be located in Australia.

Some firms indicated that head offices would not locate production or research facilities in Australia if the revenue from production were lower per unit of output than some other subsidiary locations. However, this does not appear to be profit maximising, as demonstrated by an example in box 3.3.

FINDING 3.3

Once a decision has been made to supply the Australian market, price is likely to be much less relevant to global location decisions by pharmaceutical MNEs than other factors such as costs and quality.

Of course, to the extent that government or a powerful large private agent secures rents from pharmaceutical companies, these can have economic effects. These rents are ultimately the payoff for risky R&D undertaken by these firms. On a global basis, low drug prices would be likely to adversely affect incentives for undertaking risky innovation by pharmaceutical firms.

> **Box 3.3   Why gross margins should have limited relevance to location decisions**
>
> Say that the cost of making a drug (including any contribution to capital required) is constant at $5.00 per script in Australia, its suppressed price is $7.00 and that 2 million scripts are sold per year in Australia.
>
> Alternatively, the UK could supply Australia. In the UK, suppose that the cost of production is $4.00 per script and its price to government is $9.00 with sales of 5 million scripts a year. The UK operation can also supply all of the Australian market at a cost of $6.00 per script (including freight costs).[29]
>
> The profit per script is $2 in Australia; that is:
>
> $$\text{Profit margin (Australia)} = \frac{20,000,000 \times (\$7.00 - \$5.00)}{20,000,000} = \$2.00$$
>
> Alternatively, if the UK were to supply Australia as well as itself, the profit per script is $3.86; that is:
>
> $$\text{Profit margin (UK only production)} = \frac{50,000,000 \times (\$9.00 - \$4.00) + 20,000,000 \times (\$7.00 - \$6.00)}{(50,000,000 + 20,000,000)} = \$3.86$$
>
> Revenue per script is thus significantly higher in the UK subsidiary than the Australian subsidiary.
>
> However, it is better to produce in both Australia and the UK, making an average of $4.14 per script; that is:
>
> $$\text{Profit margin (separate production)} = \frac{50,000,000 \times (\$9.00 - \$4.00) + 20,000,000 \times (\$7.00 - \$5.00)}{(50,000,000 + 20,000,000)} = \$4.14$$
>
> This is true regardless of the price set for the products the firm is willing to supply to Australia from some source.

However, the adverse effects of low Australian prices alone on the global R&D of any foreign MNE is likely to be negligible given the small importance of the Australian market to such firms. In any case, where efficiency effects occurred as a

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[29] The example has been set so as to qualitatively match the cost and price relativities that may be genuinely encountered. The Commission has been told that many overseas plants can achieve low costs for very large runs, and that Australian plants could not usually match these costs. However, demand is unpredictable and inventories are costly, so quite commonly a large overseas plant will not produce enough of a batch of a specific drug to meet world demand. It cannot then simply make a short run of the relevant drug to fill demand because this would be excessively costly (this is why the marginal cost of supply to Australia from the UK is set much higher than $4). In that case, small plants that specialise in short runs and that have a comparative advantage in switching production from one drug to another, fill these gaps in demand. This is the predominant market niche of Australian plants (for example, one firm said that its large sister facilities in the US took 5 days to clean between production runs of a different drug, whereas it took 16 hours in Australia).

result of the bargaining pursued by Australia and other governments, their effect would be to render uneconomic some worthwhile investments in drug R&D by such MNEs. But there would be no presumption that Australia would be the location where this R&D was forsaken.

The story may be different for any pharmaceutical firms that are more exposed to the Australian market. Such firms (in all likelihood Australian-owned) may be more highly exposed to the Australian market because they seek to list their product in Australia first or find it hard to get access to global markets quickly. Where they are exposed in this way, low prices for in-patent drugs would significantly reduce the overall return to innovation, and would be likely to dampen incentives for future innovation, with likely adverse effects on the amount of R&D undertaken in Australia. CSL (sub. 13, p. 1), for example, noted that:

> For local companies, the business paradigm and decision-making is simple and clear. Our ability to invest in R&D and plant and equipment is directly linked to the margins that we can generate, which depend in turn on the price and volume we can achieve in selling our products. Any significant degree of suppression in either of these parameters has therefore a major impact on our ability to grow our business, invest in R&D and create a virtuous cycle of investment and reward.

(Similar reasoning suggests that low drug prices in the US might well have damaging effects on investment in innovation by pharmaceutical firms exposed to that market.)

FINDING 3.4

Low PBS prices for drugs may adversely affect incentives for future investment in innovation by any pharmaceutical firms that draw a significant share of their global revenue from Australian demand.

While having some effects, the direct effects of price suppression on activity in Australia are likely to be muted for most pharmaceutical firms. However, there may be other, more subtle, routes by which prices have effects on activity. These include:

- the possible importance of local profits, principal-agent problems and liquidity constraints;

- whether price suppression and PBS processes act as signals of a 'bad' and uncertain operating environment;

- country of origin pricing;

- the links between price suppression and listing constraints; and

- strategic behaviour by global MNEs.

These are examined in turn, prior to considering the implications of pricing heterogeneity on activity and some empirical evidence on the effects of prices on activity.

Does the PBS aggravate liquidity constraints?

To the extent that lower prices generate lower domestic revenues for a firm, it reduces the scope for investment from retained profits. In theory, firms could still issue new equity or borrow for investment expansion, but monitoring costs and incentive problems can lead to cases where good investment prospects may not be funded externally. These are referred to as liquidity constraints. They are usually regarded as most severe for small domestic start-ups seeking to finance large R&D or investment expenses.

The BIE (1991, p. 44) claimed that discretionary expenditure by MNEs — for example, on R&D or investment under some threshold amount — are typically funded from profits on local sales. It was argued that price suppression can, therefore, generate liquidity constraints that reduce the scope for such discretionary spending by global companies.

However, the effects of price suppression on financing capacity is less likely to be a significant issue for the subsidiaries of MNEs operating in Australia than for liquidity-constrained domestic start-ups. The former, unlike the latter, often have recourse for funding from head office for projects that exceed some hurdle rate of return, even if local cash flow is insufficient to fund the projects. The monitoring costs and incentive problems that underlie liquidity constraints should not be present to such a large degree between horizontally-integrated entities — this, in part, is why they are integrated.[30]

Even so, there may be some transaction costs in getting funds from the head office (such as overcoming information asymmetries, meeting their approval processes and so on) so that, at the margin, some projects may not go ahead, or be undertaken at a lower scale.

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[30] Moreover, it is generally accepted that, for horizontally integrated entities such as MNEs, the accounting system used for tax purposes and that used for management purposes may differ. For example, at the managerial level the firm may set prices for outputs traded internally across the globally integrated arms of the business at marginal costs, while its tax accounting system may require the addition of profit margins to internal cross-border transactions to comply with transfer pricing regulations of tax authorities (Durst 2002). Global corporate managers penetrate the veil created by tax accounting systems to look at other financial management measures that disclose relative efficiency across different operating arms. It would be strange, therefore, to use book profits as the basis for a discretionary fund, when those profits were an artefact of a particular accounting system.

Accordingly, the presence of liquidity constraints could have some (relatively minor) effects on the activities of pharmaceutical firms. (The activity of domestically owned firms may be more affected as their liquidity is likely to be more constrained by the operation of the PBS.)

While this may be true, it provides a generally weak rationale for compensation of pharmaceutical firms. Anything that affects current profits — be it private or government bargaining, a dip in domestic demand or increased costs — must have implications for funding of new investment for liquidity constrained firms *in any sector* of the economy. An industry-specific response is not appropriate in these circumstances. Instead, governments resolve such problems by attempting to increase the efficiency of the financial sector — and sometimes through generic programs (such as pooled development funds) that provide liquidity for certain kinds of risky ventures.

FINDING 3.5

To the extent that it affects profits, the operation of the PBS could affect pharmaceutical activity by exacerbating liquidity constraints, particularly for domestically owned firms not able to access global capital. However, given that there are better ways of overcoming liquidity constraints, they provide a weak rationale for compensation to pharmaceutical firms.

Does the PBS produce bad signals for footloose MNEs?

Overwhelmingly, the Commission's consultations with the local subsidiaries of MNEs suggested that their (overseas) head offices had adverse perceptions of the Australian pharmaceutical environment arising from the PBS arrangements. It was claimed that these perceptions, unless countered by some other advantage (such as the PIIP), would lead to reduced activity in Australia.

A variety of reasons were given for the importance of head office impressions.

Rules of thumb may be used for location decisions

First, it was often claimed by pharmaceutical firms visited by the Commission that Australia was a small market that was, as one executive put it, 'barely on the radar screen' for consideration by head offices for pharmaceutical investment. If head offices had generally adverse impressions of the Australian environment, then Australia would not be considered at all. This was reinforced by the apparent attitude that head offices did not want to reward countries with adverse pricing and regulatory environments with increased activity. This suggests that, at least for

small markets, head offices may use rules of thumb for investment decision-making. On the other hand, there is evidence that large MNEs are very deliberative and hardheaded in their investment allocation decisions, using complex models and decision-making processes that attempt to maximise long-run returns and minimise long-run costs.[31] This suggests that investment location decisions will typically be driven by an astute appraisal of the fundamentals of competing locations, and except in trivial cases, not by simple rules of thumb.

Price suppression may signal a generally poor policy environment

Secondly, pricing and regulatory decisions by governments may signal their future policy responsiveness to problems that may affect the pharmaceutical industry more generally. These adverse perceptions might matter very little were head office certain about the current and future environment in which its subsidiaries operated in Australia compared with other countries. But they cannot be certain and are exposed to future policy-related risks specific to their industry, such as through policies for intellectual property, industrial relations, education, drug registration and listing.

If a country has a positive attitude to the industry ('we want to have you here') and can signal that credibly, it reduces the perceptions about the risks arising from future policy decisions that can adversely affect the industry. This is particularly the case if the government has actually provided resources in attracting new investment. Such a government would be more likely to intervene to deal with an emerging problem — such as an industrial relations issue — to protect its past investment in the industry.

Without any offsetting signals, price suppression, listing difficulties and price-volume measures may be interpreted by local and head offices as saying that there is a reasonable likelihood that future policies will be inimical, or that the industry's concerns might not be considered. In this context, many local firms indicated that their head offices could not understand the requirement that key ministers in the Government must approve a drug for PBS listing if its expenditure is expected to exceed $10 million a year. They took this as an adverse signal of the general policy

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[31] For example, firms examine costs, quality and capacity utilisation at their global sites and make continuous improvements to optimise plant utilisation and factory to market lead times. Expertise has developed to examine costs, optimal outsourcing and best practice in pharmaceutical firms — both in specialist consultancies and within the pharmaceutical industry itself (for example, Best Practices LLC [http://www.best-in-class.com/pharma/]. Major pharmaceutical firms participate in cooperative benchmarking groups to improve processes at the micro level to reduce costs (for example, http://www.pibg.org).

environment, which fuels uncertainty. All other things being equal, firms facing such uncertainty may prefer to site in other locations.

The problems of uncertainty would be reduced were Australia to have marked comparative advantages in pharmaceutical manufacturing or a large domestic market for prescription drugs. The first would dominate any consideration of location, while the second would make it worthwhile for head offices to use less impressionistic methods for reaching judgments about future risks. But while Australia may have some regional advantages in undertaking some forms of pharmaceutical R&D and flexible manufacturing, it remains a small, and therefore dispensable, global player. Pharmaceutical investments in formulation and packaging capacity and clinical R&D are quite footloose — easily moved among a range of countries with similar endowments.

In this context, some head offices may see price suppression and PBS listing problems as an adverse signal of a broader policy environment such that — without some countering influence — they require higher implicit hurdle rates for investments to take place in Australia compared with other countries.

However, this argument can be overstated. A government that bargains hard in negotiating drug prices may encourage a pharmaceutical capability in other ways (such as through public research, ensuring a satisfactory industrial relations environment, resources for universities, and improvements to drug registration processes). Price suppression is therefore a relatively poor signal of overall government policy with respect to the pharmaceutical sector.

In conclusion, perceptions by pharmaceutical head offices about the suitability of Australia for pharmaceutical activity may be conditioned by price suppression, with possible adverse effects on investment decisions in some cases. However, in general it is likely that the fundamental qualities of the micro and macroeconomic environment — such as input costs, skilled labour availability, quality, access to regional markets and innovative capabilities — are more important determinants of location choices.

FINDING 3.6

Price suppression and PBS listing problems may create a wider adverse perception by head offices of the suitability of Australia for pharmaceutical activity. This may have possible effects on investment decisions in some cases. In general, however, it appears that large MNEs are deliberative and hardheaded in their investment allocation decisions, using decision-making processes based on business fundamentals.

Does country of origin pricing influence locational decisions?

Country of origin pricing occurs where a country importing a drug requires the price to be no more than the price that holds in the market of the exporting firm. This pricing strategy could increase the likelihood that MNEs will locate capacity for exporting to such destinations in higher price countries. Consequently, price suppression in Australia may affect the export viability of Australian plants and — if their scale or capacity utilisation is then sub-optimal — their viability altogether. This was raised as a significant issue in the Commission's 1996 inquiry (IC 1996, pp. 333–6) into the industry, but was not emphasised by participants in this review.

Country of origin pricing is uncommon among OECD countries, which constitute the main destination of Australian pharmaceutical exports (BIE 1995). But pharmaceutical firms suggest that country of origin pricing is relatively widespread in the Middle East and Asia and, more critically, that head offices are concerned about the potential for the practice to spread (IC 1996, pp. 334-336). In theory, this could limit the willingness for head offices to endorse investment in long-lived assets in Australia —whose viability may be affected by the wider adoption of country of origin pricing in the future.

That said, the notion that country of origin pricing could become quite so pervasive, or that it possesses the significance given to it, is unconvincing. Pharmaceutical firms possess market power conferred by patents and knowhow. The prices that are determined for supply to a particular country for a given drug cannot merely be decided by the election of country of origin pricing by an export destination. The supplying firm can presumably say no. If they can't say no, then it reflects significant countervailing power by the buying country, which will exist whether they wield it through an insistence on country of origin pricing, the price in New Zealand or just a very low price. It seems naive to suppose that a country could:

- demand country of origin pricing from Australia for a drug that yields a price of, say $10 per script; and

- yet, be unable to respond were exports now to come from Germany at, say $30 a script.

In that context, country of origin pricing is likely to be an *expression* of countervailing power that is likely to persist in another form if the country of origin pricing strategy no longer yields good prices. To the extent this is the case, country

of origin pricing would not have the claimed effects on the profitability of Australian exports under price suppression.[32]

FINDING 3.7

Country of origin pricing by other countries does not provide a credible rationale for compensation for PBS pricing in Australia.

Do listing and volume constraints cut pharmaceutical activity?

While the *direct* links between price suppression and domestic production and R&D activity are tenuous, some firms indicated that there were links between PBS listing/volume constraints and reduced domestic activity:

- if a drug is not listed on the PBS or significant volume controls are applied to listed products, then prospective sales are low (box 3.4). The fewer key drugs that are listed for a given company (or the greater are any volume controls if it is listed), the less likely that the firm will place capacity in Australia to formulate and package drugs, since the overall regional volumes may be insufficient to warrant investment in such capacity. (Some firms manufacture non-listed drugs in Australia for export, but the sales volumes are usually small);

- 4th-stage clinical research only occurs after a drug is in wide use. Non-PBS-listing would typically make such trials infeasible in Australia; and

- while earlier-stage human clinical trials do not require listing, a pharmaceutical firm will not undertake such trials if they do not expect to ultimately list in Australia because of ethical concerns. It would be regarded as inappropriate to conduct trials, but not to have the relevant drug available for participants on the subsidised formulary after completion of a successful trial.

However, as discussed below, no country comes close to listing all new molecular entities (NMEs). In this context, the extent of non-listing in Australia would need to be substantially worse than other countries to result in a material effect on domestic activity.

In addition, whether listing and volume constraints are of relevance to industry policy depends on the grounds for their existence. On the one hand, where the constraints reflect informed decision-making by the PBAC based on maximising patient welfare, then there would usually be no basis for any policy remedy. The situation is akin to that of an informed consumer that decides not to buy a product

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[32] If country of origin pricing is not an expression of such power, then it is either irrational (because it would shift the source of imports to high pricing countries) or it would have to be shown that there was some saving from applying such a rule of thumb pricing strategy.

— it would be odd to compensate a producer for sales that would have occurred had consumers been less well informed.

Box 3.4   Case study of COZAAR

Merck Sharp & Dohme provided the following on COZAAR, a blood pressure medicine:

> When COZAAR was delisted from the PBS for pricing reasons, MSD was unable to attract additional export markets, such as Taiwan, and manufacturing volumes declined.

> If manufacturing volumes are low (approximately 50 per cent of Merck Sharp & Dohme's local overall production is for the Australian PBS market), then opportunities for futher investment decline. In the COZAAR example, the loss of volume translated into the loss of $8-10 million total investment in a new packaging line. If volumes had been maintained, a new packaging line ($5 million) would have been purchased and another $3-5 million would have been spent locally to install and validate the line. The new manufacturing opportunity would have created an additional 10 jobs.

Source: Merck Sharp & Dohme (sub. 11, p. 12).

On the other hand, sometimes a product will not be listed as a result of price and volume bargaining between government and firms. This may arise in two circumstances. First, rationally a Government may bargain hard, even if a cost-effective treatment is ultimately not listed, in order to achieve lower prices for other drugs and greater overall benefits in the future. Secondly, it may also occur because pharmaceutical firms also bargain hard and may rationally refuse to allow a drug to be listed at a low price (even where it is sufficient to cover marginal costs) so as to get higher prices for other drugs in the future. Pharmaceutical firms also may rationally refuse listing at a suppressed price because of concern over 'contagion' effects from Australian prices on other markets (box 3.5). In some cases, firms claimed that they did not even seek TGA approval for a drug because of anticipated price suppression.

The argument that price suppression is a major (indirect) source of restricted, delayed or non-listing may in part be resolved through empirical evidence on the relative extent of the phenomenon in different countries. If the argument were robust, then it would be expected that it would be more severe in countries with greater degrees of price suppression.

Unfortunately, appropriate data to resolve the question are scarce. The IC (1996) cited several cases of drugs that were delayed or not listed, but the figures relate only to Australia and so provide no picture of Australia's relative standing. The Productivity Commission (2001, pp. 75–6) found some evidence that volume restrictions were more likely to be used in Australia than New Zealand and Canada, but did not have results for other countries.

> **Box 3.5   How realistic are contagion effects?**
>
> Contagion effects may arise in several ways. The most explicit mechanism is benchmark pricing, which occurs when a country insists that prices be based on the average or lowest of prices applying in other countries. For benchmark pricing to be a significant concern, it would have to be demonstrated that:
>
> (i)   key markets included Australia as one of the comparator countries;
>
> (ii)   Australia was given a weight that made a noticeable difference to prices; and
>
> (iii)   in the absence of Australia's inclusion, the buyers concerned would not extract the gains in some other way.
>
> While benchmark pricing is used widely in the EU, at least in 1996 it was often without reference to Australia (IC 1996, p. 207) — casting some doubt on condition (i) above. However, one firm approached by the Commission during this review claimed that Sweden and Canada included Australian prices in their benchmark pricing basket, although with an unknown weight.[33] Taiwan's Bureau of National Health Insurance uses median prices of pharmaceutical drugs in 10 industrialised countries, including Australia, as the basis for reimbursement.[34] South Korea and Brazil also apparently use Australian prices in their price baskets. One participant indicated that Germany was currently introducing a requirement for reference pricing to Australia.
>
> As in the case of country of origin pricing, it also seems unlikely that (iii) could be met were buyers able to obtain any marked reduction in price by merely including Australia (with a large weight) in their basket of comparators. It is improbable that buyers only possess countervailing power that can be expressed in one form. However, at the margin, the threat of future benchmark pricing may have an effect on firms' willingness to list products in Australia when prices are suppressed — and that can then affect activity levels.
>
> Another possible mechanism for contagion effects is more indirect, informal and hard to verify (Merck Sharp & Dohme, sub. 11, p. 9). Australian prices are readily observable and could be used informally by negotiators in other countries to attempt to leverage price arrangements at the margin. However, firms could counter such bargaining by undermining the relevance of the Australian case by emphasising factors that differ across the markets (such as lower labour and marketing costs).

Firms interviewed by the Commission cited particular molecules that were not listed or where delays have been experienced (and some of these concerns are taken up in more detail in chapter 8). They also claimed that non-listing was an increasing problem for Australia relative to many other OECD countries. Medicines Australia (2002, p. 18) cite evidence that suggests that Australia had the lowest level of

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[33] This was also claimed by another firm, Glaxo Wellcome, at the time of the IC's 1996 review (IC 1996, p. 208).

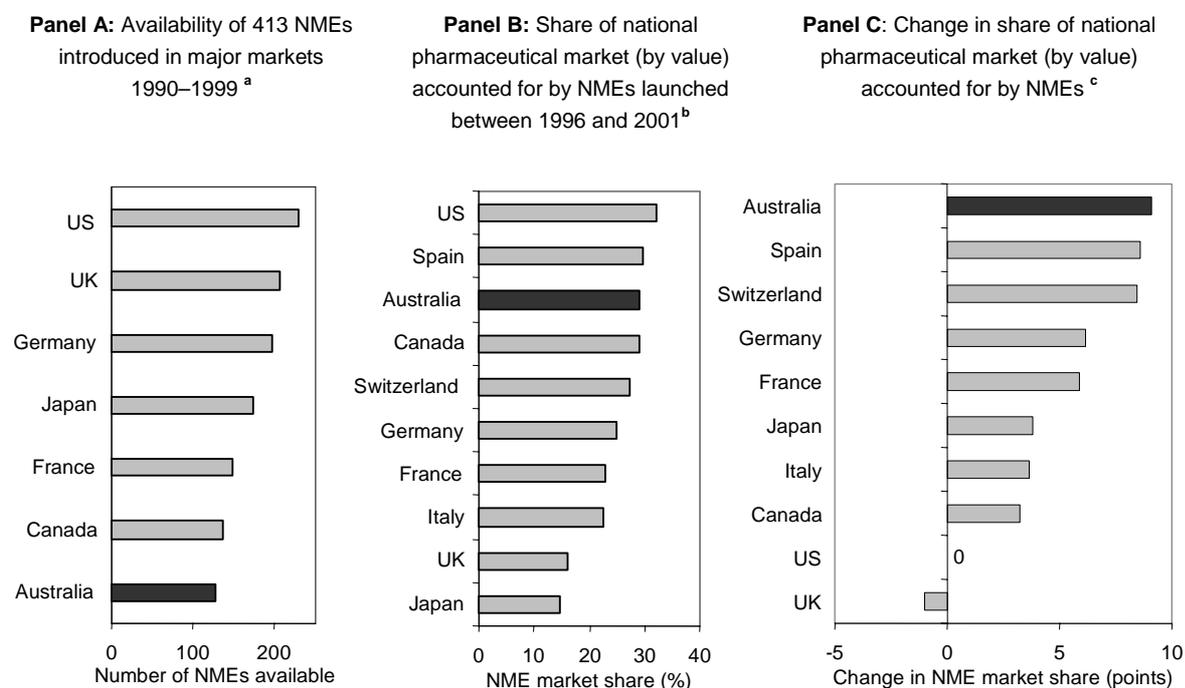[34] http://www.nhi.gov.tw/02hospital/hospital_file/chi65-3.doc.

product launches of new molecular entities (NMEs) first launched in global markets between 1990 and 1999 (figure 3.1, panel A).

Unfortunately, the link between price suppression and product launches of NMEs cannot be reliably ascertained. There are only five countries for which the Commission has both price data and product launch data. There appears to be a positive relationship between pricing and the introduction of NMEs, but it is not statistically significant — reflecting the fact that Canada has higher prices relative to Australia than does the UK, but has around 35 per cent less NMEs launched than the UK. And while the low level of new product launches in Australia may in part reflect PBS arrangements, the pattern shown in figure 3.1 (panel A) may also be explicable in terms of Australia's small market size and the absence of large domestic pharmaceutical firms that develop new drugs in Australia. (Market size is seen as the single major determinant of the location of new drug releases.)

In any case, while Australia tends to have a relatively low acceptance of NMEs as measured by the *number* of such entities, arguably a better indicator of acceptance is the market share acquired by NMEs that are successfully launched. This takes account of the fact that many NMEs are not therapeutically important given existing treatments (after all, most countries launch less than half of the NMEs anyway). On this measure Australia has the fifth highest penetration of the market by NMEs of ten major countries (figure 3.1, panel B).[35] There appears to be little relationship between this measure of product acceptance and price differences (on the basis of information on pharmaceutical prices for six of these countries). Australia also has the fastest rising share of NMEs over time among the cited countries (panel C). On this basis, while individual companies may sometimes encounter listing problems and volume constraints that affect NMEs, there does not appear to be a severe systemic problem associated with listing of therapeutically significant new drugs in Australia. As noted in chapter 8, the industry has claimed this has changed very recently.

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[35] In addition, a study based on interviews with head office decision-makers suggests that most thought that Australia's access to pharmaceuticals was average, and about as many thought it was good to excellent as thought it poor or very poor (Lewin Group 2001).

Figure 3.1   **Measures of the penetration of new molecular entities in different countries**

Panel A: Availability of 413 NMEs introduced in major markets 1990–1999 [a]

US
UK
Germany
Japan
France
Canada
Australia

0   100   200
Number of NMEs available

Panel B: Share of national pharmaceutical market (by value) accounted for by NMEs launched between 1996 and 2001 [b]

US
Spain
Australia
Canada
Switzerland
Germany
France
Italy
UK
Japan

0   10   20   30   40
NME market share (%)

Panel C: Change in share of national pharmaceutical market (by value) accounted for by NMEs [c]

Australia
Spain
Switzerland
Germany
France
Japan
Italy
Canada
US
UK

-5   0   5   10
Change in NME market share (points)

[a] This represents the number of 413 new molecular entities (NMEs) that were first launched onto the world market between 1990 and 1999 that have been launched in each of the markets. [b] This is the share of the market for prescription drugs accounted for by NMEs launched between 1996 and 2001. Shares are calculated on the basis of market value. [c] This is calculated as $S_{1996-2001} - S_{1994-1998}$ where S_i is the share of the market for prescription drugs accounted for by NMEs over the ith period.

Data source: PICTF (2002) based on IMS data for data in panel A and for $S_{1994-1998}$ in panel C. $S_{1996-2001}$ for panel B and C is from IMS World Review cited in www.abpi.organisation.uk/statistics.

Thus, while, in theory, there is a possible mechanism by which price suppression can affect domestic activity levels by precluding the listing of certain (cost-effective) drugs, in practice it is questionable whether this justifies compensation through an industry program. This is because:

- some non-listing and volume agreements can be ascribed to the application of evidence-based medicine and would not warrant compensation;

- while listing problems may sometimes occur for particular drugs, the relevant issue is whether there is a systemic problem that is worse than other countries; and

- where cost-effective drugs were not listed or subject to unreasonable volume controls, an industry program would be a largely ineffective and partial response to such a problem. While it might resolve some industry concerns, it would not help consumers get greater access to cost-effective drugs. To the extent that the emerging drug listing problems described by industry are severe, the appropriate

remedy would be to deal with these problems at their root — reforming the listing processes of the PBS. This issue is taken up further in chapter 8. That said, a possible benefit of the PIIP is that it has allowed (so far) one pharmaceutical firm to use their PIIP payments to achieve notional price increases for drugs that head office would not permit to be listed were such supplementation unavailable. These benefits have been included in the cost-benefit analysis in chapter 6.

<div align="right">

FINDING 3.8

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Problems in PBS listing could have some effects on activity. However, these would best be countered by targeting them directly.

Is domestic activity a bargaining chip that can be lost in strategic games between the Government and MNEs?

Low trade barriers and transport costs[36] and small cost differentials between several alternative locations, mean that head offices have choices about where to site pharmaceutical formulation and packaging activities (BIE 1991, pp. 18–19). Different governments — perceiving that the industry brings benefits to their economies — wish to be chosen (the question of whether this perception has validity is examined in the next chapter). Competition between governments 'bidding' to acquire activity provides pharmaceutical firms with additional negotiating leverage beyond that obtained from their ownership of patents and knowhow (BIE 1991, p. 19). For example, Singapore, Ireland and Puerto Rico have at various times, set out to attract pharmaceutical companies with tax and other concessions.

The bargaining power held by pharmaceutical firms is strengthened further by the perception that the opportunity to acquire (or retain) production facilities is a fleeting one. This may be true for new generation greenfields investment (for example, in biotechnology active ingredients), but warnings about a narrow window of opportunity for conventional formulation and packaging capacity does not appear to have eventuated (box 3.6).

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[36] Transport costs were said to be less than 1 per cent of total costs for an imported product.

Box 3.6   **The imperative to be first in the race to acquire facilities**

In visiting the domestic arms of MNEs, the Commission was advised that the packaging and formulation industry was being rationalised world-wide, and that a relatively few regional hubs would serve their regional markets. It was advanced that there was a narrowing window of opportunity for Australia to act as a regional hub — and that in the absence of a program such as PIIP, pricing suppression would make Australia unattractive as a locational choice.

The same issues were raised in 1991:

> In the event of the environment improving, and to the extent to which it already has through Factor f, a 'window of opportunity' may exist in the current atmosphere of firms assessing and rationalising manufacturing activities on a global basis (BIE 1991, p. 31).

And four years later in 1995, the apparently ephemeral window was still open:

> Against the background [of a spate of mergers and locational rationalisation], factors influencing the attractiveness of Australia as a location for pharmaceutical activity take on increased importance, because the window of opportunity provided by this company re-structuring may only be open for a relatively short period of time (BIE 1995, p. 11).

This underlines the continuing (albeit somewhat questionable) perception of a narrow window of opportunity to attract production facilities.

To the extent that a country does not provide sufficient enticements to a globally footloose industry, then MNEs may decide not to locate there. In some circumstances it may even make strategic sense for an MNE not to locate in a country with 'excessive' price suppression, even if production is more efficient in that location. Such an MNE may be willing to make a (small) short-term loss from such a decision, if it subsequently reaps long-term gains. The strategy may realise these overall gains for two reasons. First, it may persuade the country concerned to change its policy if its government values local pharmaceutical activity. Second, it provides credibility for its implicit threat to other countries considering following similar price suppression approaches that the result may be the loss of R&D and production facilities.

For example, one MNE indicated that, as a matter of head office policy, it would not undertake any R&D or production business in New Zealand while the government maintained its degree of price suppression and listing controls. This was regardless of the basic quality of medical research in New Zealand or of its endowments suited to manufacturing. Another firm, Servier (sub. 7, p. 3) noted that while some firms continued to undertake R&D in New Zealand (despite its adverse pricing and listing environment), this was in decline:

> PHARMAC has been in place for about a decade now and its regressive, unpredictable approach to pricing has seen the number of companies active in New Zealand decrease by about half, from 28 to 17. R&D investment by the pharmaceutical industry is cited

as NZ $18 million per annum and is in decline. Servier has progressively had its products removed from the pharmaceutical schedule and closed its office in New Zealand in 2001 … All R&D investment in New Zealand by Servier will cease from next year as current studies are completed… The New Zealand example should also serve as a sharp reminder of what can happen if the focus is purely on short term health budgets.

It is uncertain whether the same strategy would be widely used for Australia were price suppression not to be countered by the PIIP. On the one hand, Australia is a relatively wealthy country with pharmaceutical expenditure that is higher than many other regions with higher populations. It is also has many endowments that make it a good location for supplying South East Asia (for example, sovereign risk is low, it has a skilled workforce and good infrastructure). Moreover, Australia has high quality domestic medical research capabilities in certain niches. These attributes would encourage firms to continue investment in areas of advantage in Australia.

On the other hand, Australia is still small globally, so that any static losses to individual MNEs from withdrawing activity would be small. Moreover, withdrawing activity in a low priced country would reinforce firms' bargaining power in bigger and more important jurisdictions.

It is hard to weigh up these two offsetting factors. Strategic considerations probably have some role in decision-making and provide a possible mechanism by which low PBS prices could depress activity. But it is not clear that this type of bargaining power is significant, particularly since pharmaceutical firms do not coordinate their bargaining. A threat by a single firm may be hollow if other firms continue to undertake activity.

FINDING 3.9

While MNEs may possess some additional bargaining power associated with the perceived desirability of pharmaceutical activities, this power is not likely to be very substantial.

Accounting for heterogeneity in drug pricing in determining effects on activity

While Australian prices are on average lower than in other countries, this is not true for all molecules. For the three general categories of drugs, there are some molecules that are more expensive in Australia than elsewhere, as illustrated in the case of the bilateral comparison with the UK (figure 3.2). This is particularly notable for off-patent drugs and new innovative drugs. Around 13.4 per cent of the Australian PBS sales value of new innovative drugs are accounted for by drugs that

are more expensive in Australia than the UK, while the related figures for off-patent and me-too drugs are 40.8 per cent and 5.7 per cent respectively. (It is uncertain what share of generics per se is above UK prices. But it is generally accepted that off-patent originator drugs are low priced in Australia versus other countries. This suggests that 40.8 per cent would underestimate the share of generic drugs that were more expensive in Australia).

Figure 3.2   Distribution of the Australian/UK price differential[a]
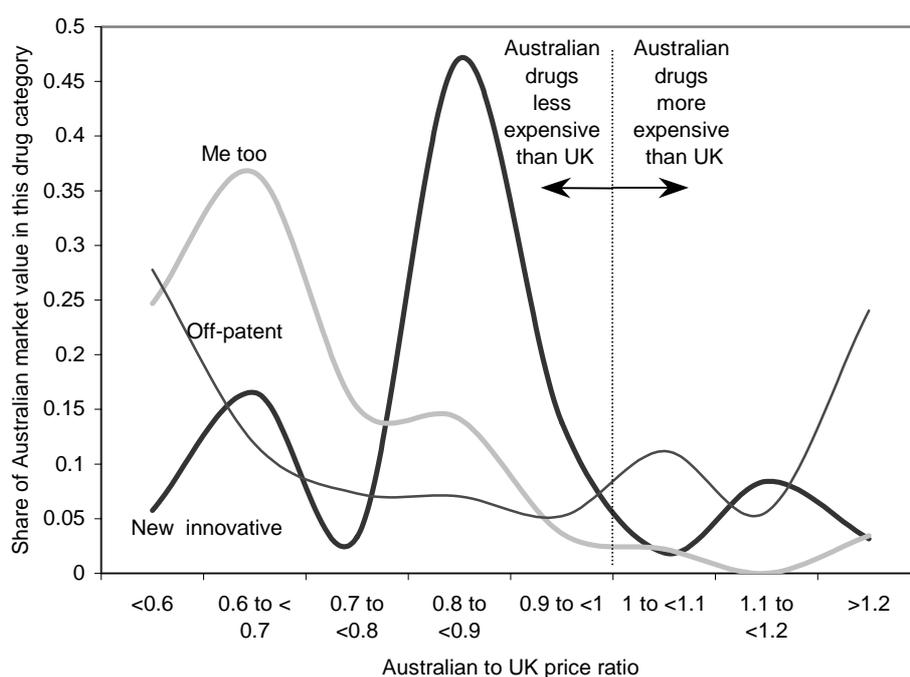
a The data is based on IMS volumes for Australia and low prices for the UK. The data set was the same as used by the Productivity Commission in its 2001 study of international differences in drug prices.

Data source: Unpublished data from the Productivity Commission — based on IMS data.

Figure 3.2 suggests that to the extent that domestic prices were really a powerful influence on activity, pharmaceutical firms would tend to shift their production towards such highly priced drugs. However, in discussing the factors that determine a firm's choice of which PBS-listed drugs to manufacture in Australia rather than import, many firms indicated that the Australian price was not a consideration in determining which drug to formulate or package in Australia. Rather, factors such as comparative production costs and gaps in global capacity were more important factors. This is consistent with global cost minimisation and generally inconsistent with the view that price suppression has direct effects on production decisions. It also weakens the credibility of both the country of origin pricing and liquidity constraint arguments since, all things being equal, firms that were concerned about these problems would have incentives to select higher Australian priced drugs in

their domestic production portfolio. Of course such a choice may not be available to domestically owned firms.

Consideration of differences between the extent of price suppression for different classes of drugs, raises the broad question of whether any PBS-based rationale for a PIIP applies equally across these drug types.

- There is some doubt about whether price suppression exists for Australian generic prices. To the extent that relative Australian generic prices are high by world standards,[37] this undermines the case for subsidising their activity on a price suppression rationale, though some doubt about this remains.

- The claimed source of price suppression is failure by the Government to pay its share of the massive R&D costs that are spent in developing new drugs. In the case of off-patent drugs (whether branded or generic), the expiry of the patent opens up drug manufacture to competition, with no expectation that any contributions be made to the original R&D. Other than through imperfections in markets (such as entry barriers) or differences in costs, it would be expected that competition would lead to close to a single world price for off-patent drugs. Clearly there is no such uniform price. But it is questionable whether a government should consider intervening to offset price differences that reflect costs or market imperfections.

On the other hand, low prices for off-patent originator brand drugs are likely to depress demand for generic substitutes, including those manufactured in Australia — 'volume suppression'.[38] This is likely to be the major reason for Australia's relatively low share of generic products in the total drug market than many other countries. Accordingly, while doubts exist about the validity of a price suppression argument for off-patent drugs, there are arguments for including generics were an industry support program to subsidise pharmaceutical production:

- *if* price suppression leads to lower domestic production for branded drugs due to revenue and other perceptions, then it could be expected that similar processes would translate volume suppression for generic products into lower than optimal domestic production of generic drugs. If that is the case, then generics should also be included in any program; and

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[37] This is suggested by figure 3.2 and Sheehan and Sweeny (2002, p. 10), but not by some other evidence in table 3.1. It should also be noted that the generic manufacturer participating in the PIIP was able to demonstrate that the prices *on certain products* were lower than the European average. However, that would not be salient if many other drugs were priced above the EU average.

[38] Indeed, there will also be some expected substitution between on-patent and off-patent drugs that have similar therapeutic effects. This is the basis for Australia's reference pricing system.

- even were generic manufacturing in Australia to be largely unaffected by price suppression in the branded drug market (for example, by gearing to the export market), the introduction of subsidies for manufacturing branded drugs would lead to resource allocation effects away from the generic drug industry. Of course, the efficiency losses from this bias are not likely to be great — simply because, by definition, generic manufacturers must make a therapeutically identical product and use almost identical processes and resources as branded manufacturers. However, there could be some losses associated with forgoing developments in new drug delivery systems or competition in improved manufacturing processes.

What does the empirical evidence suggest?

While the potency of the links seems weak, ultimately the issue is an empirical one. What empirical evidence is there that countries with higher prices tend to have higher levels of pharmaceutical activity?

There are relatively few existing studies. Using international data from 1968 to 1985, Wu et al. (1995) found that favourable patent controls and higher prices encouraged new drug development, but new drug development is largely not the issue at stake in Australia. The BIE (1991, p. 19) report a positive relationship between domestic prices and the net exports to sales ratio as the measure of activity, using data from a number of European countries. (The actual results, their statistical significance and relevant countries are not published.) The results are interpreted as being favourable to the hypothesis that higher prices have effects on the locational decisions of MNEs.[39]

However, the Commission has been unable to replicate the BIE results. Indeed, using the BIE's 1991 price data and OECD trade and production data for pharmaceuticals yields no statistically significant positive association between prices and a variety of activity measures (appendix B). Indeed, using trend data over 1980-1995, there appears to be a *negative* relationship between prices and export activity. As noted in appendix B, such a negative association would be expected where price differences arise from cost differences. The observed pattern need not imply that, where price differences lead to higher profits, the same negative

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[39] It should be noted that the performance measure used by the BIE is not necessarily relevant to this hypothesis and the finding could — in special circumstances — be interpreted in the opposite way. For example, were domestic prices to be high, but domestically sold volumes contracted sufficiently as a result of such high prices, then domestic sales would fall and export to sales ratios would tend to rise despite the country actually being a less desirable location for activity.

relationship would be found, but some other empirical investigations in appendix B also cast doubt on that link.

The empirical evidence that pharmaceutical pricing significantly influences production activities is not strong. However, this does not rule out weak effects, which would be hard to detect using the data that are available.

What is the overall effect of price suppression on activity?

The Commission has considered many possible PBS-related factors that could conceivably lead to reduced pharmaceutical activity in Australia. There are some theoretical links, but they are more complex and subtle than the simple argument that exploitation of monopsony power must lead to adverse impacts on Australian pharmaceutical activity. The evidence does not point to strong impacts in practice.

Another way of looking at the plausibility of any claim for a significant effect is to consider what would happen to Australian activity were prices for PBS drugs to be as high as in the EU (say, with no change in patient co-payments). It would be clear that profits would rise, but far from clear that firms would wish to produce much more here.

The Commission's assessment of the PBS-based rationales for a compensation policy is summarised in table 3.4 and suggests that the arguments are much weaker than often claimed.

Table 3.4   **Summarising PBS-based rationales for a compensation policy**

Rationale	Credibility of rationale	Likely overall strength
Low prices directly discourage activity	Poor generally, but a factor for domestically exposed firms	Weak generally
Liquidity constraints	A possible basis (especially for Aust.-owned firms)	Weak to moderate
Adverse signals	Possible minor effects	Weak
Country of origin pricing	Poor	Little to none
Listing problems	Possible effects	Weak so far
Strategic games by MNEs	Weak	Weak

Overall, while the activity of some individual firms may be affected by PBS-related factors, it is likely that the aggregate effects are relatively small.

3.6 Are any adverse activity effects inefficient?

Even were activity to be depressed as a consequence of local prices, the question arises as to the productive efficiency consequences for Australia. The primary concern would be that Australia was forgoing returns from allocating resources to an activity in which we possessed a comparative advantage. Thus, resources — like labour or capital — might be employed in industries other than pharmaceuticals, when they could earn higher returns from engaging in pharmaceutical R&D or manufacturing, where they would be more productively employed. And from a global perspective, the implication would be that Australia has some unexploited cost advantage over other countries. (While most pharmaceutical firms seen by the Commission considered that they had some advantages in niche markets, none saw Australia as likely to be a major site for greenfields pharmaceutical manufacturing — it is claimed that there are alternative locations which are relatively close cost substitutes.)

The conventional methodology for measuring the efficiency costs of lost activity is general equilibrium analysis. This takes into account how all markets respond to distortions that are present in a particular industry and the fact that resources displaced as one industry contracts are usually employed in other industries. Using an elaborate computable general equilibrium model, Econtech (2002) has modeled the impacts of price suppression in the pharmaceutical industry. The starting point for the analysis is the assumption — given to Econtech by the APMA (now Medicines Australia) — that price suppression leads to a 35 per cent fall in production in the pharmaceutical industry.[40] This would represent a much larger contraction in PBS-related domestic manufacturing, given that a significant part of sales of the pharmaceutical sector as defined by Econtech includes non-PBS products (such as OTC and veterinary products). Econtech models price suppression as a production tax on the industry (with the revenue passed back to consumers as an income tax cut).[41]

Econtech finds that the fall in production of 35 per cent (or $1400 million annually) translates to only an 11 per cent fall in local sales because pharmaceutical imports expand by 25 per cent. There is a loss of 5800 jobs in the pharmaceutical industry.

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[40] Medicines Australia (2002, p. 25) indicates that the 35 per cent contraction is based on industry estimates of the effects from continuing adverse PBS processes and pricing outcomes over the next three years.

[41] The method by which Econtech introduces price suppression into the model is revealing. Price suppression is not at all akin to a production tax — it affects imports as well as domestic production and is generally regarded as increasing the overall level of pharmaceuticals demanded. However, were price suppression to be modelled in this way, it would not have the activity effects assumed.

There are significant adverse downstream industry effects (mainly on pharmacies) and upstream effects (mainly on the packaging industry).

The aggregate national effects are much less severe than would be supposed by just looking at the pharmaceutical industry in isolation. As the exchange rate depreciates in response to the increased trade deficit, some other tradeable sectors expand — such as agriculture and mining. There is no net increase in unemployment as workers shift to other parts of the economy. The overall loss to consumers from the less efficient allocation of resources is $198 million annually (a loss of 0.07 per cent of private consumption) — or about one seventh of the initial production effect of price suppression. The effect on GDP is zero.

However, given the findings in section 3.5, it is debatable that price suppression could lead to as big an effect on production activity as 35 per cent. The mechanisms for effects from price suppression of this magnitude are not plausibly present. Accordingly, any welfare losses (measured as losses to consumers) are likely to be a fraction of the annual $198 million estimate.

Moreover, it should be noted that as the activity effects of price suppression fall, the efficiency costs fall by an even greater proportion (reflecting the fact that the distorting effects of tax rates are roughly a square of their magnitude). Thus, were price suppression to depress activity by 10 per cent, the welfare effect could be expected to be significantly less than $56 million annually. (Were the implicit taxes on pharmaceuticals in the Econtech model to be the only taxes on the industry and the square 'rule' were to apply, it would be $16 million.)

Accordingly, even if it is accepted that domestic pharmaceutical activity is adversely affected by the operation of the PBS, it seems likely that the efficiency costs are small.

A more fundamental issue for interpreting economic welfare analysis of the kind undertaken by Econtech is whether the base case satisfactorily takes into account any existing distortions in markets. For example, a production tax can *improve* welfare if it reduces the impact of an inappropriate subsidy, reduces tax disparities between industries or reduces output in an industry that generates costs borne by consumers or other industries. The question is whether the Econtech base case has adequately characterised any relevant distortions.

Unlike many other products, pharmaceuticals are sold in highly imperfect and regulated markets:

• consumption of pharmaceuticals is subsidised, as is consumption of complementary and substitute medical services;

- there are strict approval processes before drugs can be marketed;

- doctors, not patients, prescribe ethical pharmaceuticals. This can be justified because of large information asymmetries about drug efficacy and side effects for consumers and concerns about drug dependence. But it also means that doctors' decisions about medicines are often made without necessarily taking into account the full preferences of the consumer. For example, the differing preferences people may have for a good night's sleep if one drug produces sleeplessness, while another with slightly differing efficacy does not. Accordingly, one set of information asymmetries is exchanged for another. (It also means that many patients must pay for the cost of a visit to the doctor as well as the pharmaceutical they wish to get prescribed);

- doctors' prescribing software has often been biased against generic rather than branded pharmaceuticals (which is currently being amended under measures announced in the 2002-03 Commonwealth Budget — Patterson 2002) and doctor's prescribing habits may be influenced by marketing efforts;

- marketing direct to consumers is barred;

- drugs may not be prescribed appropriately. On the one hand, they are sometimes prescribed for conditions that do not warrant them. For example, the AMA (2002) estimated that proton pump inhibitors were intended for a target population of less than 35,000 patients, but have actually been used by 177,000 people, costing an additional $220 million per annum. On the other hand, drugs that are effective for a new indication may sometimes not be prescribed for that indication because of PBS restrictions; and

- patents give pharmaceutical firms temporary market power as an incentive to innovate. However, there is no certainty that the tradeoffs are perfect or that there are not flaws in the system — such as the potential for excessive or inadequate patent lives, the possibility of wasteful patent races, or questions about whether downstream and upstream patents should be treated symmetrically.

In this context, price suppression and other facets of the PBS are simply one side of multifaceted regulatory dice whose throws shape the nature of the pharmaceutical industry. A gambler cannot only count double sixes. Nor can an analyst of the myriad effects of the complex regulatory and market regime facing the pharmaceutical industry be similarly selective. Thus, while a production tax on the pharmaceutical industry certainly reduces economic welfare in the absence of these other distortions and market features, it is unclear what would happen to economic welfare were they to be fully incorporated.

That said, moves are afoot to deal with many of the factors that might bias consumption upwards, such as inappropriate prescribing. It is also hard to argue that current levels of subsidies given for pharmaceutical consumption are excessive given that some level of risk spreading insurance is optimal. In that context, cost-saving pressures — such as through listing restrictions and price suppression — may increasingly become more dominant influences on the industry. To the extent that these reduce activity, they may then have adverse impacts on economic efficiency.

3.7 Is there a rationale for assistance based on price suppression and PBS defects?

It has generally been accepted that the operation of the PBS lowers prices below what they would have been otherwise. This report also confirms this finding. (There is also some evidence that PBS processes can sometimes delay or frustrate listing of new drugs.) However, the impacts of price suppression on profits are not equivalent to the percentage discount for drugs achieved under the PBS.

Moreover, the link between price suppression for *listed* PBS pharmaceuticals and reduced domestic activity is at best oblique for those firms — the majority — that derive only a small share of their revenue from Australian sales. Once a decision has been made to list and supply a drug to the Australian market, it would be expected that such firms would source their drugs on the basis of business fundamentals (such as relative costs), with prices of much weaker relevance.

That said, there could be some more complex links between suppressed prices and domestic activity — such as by generally damaging head office perceptions of Australia or intensifying liquidity constraints.

Price suppression is only one of a myriad of distortions and special features affecting the pharmaceutical market. Some of these tend to push production and consumption below optimal levels, while others tend to push it above. In the presence of this whole field of distortions, it is probably impossible to determine whether counteracting a single one of them — price suppression — would improve or reduce economic wellbeing in Australia. But as policies remedy those distortions that tend to encourage over-consumption of pharmaceuticals, then the balance shifts. In that eventuality, price suppression and listing restrictions may have some small adverse efficiency effects to the extent that they impede pharmaceutical activity.

Overall, price suppression and other features of the PBS may have some adverse efficiency effects on pharmaceutical activity in Australia, though it has not been demonstrated that the effects they have would, on their own, be large enough to warrant remedying. This rules out — on PBS-based rationales — the application of generous countermeasures, simply because tax-funded interventions generate their own inefficiencies.

On the other hand, the subsidy equivalent of assistance under the PIIP is not large at around 3.5 per cent,[42] so the question is whether such small subsidies could be justified in the presence of weaker PBS effects. This is not clearcut. Small imperfections are endemic in many markets, yet, in most cases, these imperfections are not seen to justify a plethora of small counteracting measures. This reflects the transaction costs, dynamic inefficiencies and political economy issues that such interventions would elicit. On that basis, PBS-based rationales, *by themselves*, are a doubtful basis for an industry-specific program. However, as emphasised in chapter 7, where there are other grounds for such a program, it is important to take account of these PBS-based rationales in its design.

FINDING 3.12

The rationale for assistance to the pharmaceutical industry based on price suppression is much less persuasive than conventionally claimed. Nonetheless, some effects on activity are likely. While the magnitude of these effects may not justify a program by themselves they should be taken into account if there are additional grounds for an industry-specific program.

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[42] It is estimated that the Australian pharmaceutical industry value added associated with prescription medicines is around $920 million (based on the fact that human-use pharmaceutical value added is $1.15 billion in 1999-00 and that around 80 per cent of this is prescription medicines and the remaining 20 per cent OTC medicines). Annual subsidies under the PIIP are $50 million, but these are taxed and their payment is deferred so that the effective subsidy is around $50(1-t)/(1+r)$ where t is the corporate tax rate (currently at 30 per cent) and r is the discount rate (assumed to be 10 per cent). This is equal to around $32 million, which implies an effective subsidy rate of around 3.5 per cent.

4   Other rationales

The previous chapter discussed the extent to which the PIIP can be seen as a legitimate policy response to the effects of price suppression and other PBS-related arrangements. This chapter examines several other possible economic rationales for government intervention in the pharmaceutical industry and addresses some popular perceptions about why the government needs to intervene.

The main rationales and perceptions are that:

- substantial 'spillover' benefits associated with pharmaceutical production and research may lead to lower than optimal activity in the sector without government intervention. This includes the argument that a critical mass of pharmaceutical activity is needed before Australia becomes an attractive investment location for the industry (agglomeration benefits) and that government can provide funding to foster such critical mass;

- governments compete for globally mobile capital by giving industry assistance in various forms. As a result, it is argued that Australia will lose out unless it too provides industry-specific assistance;

- governments can counteract sub-optimal investment decisions made by global firms on the basis of information failures and mistaken rules of thumb; and

- pharmaceutical production capability is a strategic asset that is worth having for geopolitical reasons.

To the extent that these have validity, they provide a prima facie rationale for intervention through an industry-specific response only if either of two conditions hold.

First, such a response may be warranted if the problems are specific to the pharmaceutical industry. However, sectoral boundaries are only convenient statistical and conceptual categories for groups of firms that share certain characteristics. These characteristics may not coincide with any firm, market or government failures that provide a rationale for intervention.

A second basis for an industry-specific intervention is if different program designs are likely to be more effective for different industries (for example, because of operational issues or superior information) than a single umbrella program. For

example, the existing major generic measure for providing support for business R&D, the R&D Tax Concession, is often not exploited by the Australian subsidiaries of foreign pharmaceutical MNEs because they do not meet certain tests relating to ownership of the intellectual property (section 4.1).

But even in cases where there appears to be a potential justification for an industry-specific program, any gains from differentiating policies have to be set against:

- the costs of increased complexity in managing a diverse set of policies, both to government and to firms (which might be eligible for assistance in multiple industry programs);

- the costs of lobbying and rent seeking on the part of firms who stand to benefit;

- the costs of resisting regulatory capture on the part of government; and

- the distorting effects arising from the unequal treatment of different industries.

Because of these problems, it is often better to develop generic assistance programs that target the underlying market, firm or government failures, without regard to sectoral boundaries. Nonetheless, there are circumstances under which industry specific programs are warranted and this chapter is concerned with establishing if this is the case for the pharmaceutical industry in Australia.

Section 4.1 examines evidence on the existence and source of spillovers and assesses the difficulties faced by foreign MNEs in accessing the R&D Tax Concession. Section 4.2 analyses the merits, or otherwise, of government competition to attract FDI. Section 4.3 examines the extent to which information failure and 'rules-of-thumb' in decision making by pharmaceutical companies constitute a rationale for industry specific assistance. Section 4.4 briefly discusses the relevance of geopolitical considerations. Section 4.5 concludes.

4.1   Spillover effects from pharmaceutical activity

What are spillovers?

When the activities of a firm or a consumer have beneficial (detrimental) effects on third parties that are not paid for (compensated for), economists call the gains (losses) *externalities*. Activities that give rise to positive externalities among producers are sometimes called *spillover effects*. The most commonly cited source of spillover effects is knowledge. The reason that knowledge gives rise to spillover effects is that it has public good characteristics. In other words, it can be available to numerous users simultaneously and potential beneficiaries cannot easily be denied

access to it. The generation of spillover effects represents a strong justification for government intervention because economic agents tend to base their decisions on private returns and not to take into account benefits they create for third parties.

However, the concept of spillovers is not clear cut and there can be controversy about what constitutes a spillover effect. The examples in box 4.1 show that providing inputs to a firm can have beneficial effects on a supplier's prospects in the future. However, the mere fact that a supplier has benefited from its contract work for another firm does not show that spillover benefits were present. The supplier may have factored expected 'flow on' benefits from clinching the contract into its contract bid, in which case the benefits would have accrued to the buyer via a lower contracted price.

Box 4.1   **Ostensible examples of spillovers in pharmaceuticals**

Newpulse Systems has developed a three dimensional computer aided design system to facilitate the installation of CSL's new 'Prostak' filtration system in its influenza production facility. Newpulse is now in a position to offer this system to other pharmaceutical manufacturers. (CSL, quoted in IC 1996, p 307)

CMPS&F and Hooker & Cockram have expanded their capabilities in project management and knowledge of clean room technology and design as a result of their involvement in the construction and commissioning of CSL's sterile antibiotic dispensing facility. (CSL, quoted in IC 1996, p. 307)

Three of the four contractors shortlisted to build SmithKline Beecham's factory in China are Australian companies with previous experience in design and construction of Australian pharmaceutical factories. (Glaxo Wellcome, quoted in IC 1996, p. 306)

Even if the benefits did not accrue to the buyer, and spillovers were genuinely present, government intervention would not automatically be warranted.

Firstly, it is important to emphasise an additionality perspective when dealing with government intervention. Spillovers have no policy relevance if they are associated with pharmaceutical activity that would have occurred without a prompting subsidy.

Moreover, for intervention by the Government based on the rationale of generating spillover benefits to be warranted, the spillover benefits from the increased pharmaceutical sector activity would need to be greater than the spillover benefits from alternative intervention increasing activity in another sector. Thus, unless spillovers from pharmaceutical firms are systematically higher than from non-pharmaceutical firms, there would not even be a prima facie case for government intervention. Success stories such as those described in box 4.1 can be obtained in most industries.

It is generally accepted that certain activities, such as new knowledge generated by R&D, give rise to more spillovers than others do. Governments have attempted to overcome potential under-investment in R&D through a myriad of mechanisms, such as public provision and funding of research and education, generic subsidies to industrial R&D and enhancement of firms' ability to appropriate larger fractions of the gains from innovation through intellectual property protection. Against the backdrop of these generic measures, the threshold question for this chapter is whether there are grounds for specific measures to foster spillovers in the pharmaceutical industry.

Empirical evidence on spillovers: implications for pharmaceuticals

The empirical literature on spillovers is vast, complicated, and multifaceted. Despite continuing problems of defining and measuring spillovers,[1] the literature generally confirms that, across many sectors, R&D activity gives rise to spillover effects (for example, BIE 1994, Harris and Kells 1997, IC 1995).

However, such spillovers are not derived uniformly from the various forms of R&D and are sensitive to the characteristics and nature of the specific R&D undertaken. For example, it is usually accepted that spillovers from publicly funded research — which is generally more fundamental and less appropriable — are proportionately larger than from private research (Henderson and Cockburn 1998). This favours government assistance targeted at the basic end of the R&D spectrum.

Foreign direct investment (FDI) has long been held to be a major vehicle for the transmission of spillover benefits, primarily in the form of know-how and technology,[2] and sometimes through wage premiums for employees in MNE subsidiaries.[3] This is of substantial relevance to the Australian pharmaceutical industry, given the dominance of foreign subsidiaries.

However, it cannot be assumed that spillovers always arise from FDI. It appears that spillovers derived from attracting international investment by MNEs are dependent on the characteristics of the host economy, as well as the specific features of the investment. For example, Braconier et al. (2000) found no evidence of FDI-transmitted R&D spillovers in Swedish manufacturing. One explanation for this result may be that Sweden has very high R&D spending and that it is a technology

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[1] For a smorgasbord of articles indicating the growing methodological and econometric sophistication of the literature see, for example, Griliches (1992); Gorg and Strobl (2001); Cincera and Van Pottelsberghe de la Potterie (2001); and Keller (1998).

[2] Webster (2002); Hubert and Pain (2001); Hejazi and Safarian (1999); and Liu et al. (2000).

[3] These are intended to reduce inter-company information flows (Motta et al. 1999).

leader in many areas where MNEs operate. Thus, the benefits of FDI are likely to depend on the amount of technological catch-up required by domestic firms — suggesting FDI policies may be more applicable to developing economies (Xu 2001).[4]

In one of the few studies involving the pharmaceutical industry, Feinberg and Majumdar (2001) found that the only R&D spillovers generated by MNEs in India were appropriated by other MNEs, rather than domestic firms. This appeared to reflect the unique operating environment for such firms in India, and the legacy of patent and other regulations. In the context of these mixed results, it is hard to infer the magnitude or type of spillover benefits that might occur from pharmaceutical FDI in Australia.

Spillovers are significantly related to input-output relationships. So, as well as horizontal spillovers (between firms that make the same type of product), spillovers also follow upstream and downstream paths. Reflecting the importance of these linkages, industry clusters can enhance spillovers. For example, Forni and Paba (2002) found such links important in Italian manufacturing. These routes for transmitting spillovers provide a possible rationale for policy measures that create or reinforce industry clusters (such as Singapore is pursuing for their pharmaceutical industry) and that strengthen capabilities in the entire supply chain. However, interestingly, Forni and Paba found no evidence of linkages between relevant industries and the growth of the pharmaceutical industry.[5] Similarly, while Laursen and Meliciani (2001) found that national industry linkages improve the international competitiveness[6] of linked firms for many industries, their study did not reveal this pattern for the pharmaceutical industry.

An important question is whether spillovers are higher in 'high' technology industries. This is relevant to the pharmaceutical industry because its R&D intensity is one of the highest of all industries.[7] The empirical findings are ambivalent. While

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[4] As elsewhere in the spillover literature, there are counter-examples. Tsou and Liu (1997) generally find no significant spillovers from FDI in Taiwan, except where the technology gap between foreign and domestic firms was low.

[5] To the contrary, their study found linkages to what presumably should be irrelevant industries, namely 'Radio, TV and communications equipment' (at 1% significance level) and 'Printing and publishing' (at the 10% significance level) were the only sectors that were associated with the growth of the pharmaceutical industry.

[6] Measured by the trade balance.

[7] For example, according to PhRMA's annual membership survey, the pharmaceutical industry has the highest R&D spending to sales ratio of any major industry in the USA, estimated at 17.7% in 2001 (PhRMA, 2002, p13).

the literature on spillovers does tend to find such a pattern, this is not always true.[8] In any case, Australia's pharmaceutical industry is much less R&D intensive than the OECD average.[9]

One major avenue for reducing under-investment in R&D is to internalise as much of the spillover benefits as possible. Governments the world over have instituted patent protection for that reason. Interestingly, in a study of 650 R&D executives, Levin et al. (1987, cited in Fölster 1991, p. 43) showed that patents were seen as offering effective competitive advantages for new technology in most chemical industries, including pharmaceuticals, but to be less effective in most other industries. In addition, while patents also disclose information to rivals about promising research avenues, the large costs associated with clinical trials and product registration procedures means that the imitation costs associated with the introduction of 'me toos' are very high. This accentuates the protective capacity of patents in the pharmaceutical industry (van Reekum 1999, p. 90). If accurate, this would be consistent with less under-investment in pharmaceutical research than in most other industries.

FINDING 4.1

There is no persuasive evidence to suggest that pharmaceutical activity leads to higher spillover rates than other industries, though they are still likely to be appreciable.

The foregoing is not a full overview of the immense literature on spillover effects, but it illustrates the point that policy must consider the context in which spillovers might arise. The literature highlights that, in trying to quantify the spillover benefits from pharmaceutical R&D, it is important to consider the heterogeneity of pharmaceutical activity, the precise links between MNEs and domestic firms, and the nature of the policy environment in which these operate (for example, patent protection regimes). For example, it is important to take account of the differential potential for spillovers from different types of R&D, such as that involved in the different stages in the drug discovery and development process.

The next section examines where spillovers might arise in the supply chain in the pharmaceutical industry and whether the structure of the Australian industry is weighted to areas where such effects might be found.

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[8] As in Forni and Paba 2002.

[9] While R&D intensity is estimated to be 11 per cent of gross output over the period 1991 to 1997 in the OECD at large, it is estimated to be only 5.1 per cent in Australia (Messinis 2002).

Sources of spillovers in the pharmaceutical industry

While some pharmaceutical R&D can potentially give rise to large spillovers, other R&D activity is not likely to generate many spillovers (for example, routine procedures that use standardised laboratory tests for toxicology or in meeting regulatory requirements). Furthermore, definitions of R&D are somewhat arbitrary and can include activities that do not systematically generate knowledge likely to be useful outside a particular specialised use. Some activity that is counted as R&D in the pharmaceutical industry has no obvious equivalent in many other industries (such as some aspects of clinical trials). The type and magnitude of spillover benefits associated with these activities could be expected to be different. Thus, given the heterogeneity of pharmaceutical R&D, it is important to understand the relative importance of various types of activities in generating spillovers, if estimates of their magnitude are to be obtained.

Table 4.1 gives a brief description of various R&D activities in the drug pipeline and also gives estimates of their relative importance in the overall drug discovery and development process.

Discovery/basic research

In general, the larger the portion of an innovation that is not appropriable by the researching firm, the larger the spillovers (ie the larger the benefits conferred on third parties that they are not paying for). Other dimensions, such as the speed of diffusion and the absorptive capacity of recipient firms, also play an important role.

Given that the fruits of R&D are more likely to be appropriable the more developed the innovation, one would expect spillovers to be stronger at the discovery/basic research stage than at clinical trial stages for example.[10] However, most pharmaceutical firms in Australia undertake relatively little basic research. Nonetheless, pharmaceutical firms in Australia do fund some basic research and collaborate with universities and biotechnology companies. The PIIP encourages such involvement, for example through Broad Activity Commitments.[11]

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[10] This is consistent with evidence that spillovers from publicly funded research — which is generally more fundamental and less appropriable research — are stronger than for private sector research (Henderson and Cockburn 1998).

[11] For examples see sub. 17, p. 19 and sub. 11, p. 19.

Table 4.1   Contribution to costs of different R&D stages in the US (2000)

Stages in drug discovery and development (not in chronological order)	%
Discovery/basic research	**21**
Synthesis and extraction — process of identifying new molecules with the potential to produce a desired change in a biological system.	9
Biological screening and pharmacological testing — studies to explore the pharmacological activity and therapeutic potential of compounds.	12
Preclinical trials	**9**
Toxicology and safety testing — tests to determine the risks a compound poses to humans and the environment and involve use of animals, tissue cultures and other test systems.	4
Pharmacological dosage formulation and stability testing — the process of turning an active compound into a form and strength suitable for human-use.	5
Clinical trials	**34**
Clinical evaluation	26
• *phase I* — testing of a compound in 20 – 80 healthy human volunteers to determine tolerance and pharmacological effects as well as absorption, distribution, metabolism and excretion (AMDE) patterns;	
• *phase II* — trials on 100 – 300 patients with the targeted condition to determine effectiveness in treating disease or medical condition and short term risks;	
• *phase III* — trials on 1000 – 5000 patients to determine clinical benefit and incidence of adverse reactions.	
Clinical evaluation phase IV — post marketing trials to identify undetected adverse effects and long term morbidity and mortality profiles.	9
Other	**25**
Process development for manufacturing and quality control — engineering and manufacturing design activities to establish capacity to produce in large volumes and to ensure stability, uniformity and overall quality.	7
Regulatory: — application to regulatory authority to use compound in human testing. And to market a new drug.	3
Bioavailability — use of healthy volunteers to show that formulation used in trials is equivalent to product to be marketed.	2
other	13
Uncategorised ethical pharmaceutical R&D — represents companies that provided total R&D expenditure figures but not individual details.	**11**

Source: PhRMA (2002, p. 79); Sweeny (2002, p. 3-4).

Preclinical trials

Preclinical trials and early stage clinical trials are not likely to produce many spillovers in their own right, but are likely to have an enabling role for discovery/basic research. The location of pre-clinical trials also has an influence on the likelihood of phase I clinical trials going ahead in the same location. Similarly, the location of phase I trials affects the location of phase II trials, and phase II trials that of phase III trials. As such, preclinical trials and early clinical trials may form an integral part of the 'critical mass' of pharmaceutical capability required for the sector to prosper and may, thus, constitute an example of so-called 'agglomeration' benefits (box 4.2).

Box 4.2 **Agglomeration benefits?**

Concentration (industry clusters) of industrial activities may increase beneficial linkages between firms. The exact drivers of agglomeration benefits are not well understood. However, it is thought that geographic proximity allows firms to gain access to:

- competitors' information and know-how through increased sharing of staff, who are generally more likely to be willing to change employers if that does not require them moving cities or even countries;[12]

- lower coordination and cooperation costs among co-locating firms;

- lower input costs due to economies of scale for input providers, coupled with lower transportation and communication costs; and

- better quality inputs as the innovations required of input producers for one firm can benefit other firms.

Currently, the Westmead Biohub in Sydney, the Alfred Medical Research and Education Precinct in Melbourne and NuroSciences Victoria are clusters that attempt to harness such agglomeration benefits. The National Health and Medical Research Council encourages and supports research collaboration and clusters through its recently introduced Program Grants, Health Research Partnership Grants and Centre of Clinical excellence Grants (ITR 2002a, p 32). Potentially, however, these programs are insufficient to harness the full gains available from agglomeration.

For example, the pharmaceutical Industry Action Agenda (ITR 2002a) argues that there are currently gaps in Australia's pre-clinical capacity because of the minimum scale of many new infrastructure or research facilities. Although each company would benefit from being able to use a particular facility, their individual R&D operations in Australia may not be large enough to justify the expenditure by any one company. Thus, it is argued that additional investment by the Government would boost the capability of all pharmaceutical participants and biotechnology companies.

However, such potential benefits need to be balanced against the potential costs of intervention. Generally, governments find it difficult to determine the extent of agglomeration benefits and industry has an incentive to exaggerate them. If a government erroneously assists projects with small agglomeration benefits, the efficiency losses associated with taxation and the administration of assistance can outweigh the benefits.

Furthermore, if an industry does require critical mass, it is crucial to identify at what point it is achieved, because any assistance beyond critical mass is likely to engender little additionality and simply constitute a transfer.

Finally, by focusing assistance on specific industries, governments (which generally have difficulties discerning industries that are most likely to require 'critical mass' before they can compete) are more likely to allocate scarce resources to projects with no net benefits than if generic assistance programs are used.

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[12] Of course there is a downside as well. Higher labour mobility within a cluster increases the cost of secrecy and hence reduces the appropriability of innovations. However, the existence of spillback effects (improvements to innovations flowing back), combined with lower spillovers to firms outside the cluster, may well increase productivity vis a vis outside firms and, hence, enhance the competitiveness of firms within the cluster.

Late stage clinical trials

Phase III clinical trials can have positive external effects because patients suffering from the targeted disease get access to the newest drugs earlier. On the other hand, like stage II trials, drugs trialed at stage III are not always effective or free from complications. It is precisely the recognition of the potential for unforseen and costly consequences that underpins the need for trials. Given this, it is doubtful if there would be any net gains to consumers from stage III trials.

There may be some spillover benefits to clinicians and other parties. For example, Eli Lilly Australia submitted that in the course of its database design for a project 'academic researchers and health outcomes consultants [were involved], both of whom have gained experience with this type of large survey-based costing approach' (sub. 9, p. 13). To the extent that clinicians, researchers and consultants that are involved in trials are exposed to new technologies, such as medical informatics or experimental or expensive diagnostic methods, which might not otherwise be available in routine practice, spillovers may be present. For example, such exposure may increase the rate of diffusion of new technologies among leading-edge practitioners in Australia.

However, some aspects of clinical trials may not involve significant additions to knowledge that have benefits outside the firm. This is recognised in the eligibility conditions for Australia's Tax Concession. For example, the Guide to the R&D Tax Concession (AusIndustry and ATO 2001, p. 78) note that:

> … additional clinical trials (eg. conducted in Australia to obtain more data required by the TGA), after the principal registration of a product for a particular indication would prima facie not be eligible [for the concession] unless it could be demonstrated that the trials were not simply to meet regulatory requirements. That is, they added to new knowledge or the creation of new products, and involved innovation or high levels of technical risk.

The IR&D Board generally does not consider a relatively wide range of pharmaceutical R&D as eligible, including phase IV trials, post-marketing studies, cost effectiveness studies, meta-analysis, co-prescription studies on two or more approved drugs and epidemiology studies — with the implicit judgment that the social returns (as opposed to the clear private benefits) may not be sufficient to meet the costs of any scheme intended to stimulate such activities.

Process development for manufacturing

Most process development R&D is not likely to produce many externalities so long as it is mainly concerned with the implementation of manufacturing systems using established know-how. However, occasionally, the spillovers from genuine process

innovations can be large. Evidently, such genuine process innovations are very valuable to firms and they guard them jealously so as to appropriate as much of the gains as possible. Ultimately, however, the innovations do 'leak' out of the originating company and bring spillover benefits to other firms.

Pharmaceutical company growth and consolidation help to minimise such 'leaks'. However, increasingly, innovations in the pharmaceutical sector — especially process-based innovations — are taking place outside large pharmaceutical companies and in relatively small specialised biotechnology firms. Such innovations have lead to large improvements in drug discovery and development techniques, somewhat countering both the increasing cost of bringing drugs to market and the consolidation trend (box 4.3). While it is clear that such spillovers may be significant where there are dense clusters and strong capabilities in biotechnology and pharmaceuticals, it is less clear that they would be large in an Australian context. Australian biotechs are small by international standards, while pharmaceutical manufacturing in Australia is mainly oriented to formulation and packaging, where new process technologies derived from the biotech industry are not relevant.

Gains from global connections

Pharmaceutical subsidiaries of MNEs are connected to wider global, capabilities and sources of knowledge (and thus generate and benefit from agglomeration benefits, box 4.2 above). By participating in these intra-company networks, employees and suppliers of such subsidiaries may learn new techniques, gain access to frontier knowledge in their field and also overcome some of the information asymmetries that may exist about Australian capabilities. Such benefits would partly be appropriated by the foreign subsidiary. However, as employees move between foreign and domestic firms, these benefits can partly be appropriated by the employees and Australian firms.

Also, a number of submissions emphasise the benefits pharmaceutical activity to the biotechnology sector.[13] The Commission agrees that this is a major source of spillovers and agglomeration benefits (box 4.2), indeed, if it were not for the benefits to the biotechnology industry, the spillover rates used in chapter 6 (assessing the efficiency of the PIIP) would be hard to justify.

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[13] For example, AusBiotech (sub. 14), Medicines Australia (sub. 10, pp. 23), Servier (sub. 7, p. 3) and ITR (sub. 8, p. 5)

Box 4.3   **Pharmaceutical industry structure**

Ever since 1897, when Felix Hoffmann's discovery of Aspirin turned Bayer (until then a dye making firm) into the first pharmaceutical company, consolidation pressures have been prevalent — economies of scale, coordination issues and the need to keep as much of the early stage discoveries/innovations secret being the main reasons. One hundred years later, the top 20 pharmaceutical companies alone were collectively capitalised at about US$1.3 trillion (PWC 1998, p. 2). Thus, a characteristic feature of the pharmaceutical industry is the pervasiveness of very large multinational firms with a large measure of vertical integration.

This consolidation trend is continuing with a flurry of mergers and acquisitions.

> The value of pharmaceutical mergers and acquisitions announced in 2001 almost doubled to [US]$61 billion from [US]$33 billion in the year 2000 (excluding the [US]$76 billion formation of GlaxoSmithKline) bucking the significant downward trend witnessed in most other sectors. (PWC 2001, p. 4)

And the trend to vertical integration may continue through expansion into the health care business (Rasmussen 2002, p. 10). This trend is counteracted by biotechnology firms and high-tech specialist services providers that are emerging as increasingly important partners in the drug discovery process.

Traditionally, pharmaceutical companies have attempted to find new drugs by synthesising variants of small molecular weight compounds, which were initially discovered by a combination of accident and luck. The processes of discovery were improved over time with the increasing use of chemical, biological and medicinal knowledge and of increasingly large libraries of compounds (Sweeny 2002, p. 6).

Concurrently, pharmaceutical firms have increasingly employed techniques developed in the field of biotechnology to identify disease targets. The reason is that the cost of finding drug candidates by 'brute force' methods has been increasing, partly due to the fact that simple disease targets have already been identified and used and those that are left are not well understood or difficult to address from a traditional chemistry perspective (Sweeny 2002, p. 1).

Thus, more and more, pharmaceutical companies have relied on new technologies — in particular genomics, combinatorial chemistry, improved screening technologies and bioinformatics — to overcome the productivity crisis they are faced with. However, despite best efforts to gain access to such technologies (mainly through acquisitions[a] and by building capacity in house), even the largest companies are finding it impossible to amass all the necessary expertise. As a result, the consolidation trend described earlier is paralleled by a trend toward strategic alliances with a new set of players in the pharmaceutical industry — the biotechnology firms. Already, in America for example, less than half of the substances undergoing clinical trials in 1998 originated within the laboratories of traditional big drug firms (Economist 1998).

[a] The biotechnology sub-sector was responsible for US$27 billion of the US$66 billion of total M&A activity in the pharmaceutical sector quoted above. In the absence of mega-mergers of large pharmaceutical firms in 2001, this represented 44% of the total value of disclosed deals in the pharmaceutical sector (PWC 2001, p. 5).

Spillovers from new medicines

Other benefits to consumers associated with the use of new medicines are sometimes also advanced as possible rationales for industry assistance in the pharmaceutical sector. However, such benefits are realised through use not through local production or R&D and are therefore not relevant to issues of industry assistance.

Another argument sometimes put for industry assistance is that research into, and the development of, treatments for local diseases, such as Ross River fever and Murray Valley encephalitis, is likely to be under-provided in the absence of intervention. However, to the extent that assistance for such research is warranted, it would be better targeted at the particular diseases. General subsidies to the pharmaceutical industry would be an indirect and inefficient way of promoting such research.

Do spillovers justify intervention?

Globally, it is likely that the pharmaceutical industry generates appreciable spillovers, though their magnitude, nature and mediums are still not well understood. It also seems likely that pharmaceutical MNE subsidiaries operating in Australia generate spillovers to the benefit Australian domestic firms in the biotech and generic pharmaceutical industries and to suppliers of these subsidiaries from other industries. On the other hand, it would also seem probable that many spillovers accrue to other MNEs, both within and outside Australia, giving no rationale for intervention.

The existence of spillovers does not necessarily mean that there is sub-optimal under-provision of R&D — which is the market failure that government intervention may remedy. There are several reasons why the amount of under-investment might be small even in the presence of spillovers, or in the extreme case, why over-investment might sometimes occur:

- Firms are aware that spillovers exist and that these are valuable to them. However, firms are not like sponges, able to costlessly soak up spillovers from other firms. Instead, they must themselves invest in a research capability to be able to absorb others' knowledge. These investments in absorptive capacity imply that the amount of under-investment is less than often supposed;

- The relevant issue for government intervention is whether there are spillovers for marginal investments, not whether spillovers might on average exist. In the presence of strategic behaviour in oligopolistic industries, such as pharmaceuticals, it is possible to have over-investment in R&D. For example,

firms may compete to be first in a patent race, with ultimately only one winner, but significant duplicated research effort. The more an industry is characterised by 'winner take all' outcomes — whether this be due to patents or large first-mover advantages — the more likely is there to be such over-investment.

Even where under-investment is a problem, this only establishes a prima facie case for some intervention. Two other hurdles must also be overcome for an industry-specific program to be the appropriate solution:

First, the program design of the intervention must be such that the benefits of intervention outweigh the costs. This is not necessarily straightforward. It is difficult to design R&D policies that only stimulate new R&D, rather than subsidise activity that was going to occur anyway.[14] The program must be funded, which in turn, generates costs elsewhere in the economy. These inevitable frictions of intervention mean that it can sometimes be rational to forgo R&D spillovers.

Secondly, an industry-specific program must be superior to generic R&D support programs that apply across the Australian economy (appendix C). This can sometimes arise where an industry has unique features that enable a specially designed program to extract greater public benefits:

- it may be that the mechanisms for transmission of spillovers are idiosyncratic in the pharmaceutical industry, justifying a different target for subsidies;

- it may be that the knowledge about which projects are likely to generate spillovers is greater for the pharmaceutical industry than others, enabling more discretion in choice of projects; and

- there may be practical or operational limits to the pharmaceutical industry accessing generic measures.

It is not clear that either of the first two conditions are met. But problems relating to access to the R&D Tax Concession by foreign-owned MNEs with subsidiaries resident in Australia do appear to be significant. These are considered next.

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[14] In many cases the effect of government intervention may be to bring forward investment timing and not to bring about an overall increase in investment. Thus, the spillover value attributable to induced R&D may best be captured by the difference in social surplus from the timing change of the innovation in question, not its absolute magnitude.

Access to the R&D Tax Concession by pharmaceutical firms

Where do access problems arise?

The R&D Tax Concession has evolved over a number of years and is the Government's principal (generic) mechanism to support innovation. It allows firms to obtain a concessional rate of deduction of 125 per cent on a base level of eligible R&D and up to 175 per cent on any R&D that exceeds a particular base. It also allows firms in tax loss to receive an immediate tax benefit for R&D, rather than carry forward deductions that may never be realised as a future tax benefit.

There are several limits on access to the concession, of which the most significant for the pharmaceutical industry is the requirement that intellectual property (IP) arising from R&D must be owned in Australia. (The exemption of such R&D from eligibility to R&D subsidies is also a common feature in other countries.)

The IP ownership restriction reflects several aspects of Commonwealth legislation:

- The *Income Tax Assessment Act 1936* (section 73B(9)) requires that eligible deductions not be allowed for expenditure undertaken 'on behalf of any other person', which includes an overseas parent company. Among other things, the intention of this section is to stop a tax exempt body from effectively accessing the tax concession by contracting out R&D to a taxable entity (ITR sub. 8, p. 2). Tax rulings dictate that to be eligible for the concession claimants must:

  … bear the financial risk associated with undertaking the R&D activities, control the activities and be the beneficial owner of the results of the R&D activities (AusIndustry, 2002).

- As noted in the *Guide to the R&D Tax Concession* (AusIndustry and ATO 2001, p. 80), Section 39C of the *Industry Research and Development Act 1986* requires that R&D eligible for the concession be exploited on 'normal commercial terms' only. This reduces circumstances where a firm engages in tax 'arbitrage', obtaining R&D deductions in the higher tax rate jurisdiction, and bearing most income taxes in a lower one by adjusting the price of IP. Section 39D of the Act requires that eligible R&D be exploited in 'a manner that is for the benefit of the Australian economy'. The section of the guide pertaining specifically to the pharmaceutical industry suggests that a situation where there may not be sufficient exploitation of the results of pharmaceutical R&D is where:

  … the parent company or related companies around the world have access to the technology without making an appropriate payment to the Australian company (AusIndustry and ATO 2001, p. 81).

While there are exceptions, such as Mayne Pharma, Sigma and CSL, most large pharmaceutical companies in Australia are subsidiaries of large foreign MNEs.

Were such subsidiaries to claim that they were beneficial owners of the IP generated by their R&D (the requirement for eligibility for the concession), the above legislation would generally require them to have commercially reasonable royalty streams and license fees for any transfer of IP to the parent or other subsidiary arms of the MNE. This, with other factors (box 4.4) explains why foreign pharmaceutical

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Box 4.4   **Why don't pharmaceutical subsidiaries of MNEs hold their IP in Australia?**

The preference by foreign pharmaceutical MNEs to hold the IP at their head offices reflects several factors:

- The differential taxation treatment of royalties associated with IP can affect MNE's decisions about where to own IP (Grubert 2002). In a related point, the ability of an MNE to defend its pricing of intangible assets for tax purposes can depend on the form and location of ownership of patents and trademarks (Durst 2002, p. 7). The Commission has not examined the highly complex differences between countries of the tax and compliance regimes that can affect the optimal location of IP. However, it appears to be an important consideration for pharmaceutical firms when determining the ownership form of IP (and is, for example, recognised by global law firms in their advice to pharmaceutical firms). Local affiliates of foreign pharmaceutical MNEs have indicated that tax issues strongly influence their reluctance to hold IP in Australia.

    – In particular, they drew attention to added complexity and uncertainty related to the tax treatment of any licence revenue associated with owning the IP in Australia, relative to holding it in the head offices (usually the US or Europe). Were the IP to be owned in Australia, it would be expected that the subsidiary would licence its use to the parent (and potentially other affiliates). Compared with circumstances where the subsidiary was not the beneficial owner (and was reimbursed any R&D expenses by the parent), the ATO would usually give particular attention to any license agreement and associated revenue flows — to ensure compliance with transfer pricing rules or other mechanisms to reduce tax revenues. This entails significant compliance costs associated with documentation and legal advice and, over the full period of the royalty stream, some uncertainty about the ultimate post-tax earnings associated with the IP.

- The R&D undertaken by subsidiaries is usually of global relevance, rather than just to serve local needs. Given its global relevance, the parent MNE must have a method for determining how to spread and charge for any R&D undertaken among all subsidiaries on an administratively (and managerially) efficient basis. Usually this entails a 'hub and spoke' arrangement in which IP ownership is vested with the head office (the 'hub'), which oversees dissemination of IP to each of the subsidiaries (the spokes). This economises on the transaction costs that would prevail were each subsidiary to instead have its own arrangements for licensing and knowledge diffusion to each of the others. It also reduces any risks that the head office may not be able to completely control its IP because of differences in IP protection across countries.

It appears that the preference for holding IP at head offices is particularly strong in the pharmaceutical industry (with many MNEs from other sectors establishing companies that hold the IP in Australia, thereby getting access to the R&D Tax Concession). This may reflect the fact that R&D is the most important asset in the pharmaceutical industry and that R&D conducted by one subsidiary in one location usually has relevance to all other affiliates.

MNEs are generally reluctant to hold IP in Australia. Rather, R&D is typically undertaken on behalf of the parent and is reimbursed by the overseas party. In that case, the beneficial owner requirement under section 73B(9) rules their R&D as ineligible for concessionary treatment.

Collectively, therefore, the provisions in the *IR&D Act* and *Income Tax Assessment Act* have meant that Australian subsidiaries of foreign MNEs have not been able to gain full access to the R&D Tax Concession for the R&D they undertake in Australia.[15] Through the Pharmaceutical Industry Action Agenda (2002a, p. 76), the pharmaceutical industry argues that the R&D Tax Concession should be changed to allow access to the concession, regardless of where the beneficial owner of the intellectual property is located.

Should ownership of IP determine eligibility for the concession?

It is appropriate that the R&D Tax Concession only apply to activities that yield a sufficient benefit to Australia. From an economic perspective, the principal argument for assistance to business R&D is knowledge spillovers (section 4.1). By definition, spillovers are gains to firms and other agents separate from the innovator. Accordingly, realisation of these gains does not depend on whether a subsidiary of a foreign MNE holds the IP or whether it is held by the parent or some other affiliate.

The current restricted access to the R&D Tax Concession implies that Australia may not be sufficiently stimulating R&D in the pharmaceutical industry, thus forgoing some spillover benefits for Australia.

FINDING 4.2

Intellectual property ownership requirements effectively reduce access by the Australian subsidiaries of foreign multinational enterprises to the R&D Tax Concession. Unless countered by other initiatives, this may lead to lower levels of pharmaceutical R&D in Australia than ideal.

Restricted access for pharmaceutical firms to the R&D tax concession provides a prima facie argument for either:

- amending of the existing R&D Tax Concession (at least for pharmaceutical firms) so as to allow eligibility of R&D even when the IP is to be held overseas; or, if that is not appropriate or practical;

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15 Similar restrictions relating to intellectual property apply to the R&D Start program, although it is generally targeted toward smaller companies.

- use of an industry-specific assistance arrangement, such as the PIIP, to foster R&D by the pharmaceutical sector.

These issues are further examined in chapter 7.

4.2 Inter-governmental competition for investment

Reduced barriers to trade and investment, as well as substantial reductions in communication and transportation costs, have increased the ability of firms to service global markets from a small number of locations. This is true particularly for the pharmaceutical industry, where relentless consolidation pressures have seen large multinational companies become the hallmark of the industry (box 4.3 above).

The increased global mobility of factors of production, coupled with a desire by governments to attract investment to their jurisdictions, particularly in industries with the lure of high technology and knowledge economy jobs, has led to competition among governments for international investment. This has often taken the form of tax and other concessions and direct subsidies. This approach has been fuelled by the perception that relatively interventionist industry policies have resulted in very strong growth rates (for some time) in a number of countries, including Malaysia, Singapore, South Korea and Ireland.

In particular, the assistance measures and taxation arrangements available in Singapore and Ireland have seen the proliferation of pharmaceutical production in those countries and associated high industry growth rates. It is sometimes argued that Australia is well positioned in the regional pharmaceutical industry, having some cost advantages relative to others,[16] but may not capitalise on such advantages unless it also offers incentives for inwards investment.

However, there are many pitfalls in deducing that an industry-specific program would be an appropriate or welfare-enhancing intervention in this context:

- It is far from clear that a specific industry assistance program — like the PIIP — is well geared to attracting truly additional and beneficial FDI. The program supports value added, not investment, and it is not oriented towards foreign entities alone.

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[16] For example, the Benchmarking Study of R&D Costs in Selected Segments of Australian Biotechnology (Agri-food, Bio-medical, Pharmaceuticals and Human Therapeutics, Diagnostics and Clinical Trials) found that Australia is the lowest cost country for an R&D centre across the five biotechnology sectors investigated (Ernst and Young, Hay Group and Strategic Industry Research foundation 2001).

- Governments have a limited capacity to discern welfare-enhancing opportunities for FDI. Much of the endemic global over-capacity of current pharmaceutical production facilities is a reflection of licensing and other inducement policies governments have put in place to secure FDI and domestic pharmaceutical capability. These facilities are now being rationalised. In another similar footloose industry, semiconductors, global oversupply partly associated with government rivalry for national capabilities led to depressed prices. This is good for consuming countries — like Australia — but less so for those that subsidised investment in such capacity. Even where governments may make good choices in backing particular FDI projects, these have to be balanced against poor choices.

- Government assistance to a specific sector or to specific projects inevitably imposes costs on other industries and consumers, generally in the form of higher taxes. This distorts consumption and investment decisions in the economy at large.

- It is extremely difficult to determine which investments are marginal. At least some assistance can be expected to go to investment projects which would have taken place regardless, thus raising the cost (and associated distortions) on average for each induced investment.

- Investments that are responsive to inter-governmental competition tend to be *footloose* (involve capital that can be relocated relatively easily).[17] But the gains from footloose investment are often not sustained once assistance is removed, and thus less likely to lead to net gains in the long run.

- The gains from assistance-induced investments tend to be low because inter-governmental competition to attract investment is likely to bid away prospective gains.

These factors caution against expectations that government incentives for pharmaceutical FDI can make Australia significantly better off. That said, FDI can bring substantial advantages to host countries and it should not be assumed that global investment flows are at all optimal given a panoply of distorting taxes, regulations, absent markets and information deficiencies. But there are wider and better choices for dealing with this issue than a pharmaceutical industry-specific program:

- Invest Australia already provides a capacity for supporting particular foreign investments that are deemed likely to make Australia better off, regardless of

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[17] This is because footloose capital is more likely to chase the subsidy dollar than less reversible investments which are more likely to be determined on the basis of long term economic considerations.

which industry they pertain to. To the extent that investment attraction incentives are employed, this generic approach at least requires pharmaceutical projects to compete with those in other industries that might result in higher returns.

- There is scope for measures aimed at attracting foreign investment that correct distortions or inadequacies in taxation, regulation or government institutions. In many contexts, expenditure on human capital formation, regulatory reform and the provision of infrastructure may be more likely to both attract FDI and simultaneously make Australians better off than investment attraction incentives per se.

FINDING 4.3

The PIIP is not well geared to attract FDI. Promoting FDI should be done by getting the broad policy settings right, not through an industry specific program.

4.3 Information failure, 'rules of thumb' and firm location decisions

As discussed in chapter 3, it was often claimed by pharmaceutical firms visited by the Commission that Australia was a small market that was, as one executive put it, 'barely on the radar screen' for consideration by head offices for pharmaceutical investment. Furthermore, it was repeatedly put to the Commission that head offices make investment decisions on the basis of rules of thumb and that they perceive the Australian pharmaceutical environment as adverse due to its PBS arrangements. It is argued that the PIIP, by showing commitment to the pharmaceutical industry, plays a vital role in counteracting such perceptions, and thus leads to higher levels of investment.

Chapter 3 has already examined the degree to which adverse perceptions stemming from PBS pricing might affect investment decisions. The question examined here is whether other perception issues, head office decision-making processes or information deficiencies could adversely affect pharmaceutical FDI in Australia.

Information deficiencies and perceptions

It is sometimes argued that firms do not necessarily have full information about the possible investment opportunities in a given country (especially in relatively small countries) and that an assistance program can motivate global investment decision makers to find out about potential opportunities. Thus, if there are unrealised opportunities in the pharmaceutical sector in Australia — as a number of

pharmaceutical firms visited by the Commission considered — the PIIP may act as a catalyst for the scoping of pharmaceutical investment opportunities.

However, this argument has some limitations. Pharmaceutical MNEs have been operating in Australia for many decades, many with research and production capabilities. Local subsidiaries have very strong incentives to find profitable investment opportunities as they compete for funds from headquarters with other subsidiaries of their parent companies. Australia's science and medical base is well recognised and it is common for Australia or Australasian market results to be reported in the annual reports of global pharmaceutical firms.

Assistance measures to the industry have been in place since the late 1980s. Information failures should, by their nature, be transient, and would not usually justify additional specific measures after this long.

Nor in any case would information failures or incorrect perceptions best be targeted by a PIIP-type program, but rather by measures that aimed more specifically to deal with information or perception problems. Invest Australia was specifically set up to promote Australia as an investment destination and it has a number of programs available to assist industry where barriers are established. The most relevant program in this context is the Feasibility Study Fund that provides grants of up to A$100 000 to potential investors to undertake pre-feasibility or feasibility studies for new investment projects (Blake Dawson and Waldron 2002). Another relevant program is the Strategic Partners program:

> Invest Australia identifies international strategic partners for Australian businesses by means of promoting quality investment briefs. It also actively seeks interested and capable overseas investors who may be considering locating a new productive activity in Australia. Mutual benefits arise for the companies involved by matching their capabilities relative to the venture proposal. (Invest Australia, pamphlet: what can Invest Australia do for me)

As the pharmaceutical industry does not appear to have special characteristics that render these generic assistance programs inadequate, addressing information deficiencies and perceptions would not seem to present a strong rationale for *industry specific* assistance.

The use of rule-of-thumb decision making by head offices

Where large or strategic investments are being considered it can be expected that head offices will carefully balance the various risks and gains of alternative locations in a bid to maximise long-term returns. In many cases, issues such as management risk — the ability to monitor an investment — will suggest location of a new basic pharmaceutical R&D facility in the headquartered country. In others,

such as the location of an actives plant (which may cost several hundred million US dollars), tax rates will be the most important determinant of location.

In this context, it is hard to see why MNEs would systematically forgo lucrative investment opportunities in Australia even if no assistance scheme existed. Thus, it is likely that any unrealised large scale pharmaceutical investment opportunities in Australia produce at best marginal gains to MNEs and not that rules-of-thumb systematically lead to sub optimal investment decision.[18]

However, for smaller and less strategic investments, the transaction costs of decision-making may result in firms adopting rules-of-thumb to allocate new facilities. Australia is a small country that accounts for a tiny share of global pharmaceutical activity. This, and the fact that there are many alternative locations for undertaking small-scale pharmaceutical activity at roughly similar costs, makes Australia vulnerable to perceptions and rules-of-thumb. For example, past rates of return, the size and type of existing business operations, familiarity with Australia by the investment decision maker and reputation could be among those factors that shape location decisions. As noted in chapter 3, an adverse perception of pricing might also be one of those factors.

The problem with conditioning policy on the use by MNEs of rules-of-thumb is not so much whether such decision making occurs, but that unless such behaviour can be characterised precisely, it is not clear how to determine a policy response. For example, which decision-makers follow which rules of thumb for which types of investment? Nor should it be assumed that Australia is always hurt by the operation of such rules. It is possible that Australia has been the beneficiary of rules-of-thumb that give a large amount of weight to low sovereign risk (which is true for Australia, but not so for some alternative low cost South East Asian locations). It is precisely this inability to work out cheaply enough what would be better than the existing set of rules-of-thumb that makes some such rules optimal for firms in the first place.

Moreover, to the extent that rules-of-thumb are sub-optimal in a way that is detrimental to Australia's interests, progressive increases in the efficiency of multinational enterprises, should reduce their adverse effects.

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[18] The costs and benefits of scoping from a firms' perspective may be different to those from governments' perspective so that assistance in identifying investment opportunities may be in the interest of Australia. Indeed, this is one of the main reasons for the existence of Invest Australia. However, it is an externality rationale for intervention and does not constitute an additional rationale for assistance to the pharmaceutical industry.

It is implausible that mis-perceptions by head offices about Australian capabilities are widespread. Multinational pharmaceutical firms have had an involvement in Australia over several decades — many with production and research facilities. In any case, there are more efficient direct ways of dealing with mis-perceptions than subsidising activity.

4.4   Geopolitical considerations

It is sometimes argued that production capabilities are required in the event of worldwide shortages of crucial drugs. The concern arises out of the view that if critical pharmaceuticals (such as certain vaccines) are manufactured overseas and a world wide shortage ensues, countries with production capabilities will satisfy their domestic demand first and only export surpluses. Thus in the event of a widespread outbreak of some disease, it is argued that, without a sufficient production capability, Australia may not benefit from available drugs if its usual supply sources are cut off.

However, this argument implies that Australia would need capability in the entire production chain, from the manufacture of actives, through to formulation and packaging, of all drugs thought to be subject to this problem. But, because of strong economies of scale, each active is manufactured in two to three plants worldwide. Self-sufficiency in actives manufacturing is not an economically feasible option for a small country like Australia.

Other options, such as stockpiling the active ingredients most likely to be the source of a global supply shock and to formulate/package domestically and international quick response mechanisms may be far cheaper and more effective. It seems likely that assistance to the pharmaceutical industry to secure access to drugs would not be effective as well as being very expensive. Thus, geopolitical considerations do not constitute a strong rationale for assistance to the pharmaceutical industry.

A desire to secure access to drugs in times of crisis is not a compelling rationale for assistance to the pharmaceutical industry. Where a need of domestic access to drugs can be made — on the basis of sound risk management analysis — other options appear more realistic.

4.5   Conclusion

The pharmaceutical industry is an important, complex and global industry. Reflecting its use and generation of knowledge, the industry is characterised by high R&D and human capital intensity. It is dominated by giant sophisticated multinational enterprises that coordinate pharmaceutical activity by their subsidiaries and, increasingly, separately owned suppliers across a myriad of countries. It seems likely that the production of knowledge — especially associated with pre-clinical research — produces benefits that transcend the boundaries of the firms concerned. It is also likely that host countries can benefit from investment by such managerially and technologically sophisticated firms.

These features suggest that governments should try to garner some of these gains through measures that attract such firms and encourage them to undertake R&D in their countries. A key question is how to realise this objective. Generally, there are substantial advantages in using generic programs to elicit these gains, rather than specific ones. Otherwise there is a risk of an overly complex, fragmented and sometimes inconsistent set of industry by industry arrangements for encouraging innovation or inwards investment. However, chapter 7 examines pharmaceutical sector-specific characteristics that could, nonetheless, warrant an industry specific program.

5 Effectiveness of the PIIP

This chapter outlines an assessment of the effectiveness of the PIIP in achieving its objectives. Section 5.1 makes some general observations about the program's effectiveness. Section 5.2 sets out some of the methodological issues associated with assessing effectiveness. Section 5.3 considers statistical evidence about the effectiveness of the program in increasing pharmaceutical value added. It also considers the effects of the program on exports, investment, employment and the structure of activity. This is relevant to the assessment of the impact of the program on value added, but also assists in considering whether the program has genuinely increased the industry's general capability (another thrust of the PIIP principles outlined in chapter 2). Section 5.4 considers the impacts of the PIIP on the level and nature of pharmaceutical R&D. Section 5.5 considers some of the case study evidence of effectiveness. Section 5.6 describes past assessments of similar programs to place our results in a context. Section 5.7 draws general conclusions about the PIIP's effectiveness.

The key criteria for effectiveness

Assessing the effectiveness of the PIIP involves four important components:

- the program effect must have the right *sign* (some programs have been known to have perverse effects). For example, the PIIP must *increase* pharmaceutical activity;

- the effect must have sufficient *size,* given the resources spent on the program. In some cases, it is not just the size of the direct desired effect — R&D and value added — but also changes in underlying variables that measure the sustainability of changes (such as employment, investment or the character of the R&D and value-added);

- the program, and not some other factors, should be the likely *cause* of the desired outcomes. Reflecting the difficulties in assigning causality, often evaluations only show an association between a desired effect and a program; and

- measures of effectiveness should be as *reliable* as possible. For example, an assessment might show that a program increased industry R&D by 50 per cent, but the results may not be reliable (say, because there may be so much variation

among firms that the 50 per cent estimate is merely an artefact that could not be expected to be repeated in the future). When reliability is an issue, confidence about the results can be increased by employing a variety of indicators of effectiveness and gauging the extent to which these paint a similar picture.

5.1   General observations on inducement

Many of the firms visited by the Commission indicated that the PIIP had assisted them to undertake more value added and R&D than they would have otherwise. They convincingly cited specific R&D or production activities that they would not otherwise have undertaken. However, some also acknowledged that at least some of the activity that was supported by subsidies would have occurred anyway. (Specific case studies are considered in later sections).

The use of a rolling nominal value added base and a fixed nominal R&D base also implies that inflation and general economic growth would lead to activities that would attract a subsidy even though they would have occurred anyway. On these bases, the proposition that all of the activity attracting a subsidy is induced is not credible.[1]

On the other hand, the pessimistic view that the program induces no new activity also seems highly improbable. The existence of a subsidy implies that the incremental cost of expanding activity has been lowered, and that a typical supply/demand response could be expected. How big it is would depend on supply elasticities in the case of value added and firm's R&D investment demand elasticities in the case of R&D. In many industries these would be relatively low, but in the pharmaceutical industry most of the firms concerned have footloose global operations and can shift activities between subsidiaries as relative costs and incentives change. While the scope for and speed of such activity shifting depends on existing capacity utilisation, the availability of skilled labour and research capabilities, it is likely that there could be reasonably significant responses to reductions in relative costs in this industry.

Assessing the effectiveness of the PIIP requires empirical analysis, using estimates of key parameters pertinent for the pharmaceutical sector. Case studies of whether particular activities are induced or evidence about the general sensitivity of value added and R&D to price changes supplement empirical estimates and provide a useful source of information about program effectiveness.

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[1] At least one firm, Eli Lilly, agreed with this diagnosis (sub. 9, p. 8).

5.2   Problems in measuring whether the PIIP has made a difference

The key measure of effectiveness of the PIIP is the extent to which it increases R&D and value added above what they would have been — the concept of 'additionality'.

Figure 5.1 illustrates the idea. A firm enters the PIIP at time T_s and stays until T_f. Its value added during participation in the program is the top, dark line, while its value added had it not participated in the program — the counterfactual — is indicated by the lower lighter line. The program impact during its participation is measured by the difference (A). Program effects may also continue after participation has ceased — for example, because participation might have affected investment in pharmaceutical production capacity or altered head office perceptions. In this case, further activity is induced after T_f (B in the diagram).

Figure 5.1   **Measuring additionality in the PIIP[a]**
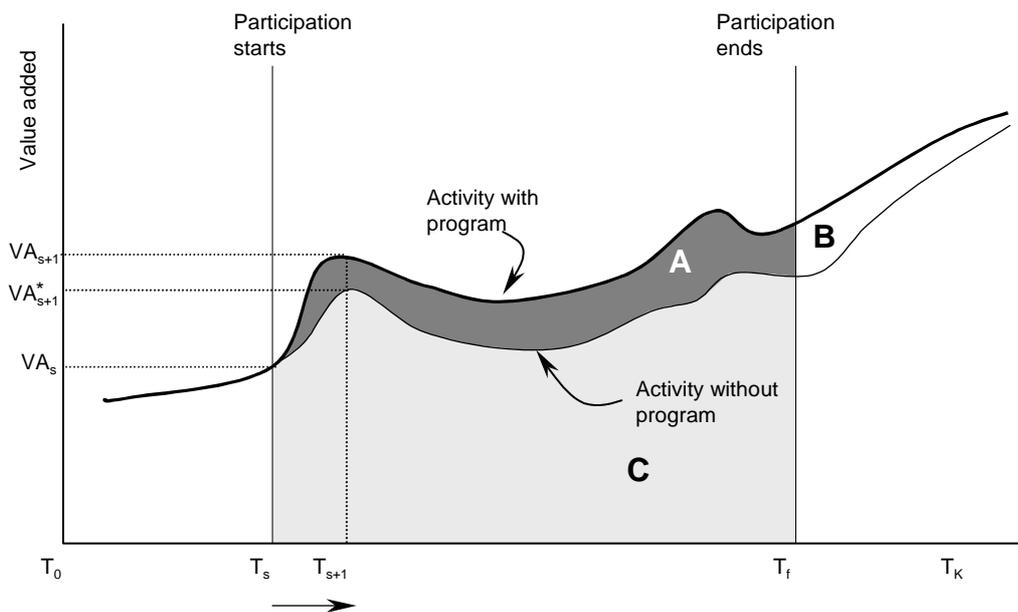
a More formally, in discrete time terms, for all of the j firms receiving assistance, a single measure of the amount of induced activity (IA) is equal to:

$$IA = \sum_{i=1}^{j} \ \sum_{t=s}^{\infty} \frac{(AWP_{it} - ANP_{it})}{(1+\rho)^{t-s+0.5}}$$

where AWP is activity with the program, ANP is activity without the program, and ρ is a discount rate, s is the starting time of the program and f is its finishing time. The induced activity is discounted back to the starting time so as to give a present value of induced activity, which can be important if a program induces different amounts of activity over time.

The rate of additionality (r) is measured as:

$$r = \frac{\textit{Observed activity with the program}}{\textit{Activity without the program}} - 1$$

For the period of participation in the program, the additionality rate would be equal to A/C in figure 5.1 (assuming a zero discount rate).

A related concept is the inducement rate, which is the amount of activity induced by a program divided by the activity that is eligible for a subsidy.[2] (The inducement rate is applied in chapter 6.) The associated measure of fiscal effectiveness is the 'bang for a buck' — the value of induced activity divided by the cost of the subsidy.

The major problem in measuring inducement is estimating the level of activity that would have occurred without the program. This counterfactual is not observed and so must be imputed. There are several methods for doing this, such as:

- *statistical methods specific to the program*: analysis of differences in activity between participants and non-participants and/or of breaks in trends within participants' activity;

- *investigating the underlying mechanisms that lead to supply and demand responses.* For example, if it has been established that a 10 per cent decrease in the cost of R&D stimulates R&D by 10 per cent, then this response should generally prevail regardless of whether the cost reduction is achieved through a subsidy, a tax change, or cheaper inputs. So evidence from studies about relevant supply and investment demand elasticities can be useful in determining the effectiveness of programs; and

- *subjective assessments* by firms about what they would have done otherwise.

Qualitative assessment of inducement can also be useful. For example, schemes that are designed to provide subsidies to incremental activity tend to have higher additionality.

No single method will be a perfect guide to additionality. In particular, statistical methods sometimes give an air of precision — but this is a false one, given data and methodological problems. For this reason, we have used several indicators of effectiveness.

While an eclectic approach has value, this does not mean that *all* approaches are worthwhile. Two commonly used ways of imputing the counterfactual are not usually sound:

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[2] It should be noted that the inducement rate can exceed 100 per cent in cases where a subsidy prompts a very elastic response by firms.

- measuring additionality as the difference between observed activity with the program and activity just prior to entry in the program. This assumes that in the absence of the program, activity would have stayed constant. Given the variability in output and other operating characteristics exhibited by firms in most markets, this would usually be an unwarranted assumption. As an illustration, applying this assumption in figure 1 would suggest additional value added of $VA_{s+1} - VA_s$, when the real additional value added one year into the program is only $VA_{s+1} - VA^*_{s+1}$, which is much smaller in size. Were activity to be declining, but intervention reduced the extent of the slump, this measure would imply negative inducement even where a program successfully induced new activity;

- measuring additionality by assuming that all subsidised activity is additional. As noted in chapter 3, under the PIIP, subsidies of 20 per cent are paid for increments in activity up to a cap.[3] By definition, this implies that for a firm that exactly meets its cap, subsidised activity is equal to five times the subsidy. At times, firms exceed their target activity level, in which case, it is supposed that this additional amount is also 'leveraged' by the program. For example, ITR (2001) argued that, at the end of the first year of the program, the PIIP 'leveraged $5.50 in company activity' for every dollar of subsidy. Several participants in the program also drew attention to this apparently positive measure of effectiveness. However, the measure mistakes the formula for calculating the subsidy with the effect of the subsidy. It is quite possible that the actual effect of a program is zero and yet a subsidy has been paid (box 5.1).

Displacement issues

Inducement is measured for participating firms. However, the goal of the PIIP is to increase overall activity in the pharmaceutical industry. It is possible that increased activity in PIIP firms may be at the expense of activity in other pharmaceutical firms. For example, this could occur because increased demand for scarce resources — such as scientists or technicians with pharmaceutical expertise — bids up their costs, which then leads to reduced employment, and hence output, among firms that do not get subsidies.[4]

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[3] Where the firm exceeds its target level of activity, the target is used to cap payments. Thus, for any participant receiving subsidies (S):

$S = minimum \ \{0.2 \times (Actual \ activity - Base \ activity), 0.2 \times (Target \ activity - Base \ activity)\}$.

[4] In many other cases where subsidies are selectively applied to an industry, demand-side crowding out could also be expected (ie increased sales of subsidised products are at the expense of decreased sales of unsubsidised products). However, in the case of pharmaceuticals, this is unlikely since demand is independently determined by PBS pricing and co-payments. Additional

Box 5.1   **How a subsidy can be paid when there is no additionality**

Suppose that value added (VA) is growing at a steady state rate of g (ie $VA_{t+1}=(1+g)$ VA_t) regardless of whether a firm participates in the PIIP and that the PIIP induces r additional activity in the first year of the scheme. Under the PIIP, subsidies are paid for increments in value added above a moving base of the forecast value added (it is assumed here that forecasts are accurate). This implies a subsidy (S) of:

$$S = 0.2 \times (VA_T - Base_T) \quad where \quad Base_T = \frac{VA_{T-1} + VA_{T-2} + VA_{T-3}}{3}$$

In the absence of any intervention, the observed value added in year T (VA_T) is equal to $(1+g)^3 VA_{T-3}$. With an intervention that resulted in additional activity, one would observe $VA_T = (1+r)(1+g)^3 VA_{T-3}$. Thus, S can be represented as:

$$S = 0.2 \times \left((1+r)(1+g)^3 VA_{T-3} - \frac{(1+g)^2 VA_{T-3} + (1+g)VA_{T-3} + VA_{T-3}}{3} \right)$$

$$= 0.2 \times VA_{T-3} \times \left((1+r)(1+g)^3 - \frac{(1+g)^2 + (1+g) + 1}{3} \right)$$

Thus, even if r=0, a subsidy will be paid so long as g>0. For example, if g were 10 per cent and VA_{T-3} were $10 million, then S= $455,333, despite additionality being zero by definition. Even in cases where true additionality is high, a measure of additionality based on S/0.2 strongly overstates true additionality. For example, supposing that the subsidy increases activity by 15 per cent (r=0.15), then the additional activity measured on this incorrect basis is over 114 per cent higher than the correct measure.

Thus, a reasonably large difference can be expected between activity in a given year and the base, without this being a good guide to the effectiveness of the PIIP. For example, in the first year of the PIIP, the growth rate was 31.8 per cent for value added relative to the base.[5] On that basis, the PBPA (2001b, p. 4) claimed that: 'The PIIP *generated* [our emphasis] a significant increase in PVA and R&D activity in its first year.'

However, were pharmaceutical activity to be generally increasing by 10 per cent per annum, then it would be expected that value added would be about 21 per cent higher than the base.[6] In this case, the inducement rate that would achieve a 31.8 per cent overall growth of value added over the base is only 9.3 per cent.

These calculations do not necessarily mean that inducement *is* low in the PIIP. However, they demonstrate that proxies for the effectiveness of the PIIP, such as the amount of activity eligible for a subsidy or the growth rate in activity over the base, can be highly misleading.

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activity induced by the PIIP is therefore almost wholly in terms of exports or knowhow, not domestic consumption.

[5] The growth rate associated with eligible activity was slightly less at 28.7 per cent.

For example, some firms claimed that hospitals were now asking higher fees for clinical trials, which was having an effect on Australia as a competitive location for such activity. This might in part reflect the increased demand for such trials by PIIP participants.

Displacement also occurs outside the pharmaceutical industry, reflecting the fact that resources used to stimulate output and R&D in pharmaceuticals must come from some other use. (These specialist and high quality resources are unlikely to be unemployed were the pharmaceutical sector to be smaller in size.) Of course, to the extent that the rationale of the PIIP is to increase activity that was inefficiently lost as a result of the PBS, then, so long as the subsidy rates do not cause activity to overshoot the required increase, this displacement is a desirable outcome.

However, to the extent that the PIIP is seen partly as an industry development program aimed at stimulating technological spillovers, then displacement of R&D and loss of associated spillovers from other industries that use common scarce resources is a relevant concern. This suggests that cost-benefit analyses of the spillover benefits of R&D induced by the PIIP (the major source of the benefits of the Factor f program in the 1991 and 1995 studies of the Factor f program by the BIE) may need to take account of any R&D that may be displaced from other non-pharmaceutical areas — such as biotechnology, some medical research and biological sciences. R&D crowding out effects are probably quite low in the longer run, because the stock of R&D resources would grow over time. However, it may be an important short run phenomenon.

Effects of PIIP on non-participants

The PIIP may have various effects on the activity of non-participants, which will bias estimates of inducement based on comparing the performance of participants with non-participants.

As noted above, the PIIP might displace activity among non-participants, imparting a positive bias to estimates. Furthermore, to the extent that non-participants might aspire to participation in the PIIP in the future, its incremental design encourages them to shift activity from periods before program participation to periods after program participation. By having a relatively low initial base period for R&D and

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6 The assumption that value added grows steadily from year to year is unrealistic. It is more likely that $\Delta \log VA = \alpha + \varepsilon$ where α is the usual trend growth rate and ε is a random error that can push the annual growth rate up or down. Once random variations are introduced, all other things being equal, this increases the expected value of growth between activity in a given year and the base (depending on the variance of ε) —— but the effect is not a large one for reasonable variances in standardised growth rates.

value added such firms could increase the scope for attracting subsidies for future activity. Such intertemporal shifts in activity would tend to exaggerate the measured impact of the PIIP (by artificially inflating activity of participants and deflating that of non-participants).[7]

On the other hand, there are also several ways in which the PIIP could *increase* the activities of non-PIIP firms (as mentioned by several non-PIIP companies), leading to underestimates of the effects of the PIIP:

- Some non-participants will benefit from outsourcing by, or collaboration with, PIIP participants (both of which are relatively common practices) as a result of the stimulation arising from the program. In this case, induced activity that is undertaken by a non-participant in the pharmaceutical industry reduces the estimated additionality from the PIIP.

- As a result of the detailed application process for PIIP, unsuccessful applicants might identify opportunities for investment or activity that might otherwise have gone unnoticed. For example, one firm noted:

  … the presence of the PIIP was perceived positively by a number of unsuccessful applicants. This suggests that perhaps the very process of developing an application for PIIP may actually influence investment. The rigour required to develop and then articulate a business plan for a five year period as part of a PIIP application is probably quite positive. (Servier sub. 7, p. 2)

- To the extent that the PIIP is effective at countering generally held adverse impressions of the Australian environment, this could benefit non-participants as well as participants.

- Investment behaviour by individual firms in oligopolistic industries, such as pharmaceuticals, sometimes depend on the behaviour of competitors. So, for example, if PIIP firms investigate the therapeutic properties of Australian flora or forge alliances with Australian biotechnology firms, their competitors in the global industry may also increase their activities in these areas so as to avoid the risk of being left behind in some market niche. However, given the small global significance of the Australian industry, this is not likely to be a significant source of bias in the inducement estimates.

The contaminating effects of Factor f and selection bias

While the PIIP is a fledgling program, it followed the Factor f program, which had similar aspirations, but much more substantial subsidies. There are several ways in

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[7] Against this, it is possible that unsuccessful firms might wish to build capabilities so as to be better placed for later acceptance in the PIIP, which would partly offset the strategic incentives to defer activity noted above.

which the effects of Factor f may contaminate estimates of the effectiveness of the PIIP. To the extent that the Factor f program was successful at inducing activity, its removal would have a (potentially lengthy) chilling effect on the pharmaceutical activity of ex-participants, including those that subsequently participated in the PIIP. This apparent slowing in growth from an initial high base would be an outcome of leaving Factor f rather than an impact of the PIIP.

Another bias counteracts this one. Firms whose activity is not growing over their base at the time of the commencement of the PIIP would not be eligible for subsidies under the PIIP. This implies that firms for which Factor f particularly stimulated activity would anticipate a future slump in sales and would not be able to benefit from the PIIP. Instead, only those firms with growth prospects would participate — regardless of the source of that growth. All other things being equal, this selection bias inflates measures of the impact of the PIIP when participants are compared with non-applicants.

Other selection biases could work the other way. For example, small firms tend to have faster growth rates than larger ones, yet small firms are less likely to have been accepted as PIIP participants. In this case, controlling for firm size or application status is likely to eliminate the bias.

The point to emphasise is that firms' activity is a reflection of many factors, of which PIIP is only one. Past program involvement, selection biases, and many other factors will shape activity trends, making assessment of the real level of inducement complex. This suggests that it is necessary to control for some of these factors when measuring program effects — or to at least consider how they might bias any empirical estimates of effectiveness.

Mergers

Several major mergers and major re-structures that took place among pharmaceutical firms after the commencement of the PIIP make it harder to determine the effects of the PIIP. For example:

- Pfizer (a participant) merged with Parke-Davis;

- Glaxo Wellcome (a participant) merged with SmithKline Beecham;

- Pharmacia & Upjohn (a participant) acquired Searle in Australia;

- Rhone-Poulenc Rorer merged with Hoechst Marion Roussel to form Aventis; and

- AMRAD (a participant) sold the part of its business involved in production.

If there were hundreds of firms in the PIIP, mergers and re-structures might not cause major problems for the analysis because mergers outside the program would tend to balance those inside. However, merger activity has significantly altered the face of the industry, most particularly among the nine PIIP participants, and cannot be ignored. Any change in activity resulting from mergers may be confused with program effects.

In analysing the effectiveness of the PIIP several strategies for dealing with mergers were adopted:

- using administrative data from applications and annual reports, it was sometimes possible to 'unscramble' the merged entity into its original parts and analyse the parts separately after the commencement of the PIIP (de-merged results);

- alternatively, it was also sometimes possible to create an artificially merged entity prior to the commencement of the PIIP (merged results). In this case, entities that were separate prior to the PIIP, but which subsequently merged after its commencement, were combined prior to the PIIP, so that comparisons over time were possible; and

- using only data on non-merged entities after the commencement of the PIIP ('stripped' results), thus excluding merged entities from the results.

All of these approaches have some limitations. For example, mergers often result in rationalisation of shared activities, the effects of which inevitably affect the analysis of PIIP activity depending on which method is chosen to deal with mergers.

Weaknesses in the data

Data from a Commission survey of pharmaceutical firms, encompassing participants, unsuccessful applicants and non-applicants (box 5.2), combined with data collected as part of the application and supervision process of the program by ITR were used to assess the program. However, some firms did not provide data for all items and some firms did not fill in the questionnaire. That, combined with the inevitable inaccuracies that affect all surveys, the modest number of firms in the program, and the impacts of mergers and selection biases, make empirical analysis of the effectiveness of the PIIP vulnerable to error.[8] As much as possible, we have used several methods to try to assess program impacts.

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[8] However, the modest number of firms involved is by no means sufficient to invalidate statistical analysis, especially when it is considered that up to 6 time periods of data are available for some firms.

We caution that empirical results are subject to data error, which could over or underestimate the effects of the PIIP.

As a reflection of the uncertainty about the key inducement parameters, in chapter 6 we test the sensitivity of the net benefit results to differing parameter estimates. This sensitivity analysis is an important part of our evaluation of the PIIP.

Box 5.2   **PC survey of pharmaceutical firms**

The Commission undertook a brief survey of pharmaceutical firms in September/October 2002. The survey concentrated on several key performance indicators, such as R&D, value added, exports, employment, investment, structure of production and R&D over the period 1998-99 (prior to the PIIP) to 2001-02.

The survey was sent to 43 firms, comprising all 9 participants, all 10 surviving unsuccessful applicants (noting that some merged after the commencement of the program) and 24 non-applicants. The Commission received 27 responses overall, with a response rate of 89 per cent, 90 per cent and 40 per cent for participants, unsuccessful applicants and non-participants respectively. Respondents to the survey account for 81 per cent of PBS sales for 2000-01.

5.3   Empirical estimates of the effects of the PIIP on value added

Simple comparisons of program participants with others

Overall, participants in the PIIP have experienced faster growth in pharmaceutical value added from 1998-99 to 2001-02 than non-participants and this is true regardless of whether de-merged or merged results are applied (figure 5.2). If the participants that experienced major mergers after the commencement of the PIIP (Pfizer, Pharmacia and Glaxo) are removed from the analysis, PIIP firms still had more rapid value added growth than non-participants, but by a reduced amount. This underlines the sensitivity of the results to different treatments of mergers.

One way of estimating the impact of the PIIP is to calculate value added for PIIP participants if they had only grown as fast as non-PIIP firms. Using this approach suggests an inducement rate associated with value added of 65 per cent (de-merged data), 77 per cent (merged data) and 50 per cent (stripped data).[9] The associated

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[9] As Servier (sub. 7, p. 2) noted, it is important to test the statistical significance of the results. The corresponding tests for the three impact measures above are $F_{3,88}=0.18$, $F_{3,76}=0.23$ and $F_{3,64}=0.07$ for de-merged, merged and stripped results respectively. In all cases, these significance tests

'bang for a buck' estimates are five times these values (noting that the subsidy rate is a flat 20 per cent in the PIIP).

Figure 5.2 Indexes of production value added for PIIP and non-PIIP firms
1998-99 to 2001-02
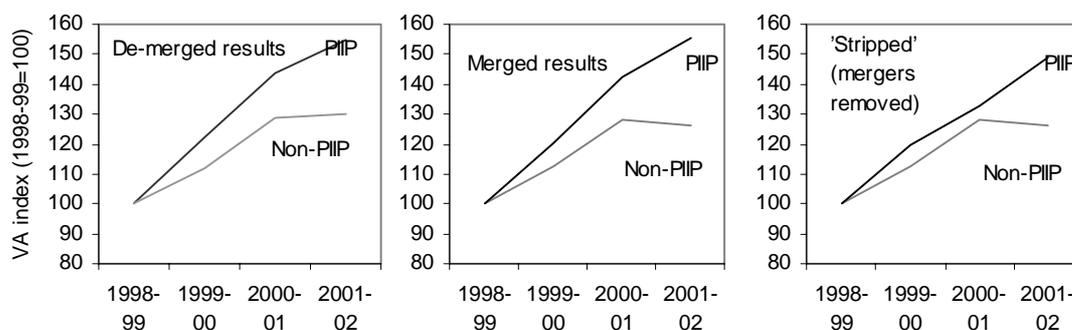
a Data only relate to those firms for which records were available for the full period from 1998-99 to 2001-02.

Data source: PC Pharmaceutical Survey and administrative data from ITR.

Controlling for differences between the control group and PIIP participants

As noted by Servier (sub. 7, p. 1), results based on simple comparisons between PIIP firms and non-PIIP firms can be confounded by underlying differences between the 'treatment' group (PIIP firms) and the control group. It noted:

> It would be useful to have the characteristics of the two groups of companies presented in a table and to assess if there are any fundamental differences between the types of companies. Possible characteristics could be: turnover, employees, number of products, number of R&D staff, expenditure on outsourcing, average time since launch of products, source of R&D funds (local vs overseas).

While some of these data are unavailable, an impression of the differences between the groups is possible by looking at some key measures of firm characteristics (table 5.1). The year 1998-99 was selected as the comparison year, since it pre-dates the PIIP. Unsuccessful applicants are similar to PIIP participants across a range of measures of firm size (value added, sales, exports, imports and investment). They have significantly lower average R&D intensities, but projections for growth of R&D and value added given in their PIIP applications were similar to successful applicants.

suggest that the 95 per cent confidence interval around the point estimate of inducement is very wide. This suggests that from a statistical perspective, the results could be generated by chance variations between firms and that the true effect could be zero (or indeed higher than that found).

Non-applicants to the PIIP appear to be markedly different to applicants (successful or not) across several dimensions. They are much smaller on average, exhibit very low export propensities and a relatively high share of fully imported sales in total sales. (Other analysis revealed that, among the sample available to the Commission, none had participated in phase II of the Factor f scheme, whereas applicants had often done so). However, they had a greater orientation to R&D than unsuccessful applicants (but not successful ones), using both R&D to sales and R&D employment to total employment ratios.

The differences between firms in the control group and participants may confound the analysis. At least some of the possible biases can be eliminated by comparing participants with only unsuccessful applicants, since these firms appear to be more similar to participants than non-applicants. It is likely that this not only deals with some of the clear differences between the control group and participants, but also some of the potential selection biases can be overcome in this way (for example, firms with slow growth projections would not tend to apply at all for the PIIP).

Calculations that examined the performance of participants relative to unsuccessful applicants *increased* the measured effectiveness of the PIIP (with an inducement rate of 78 per cent using de-merged data and 87 per cent using merged data).[10] This reflected the fact that non-applicants (at least those that responded to the PC's survey) tended to grow more rapidly than unsuccessful applicants.[11] This may stem from tendency for non-applicants to be smaller, with smaller enterprises typically experiencing faster growth rates than larger ones.

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[10] The associated probabilities associated with the significance tests were 0.95 and 0.94 respectively (cf the conventionally desired probabilities of 0.05 or less) — indicating that the results have very wide confidence intervals and are not statistically significantly different from zero.

[11] This undermines the conjecture that the PIIP significantly elevated performance in unsuccessful applicants relative to non-applicants.

Table 5.1 Differences between unsuccessful applicants, PIIP firms and non-applicants
1998-99

	Mean values of key variables 1998-99		
	Unsuccessful applicants	PIIP	Non-applicants
Value added ($)	82 684 840	87 656 905	25 933 297
R&D Expenditure ($)	5 903 582	13 942 858	3 836 829
Imports ($)	88 531 429	82 500 000	50 783 200
Exports ($)	43 675 000	40 389 966	2 228 000
Sales ($)	202 463 250	165 468 440	68 067 000
Invest ($)	9 045 143	10 232 089	6 490 333
R&D employment (number)	23	85	16
Employment	382	594	167
In house share of R&D (%)	48.0	34.4	51.9
Fully imported share of sales (%)	15.1	36.2	84.1
Packaging share of sales (%)	24.8	11.8	13.4
Formulation share of sales (%)	51.3	56.6	2.5
Trend rate of growth of projected value added 1998-99 to 2003-04 (%)	10.0	12.6	..
Trend rate of growth of projected R&D 1998-99 to 2003-04 (%)	13.0	9.6	..

a Results are means of the variables for the various sub-groupings of firms. The number of observations available varied for each variable. Results are weighted for any share or trend value.

Source: PC Survey of Pharmaceutical Firms 2002 and data supplied by ITR.

Another common approach that partly addresses differences between control and participant groups is the so-called difference in difference (DID) approach (box 5.3). A strength of this simple approach is that it does not assume that non-PIIP firms are a perfect control group, because differencing removes firm-specific factors.

Without controlling for any factors other than years and participation in the PIIP, inducement rates for the PIIP are estimated to be somewhat higher again. Across the results for merged, de-merged, and stripped results (including and excluding non-applicants) the average estimated inducement rate is around 90 per cent, but as noted in box 5.3 the technique makes strong implicit assumptions. None of these estimates are statistically significant from zero and therefore do not provide a reliable measure of the impacts of the program.

> **Box 5.3   The difference in differences approach**
>
> Information is available on value added activity prior to the PIIP — say 1998–99. In that case, it is possible to estimate the amount of value added for firms in that year for firms that will be in the PIIP and firms that will not participate.
>
> 1998-99 results: $V = a_0 + b_0$ PIIP, where PIIP is a dummy variable indicating whether a firm will be in the PIIP in the next three years and V is value added.
>
> The corresponding 1999–00 results when some firms have entered the PIIP are $V = a_1 + b_1$ PIIP.
>
> Similar regressions could be run for each of the remaining PIIP years.
>
> The effect of the PIIP for the first year of the program can be conceptualised as:
>
> $$\hat{\lambda} = (\hat{V}_{1999-00,PIIP} - \hat{V}_{1999-00,Non-PIIP}) - (\hat{V}_{1998-99,PIIP} - \hat{V}_{1998-99,Non-PIIP}),$$
>
> which is a difference in the differences. In the above case, it is simply $\hat{b}_1 - \hat{b}_0$. Rather than run separate regressions, the usual approach is to estimate something like:
>
> $$V = \alpha + \beta_1 Year_{1999-00} + \beta_2 Year_{2000-01} + \beta_3 Year_{2001-02} + \beta_4 PIIP + \beta_5 PIIP \times Year_{1999-00}$$
> $$+ \beta_6 PIIP \times Year_{2000-01} + \beta_7 PIIP \times Year_{2001-02}$$
>
> where the *Year* variables are dummy variables with a value of one in the given years. The effect of the PIIP is then equal to $\beta_5 + \beta_6 + \beta_7$ and its significance can be readily tested using an F test. In this simple form, this technique makes the strong assumption that all of the change in the effect of being a PIIP participant can be traced causally to participating in the program (If all firms are growing at the same rate, and PIIP firms are larger at the start, it will reveal apparent positive effects from the PIIP even when none exist). Variants of this difference in differences approach can add further control variables to the regression (such as Factor f participation dummies) or change its functional form (eg by using logs of value added).

A widespread concern among firms and others was that the 'overhang' effects of Factor f would bias the results (ITR sub. 8, p. 6; Sheehan sub. 15, p. 9), suggesting that past participation in this program should be controlled for. A regression approach can correct for prior participation in Factor f (in 1998-99) and applicant status by including additional 'dummy' variables in the difference in differences model.[12] The results (based on de-merged data) suggest that Factor f firms were larger than other pharmaceutical firms in 1998-99, but that, all other things being equal, past Factor f status was associated with slower growth rates of value added after 1998–99, presumably reflecting the (slow) impacts of the withdrawal of Factor f subsidies. Were this not to be accounted for, the inducement estimates would be biased (downwards). However, controlling for Factor f *and* applicant status of firms

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[12] In general, regressions were run on a weighted basis (with levels of value added as the weight).

leads to roughly the same (high) measure of inducement of roughly 90 per cent as above because the effects of applicant status and Factor f largely offset each other. But again results were not statistically significant.

Using forecast errors to gauge measures of the impact of the PIIP on value added

A unique aspect of the PIIP application process also allows another way to test the effect of the program, which is free of some of the likely selection biases that led some types of firms being selected for participation. PIIP applicants were required to forecast future value added and R&D activity were their application to the PIIP to be successful. They had incentives to give accurate forecasts after 1998-99 because of the way in which subsidies were calculated (chapter 2). To the extent that they are unbiased, these forecasts are the usually unobserved counterfactual of a program.

The difference between forecast and actual levels of value added for unsuccessful applicants provides an indication of whether non-participation adversely affected unsuccessful participants, and by implication also the effectiveness of the scheme for successful applicants.

However, it is not appropriate to regard this forecasting error as the impact of the program. It is possible, for example, that some demand or supply shock ensued after PIIP applications that meant that observed activity was greater or smaller than was expected. These shocks would affect the forecasting errors and be wrongly interpreted as the effects of the PIIP. To iron out these, the forecasting errors of the successful PIIP companies are used as the control, since these should pick up any such general shocks. A regression approach was used to model the relative forecasting error for the years 1999-00 to 2001-02. The model allowed for different forecasting errors between participants and unsuccessful applicants, ex-Factor f participants and for the different years concerned. When weighted results were calculated, the forecasting error for non-participants was close to zero over the three years,[13] while the forecasting error for participants was slightly negative (that is, they somewhat overperformed relative to their forecasts). The differences between the forecast errors implied a relatively small (and statistically insignificant) inducement rate of around 10 per cent.

Looking over a longer period

Using only single base year, 1998-99, as the pre-PIIP year in analysing the effects of the PIIP in later years places a lot of weight on that year. More pre-PIIP data may

[13] Reflecting the strong growth experienced by several large unsuccessful applicants.

provide a more reliable picture. Accordingly, regression analysis was undertaken using the growth rate in value-added from the three year pre-PIIP period, 1996-99, to the three year post-PIIP period, 1999-2002. This revealed a negative inducement rate, even after controlling for Factor f status and the starting size of firms. Clearly, such a negative inducement rate is not possible — but it indicates that the data as much supports small inducement rates for value added as high ones.

Statistical significance and likely inducement rates

The different statistical methods described above have suggested three basic levels of inducement. One set — based on panel data on observed value added from 1998-99 to 2001-02 — suggest inducement rates of around 70–90 per cent. These are very high 'bang for a buck' estimates by the standards of most industry programs. Another, based on forecast errors from 1999–00 to 2001–02, suggests a much lower estimate of around 10 per cent. Finally, using the longer span of data, the inducement rate is effectively zero.

Clearly, this is a very wide range, which reflects the fact that the underlying variability of value added between firms is much greater than that arising from the PIIP. This inevitably means that the results are very unreliable. None of the estimates of the inducement rate above were statistically significant at the conventional 5 per cent level or anywhere remotely near it. In effect, the PIIP status of a firm was found to make no statistically significant contribution to the growth in value-added, regardless of model specification. This does not prove that the PIIP is ineffective at stimulating value added, but it does suggest that its effectiveness is unproved using the empirical evidence available.

The conventional response in many economic analyses is to use a value of zero where a parameter is statistically insignificant. (For example, in a clinical trial a finding that a drug did not have statistically proven efficacy over a placebo or an existing therapy would usually suggest that the drug would not be marketed). However, for several reasons this is probably not the appropriate response when assessing the effectiveness of the PIIP. First, the database on which the analysis is based is far from perfect. Secondly, the costs of mistakenly exaggerating the effectiveness of the PIIP are probably no worse than the costs of mistakenly underestimating its impact. Thirdly, economic theory strongly suggests that subsidies will stimulate new activity. Given that the program uses an incremental design and supply elasticities tend to be higher where activity is globally footloose, this stimulation could potentially be significant. Finally, as noted in section 5.5, case study evidence, though obviously partial, is also suggestive of genuine inducement effects.

Examining related activity measures

Another approach to assess the impact of the PIIP on value added is to test whether it had any effects on the structure of activity or on related input measures, such as investment and employment.[14] For example, a shift away from importing towards greater packaging and formulation would, all other things being equal, imply greater value added.

These aspects of the impact of the PIIP are interesting in their own right since they also cast light on the degree to which the PIIP encourages activity that is different in scope to the current production structures of firms (principle 3 of the PIIP guiding principles — chapter 2).

Exports

Export growth was high among PIIP firms, growing by a trend rate of just under 20 per cent per annum from 1998-99 to 2001-02. However, growth rates were also very high for non-PIIP firms, growing at slightly in excess of 22 per cent per annum. Regression analysis, controlling for Factor f and applicant status and enterprise size did not find positive effects of the PIIP on exports.

These results appear to reflect an outlier among non-participants. One non-participant experienced very rapid growth in exports, especially in 1999-00, the first year after the commencement of the PIIP, and it is relative to this that PIIP participants' performance has been weak. If that non-participant is removed from the sample, then, relative to other non-participants, participants have experienced significant export growth. Of course, it is not appropriate to willy nilly remove observations from a sample, else one could equally argue for the removal of some high performers among the PIIP group. But this finding does expose the fragility of the export results to the construction of the sample.

Another factor that may have a bearing on the ability of the PIIP to stimulate export growth since the program's inception are delays in gaining registration approval in export locations for sourcing drugs from Australia. One participant in the review estimated that it would take three years for new exported products to be registered. Accordingly, some export growth stimulated by the PIIP may only become apparent in later years.

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[14] In undertaking this analysis, some companies involved in mergers had to be stripped from the results because otherwise the effects of mergers would be confounded with that of the PIIP. However, one merged company supplied data for the pre-merger years for the merged entity.

Investment

Investment growth in PIIP firms was lower than non-PIIP in some years (1999-00 and 2000-01) and higher in 2001-02. Overall, regression analysis suggested a small (statistically insignificant) increase in investment due to the PIIP, but variability between firms was so great that the differences between PIIP and non-PIIP firms could arise as a matter of chance.

Employment

Employment grew by over 11 per cent among PIIP companies, but by slightly more for non-PIIP firms (though the data are limited as the results of two PIIP firms had to be removed from the analysis due to merger effects). More sophisticated regression analysis could not identify positive employment effects.

The structure of production

The import share of activity in PIIP firms was relatively static, compared with a significant rise in non-PIIP firms (table 5.2). This was also borne out by regression analysis that took account of other factors that might affect import shares. Thus, it appears that the PIIP may have decreased the import share of activity over what it would otherwise would have been — and this effect is large at around 14 percentage points (that is, in the absence of the PIIP, it would have been expected that the import share would have been about 38 per cent, instead of the observed 24 per cent).

Similarly, formulation activity appears to have shrunk somewhat across the industry, but by much less in PIIP firms. Indeed, using regression techniques, it appears that the PIIP may have increased the formulation share by as much as 10 percentage points above what it would have been in the absence of the program.

The packaging share of activity has been stable over time for participants and non-participants. It increased slightly for participants and fell by a small amount for other firms, suggesting a modest relative rise (3 percentage points) in the amount of packaging that might be traced to the influence of the PIIP.

Table 5.2 Changes in the structure of activity of PIIP and non-PIIP firms
1998-99 to 2001-02[a]

	Years	PIIP	Non-PIIP	DID impact effect[b]
		%	%	Percentage points
Import share	1998-99	22.2	36.5	..
	2001-02	24.3	52.6	-14.3
Formulation share	1998-99	62.5	35.0	..
	2001-02	58.7	21.4	10.1
Packaging share	1998-99	14.9	22.6	..
	2001-02	15.9	20.3	2.9

a Shares do not add up to 100 because they were computed on the basis of different numbers of firms for each measure. All results are weighted. **b** DID is the difference in differences estimator for the effect of the PIIP, determined from a regression based on the product shares. The regression took account of possibly different effects for Factor f participants and applicants as well as PIIP participants.

Source: PC Survey of Pharmaceutical firms.

The various indicators of activity give mixed signals. The investment and employment measures above are not consistent with an apparent significant increase in value added by PIIP firms over non-PIIP firms. In contrast, the import and formulation share results imply the opposite.

How can these results be reconciled? Several possibilities arise.

First, this pattern might hold if the induced increases in value added were mainly in import replacement activities and were achieved through the use of existing excess capacity with little need for additional input factors in the short run (though it would be expected that such inputs would be required in the longer run to maintain growth).

Second, as emphasised in the previous section, outsourcing is a feature of this industry, and inputs used by these enterprises will not have been appropriately counted in the statistical techniques used.

Third, the data set for employment and investment is less reliable than that for value added and R&D and fewer observations are available. In that context, the empirical methods above may have underestimated real input growth attributable to the PIIP (and certainly will not capture the expected longer run effects on investment). Participants have argued that the PIIP has made large differences to investment and employment that would not otherwise have occurred.

Fourth, there may be strong selection biases at work, combined with unique aspects of the program design, that may help explain the patterns apparent. Firms that had

strong future growth plans for value added have strong incentives to apply to the PIIP. They would automatically receive value added subsidies even though real inducement levels were low. It could still be that the underlying supply elasticities are very high (that is firms would expand production significantly with a subsidy to value added), but that these supply responses are muted because entitlements are capped. This story is consistent with the results from the forecast regressions, which suggest that firms were able to meet their PIIP plans even if they were not in the PIIP. The other regression approaches are unable to account for the unobserved characteristics of firms that drive value added and thus could show big effects when none were present.

In all likelihood, the reality may reflect all four factors. Firms have confirmed that they were not at full capacity at the time of the PIIP and that they outsource some activity. Some have said that they have made some investments that would not otherwise have proceeded without the PIIP, while others have indicated low additionality in value added.

5.4   Research and development

R&D has grown strongly in PIIP firms from 1998-99 to 2001-02 at around 16 per cent per annum (based on the de-merged data set) (figure 5.3). However, growth has been equally strong among non-PIIP firms (and actually stronger if merged or stripped data sets are used). At face value, this suggests that the PIIP has had between a small positive to a modest negative effect on R&D.

While, in theory, programs can have perverse effects, this is not credible in this instance. A likely source of this apparent pattern is failure to adequately control for differences between the participant and the control group (in particular, non-applicants are smaller than applicants, and R&D growth is negatively correlated with initial R&D size). If non-applicants are removed from the sample, growth among PIIP firms is much greater than non-PIIP firms. The implied inducement rate is 75 per cent based on the de-merged applicant-only database and 49 per cent based on the merged applicant-only database. A regression approach (using the whole sample) that controls for Factor f participation and applicant status suggests an inducement rate of 69 per cent using the de-merged data set and 53 per cent using the merged data set (though neither are statistically significant).

If the growth rate in R&D from the three year pre-PIIP period, 1996-1999, to the three year post-PIIP period, 1999-2002, is modelled[15], the estimate of inducement

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[15] Using the de-merged data.

is reduced to 25 per cent (compared to the negative estimate found for value added using this method).

Figure 5.3 **Indexes of R&D for PIIP and non-PIIP firms**
1998-99 to 2001-02
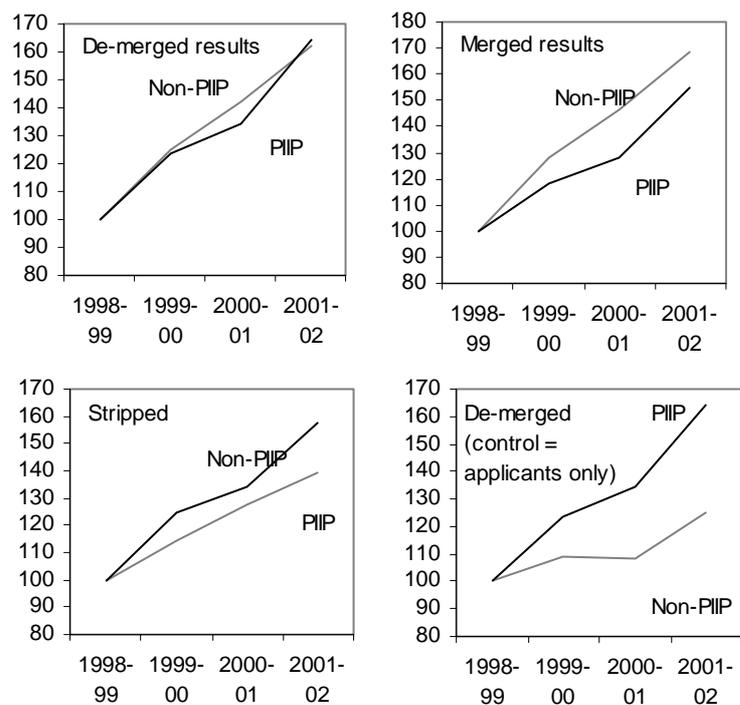
a Data only relate to those firms for which records were available for the full period from 1998-99 to 2001-02.
Data source: PC Pharmaceutical Survey and administrative data from ITR.

Another and probably more powerful way of examining the impact of the PIIP on R&D is by considering unsuccessful applicants' forecast errors (as for value added above). Here, the regression results suggest that the average difference between forecast and actual R&D was 22 percentage points (weighted) for unsuccessful applicants (that is, firms' application forecasts were significantly higher than was achieved when they failed to get access to the program). The comparable forecast error was only around 6 percentage points for participants. Unlike the results for value added, the results imply that non-participation in the PIIP had large adverse effects on R&D, and imply that the PIIP had a significant positive effect on R&D for program participants. Calculations using the estimated forecast errors as measures of forgone R&D activity suggest an inducement rate of 73 per cent.

There also appeared to be increases in R&D employment in PIIP firms. Overall, in-house R&D employment increased by around 18 persons per firm from 1998–99, with much smaller absolute increases among non-PIIP firms. While raw

(unadjusted) growth rates in R&D employment were somewhat higher among non-PIIP firms, after controlling for application and Factor f status, it appeared that growth rates in R&D employment were higher among PIIP participants. Moreover, as pointed by some submissions to the review (and confirmed through the PC's survey — see below), a large share of R&D is contracted out by firms and the importance of clinical research organisations, which provide outsourcing clinical research services to the pharmaceutical industry has increased. For example, Servier (sub. 7, p. 2) noted that:

> For Servier most of the R&D investment is with external parties such as research laboratories or hospitals who act under contract … In the case of Servier where the majority of R&D is clinical in nature, over 80 per cent of an annual investment of $25 million comprises payments made to external organisations, such as laboratories and hospitals. Employment must have increased in those organisations to deal with this increased activity.

Accordingly, a comparison of participants and non-participants will tend to obscure some of the real growth in R&D employment arising from the PIIP.

The nature of R&D

A goal of the PIIP was to shift the R&D of participants towards earlier stage R&D. There is evidence that this aspiration has been achieved. The share of phase I and II trials in total R&D has increased significantly in PIIP firms (by about 18 percentage points) relative to non-participants (where the increase was only about 2 percentage points) from 1998-99 to 2001-02. Regression analysis that controlled for the possible confounding effects of other variables[16] also suggested that the PIIP led to a large increase in the share of phase I and II trials in total R&D for participants versus non-participants (with an overall impact effect of around 19 percentage points).[17]

A further goal was to stimulate collaborative R&D among firms. Here the evidence is less clearcut. Overall, there was a slight increase in apparent collaborative R&D among both PIIP and non-PIIP firms from 1998–99 to 2001–02. After controlling for other variables, regression analysis suggests that the share of collaborative R&D appears to have been increased by the PIIP relative to what it would have been by a modest 3 percentage points. However, some firms noted that the measure of

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[16] These were Factor f and application status. Other control variables such as a firm's R&D size and R&D specialisation, which might have also affected the nature of R&D were also considered, but made no difference to the results.

[17] These results are for the value of clinical trials and were weighted by R&D value. The results verged on conventional statistical significance. Results for the volume of clinical trials revealed a smaller apparent effect from the PIIP.

collaborative R&D would include all R&D contracted out, and not just R&D which had a genuinely collaborative character (for example, Servier, sub. 7, p. 2). Accordingly, the measure above merely suggests that firms maintained roughly the same level of reliance on in-house versus external research capacity over the period since the PIIP, without revealing much of any change in the collaborative nature of their R&D. Other evidence on collaboration is useful:

- Firms reported some collaborative R&D in their broad activity commitments under the PIIP, but it is not clear whether these arose out of the PIIP or represented reporting of activities that would have taken place in any case.

- In responses to the draft report, some participants indicated that they had substantially increased their R&D collaboration in response to the PIIP. For example, this was reported by Pfizer (see the case study below).

Overall, it is uncertain across all PIIP participants how much collaboration has increased as a result of the program. However, given the apparently strong impact of the PIIP on total R&D, at least some stimulation of collaborative R&D would be anticipated. This is consistent with the experiences reported by some individual firms.

5.5   Case studies

Medicines Australia (sub. 10) legitimately claimed the relevance of case studies in illustrating how a program, such as PIIP, may have affected activity.[18] Such case studies have to be interpreted carefully because firms have an incentive to overstate the impact of a program from which they benefit and because statements that something would not have happened otherwise are not verifiable. Nevertheless, detailed case studies can strengthen claims about additionality if reasons and a context are supplied about why they would not have occurred otherwise. They also provide useful information about some of the potential qualitative effects of the program, such as in building capabilities.

Some of the case studies relating specifically to the PIIP are described below, of which the most detail was provided by Eli Lilly.

[18] In many instances they also cited case studies indicating the impact of the (more generous) Factor f program (for example, Medicines Australia sub. 10, pp. 9–10) on activity. These are relevant to the extent that while Factor f was a larger program, its basic design was similar to the PIIP, and effectiveness in Factor f is likely to be partly replicated in its smaller partner.

R&D at Eli Lilly Australia since the PIIP

Eli Lilly provided a detailed assessment of additionality associated with its Clinical Outcomes Research Institute (CORI). CORI was established as a regional centre of excellence in clinical research that would service clinical trial needs in the Asia Pacific region (Eli Lilly sub. 9, p. 9). Due to its specialisation and scope, CORI involved the development of additional and strengthened R&D capabilities within Eli Lilly Australia. For example, because the centre deals with the full continuum of clinical trials, complimentary activities have been built up in areas such as design protocols, development of software for database development and the provision of statistical and report writing services.

Eli Lilly did not claim that all R&D conducted as a result of CORI was additional, arguing that without the establishment of CORI, clinical trial activity would have increased in line with the experiences over the past three years. On that basis, it was estimated that the inducement rate in relation to clinical R&D at CORI was just over 70 per cent (figure 5.4).

Figure 5.4 **Eli Lilly's estimated induced clinical trial R&D[a]**
1999-00 to 2001-02
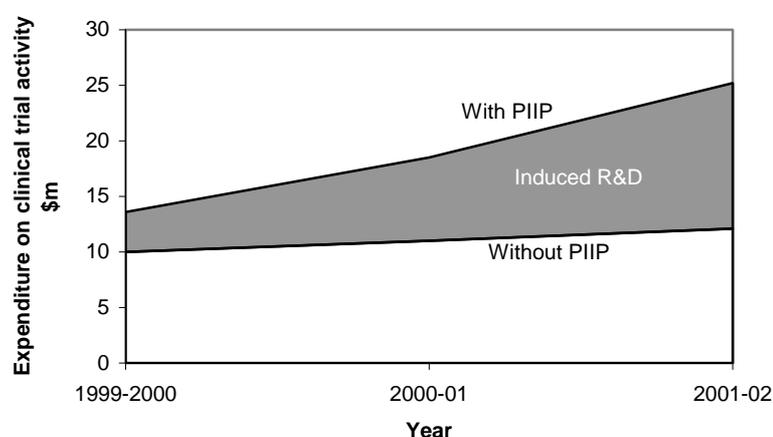
[a] Eli Lilly considered that in the absence of the PIIP (and CORI), clinical trials would have increased in line with the experience over the period from 1996–97 to 1998–99 — at the rate of 10 per cent per annum. It then calculated induced R&D by taking project clinical trial activity that would have occurred without the PIIP from that which was observed. This was equivalent to an additional $24.2 million over the three year period over a counterfactual of $33.1 million — or a 73 per cent inducement rate.

Data source: Eli Lilly (sub. 9, p. 9).

In the case of the Global Clinical Data Management Centre, Eli Lilly argued that all of the activity was induced by the PIIP — reflecting leverage from the PIIP in competition between Australia and other global sites:

> [The Global Clinical Data Management Centre] … was established to meet the corporate need for increased efficiency in processing individual patient data from clinical trials. However, PIIP was instrumental in capturing this opportunity for Australia. The centre receives clinical trial data (in the form of individual patient case report forms) from trials in many countries (mainly the Asia Pacific area, but also acts as an overflow processing centre for trials served by the other two Lilly centres of this type, in Indianapolis and Spain)… A decision to add a third such centre [globally] was made by Eli Lilly and Company at about the time of the development of the PIIP. Initial consideration was to site the centre in Singapore, where Lilly had recently established an Ethno-Pharmacology Centre with considerable assistance from the Singapore Government. Gaining entry into the PIIP was a major factor in deciding to locate in Australia (along with the usual investment considerations relating to economy, workforce and regulatory environment). (Eli Lilly sub. 9, p. 5, p. 10)

However, in another area, technology transfer, Eli Lilly considered that a considerable amount of the activity would have proceeded without the PIIP — and estimated an inducement rate of 50 per cent.

Taking account of the different inducement rates across its various research activities, Eli Lilly estimated an overall inducement rate of 76 per cent — which is roughly consistent with the upper level estimates produced by the empirical modelling in section 5.4.

Eli Lilly also gave evidence that the growth of clinical research in Australia has been very high relative to its other global operations (figure 5.5), which it argued 'further reinforces the conclusion that PIIP has been responsible for attracting an additional share of clinical research to Australia.' Only Brazil and China have increased their relative standing compared to Australia over the period from 1998-99 to 2001-02.

Pfizer's R&D collaborative program

Pfizer's Global Research and Development division allocated $25 million over five years for early-stage research in Australia. Prior to PIIP, Pfizer had one research collaboration with an Australian biotech company and one with an academic institution. By 2002, Pfizer had more than 45 research collaborations with a diversity of entities — academic, Government and biotech. Medicines Australia (sub. 10, pp. 9–10) argued that:

> It is possible that a very small number of these collaborations would have gone ahead in the absence of the PIIP, but certainly the majority can be directly attributable to PIIP.

Figure 5.5   **International ranking of clinical research expenditure[a]**

Eli Lilly Australia (ELA) versus other global Eli Lilly operations, 1998-99 and 2001-02
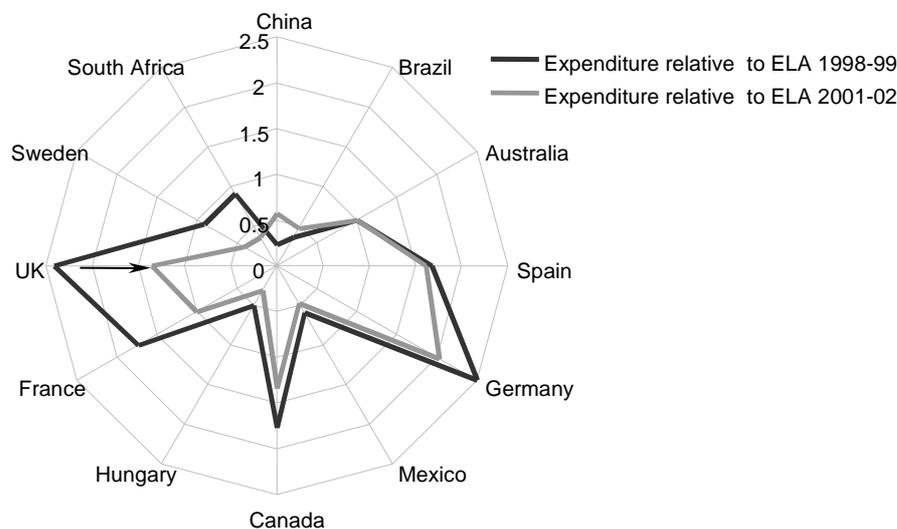
a In each year, Australia's expenditure is normalised to unity and other country's expenditures are expressed as a ratio to it. The movement of ratios over time indicates Australia's relative standing. For example, in 1998-99, Eli Lilly's UK operation undertook 2.41 times more clinical R&D than the Australian operation. In 2001–02 this had declined to 1.36.

Data source: Eli Lilly (sub. 9, p. 10).

Meeting FDA standards — the case of Bristol-Myers Squibb (BMS)

BMS has invested \$40 million in recent years to augment production facilities, upgrade laboratories, and expand offices and other facilities. This additional investment allowed BMS's manufacturing plant to meet the standards of the US Food and Drug Administration for export to the US — one of four facilities in Australia so accredited. In the first year of the PIIP, BMS was exporting to 21 countries (this was attributed to Factor f). By 2004, the time of expiration of the PIIP, this is expected to be 75 countries. Medicines Australia (sub. 10, p. 11) considered that the investments in these facilities were a direct consequence of Factor f and PIIP.

Other case study evidence

In meetings with participants, some privately acknowledged that the subsidies had variable effects on their activity. One participant, for example, claimed that they were going to undertake all the value added activity anyway because they were on a growth path (box 5.1), but that the firm had used all of the funds provided by the value added subsidy to finance additional R&D. In that instance, even though the level of inducement of value added was zero, the transfer element of the program

was effectively zero (and accordingly so too any leakages). On the other hand, measures of R&D inducement that failed to take account of the cross-subsidisation would be overstated.

5.6   Comparisons with past results

The BIE and the IC examined the effectiveness of the predecessor to the PIIP, the Factor f scheme. Given its similarities to the PIIP, these evaluations are relevant to the likely effectiveness of the PIIP.

On the basis of survey data from the APMA (now Medicines Australia), the IC found exports to turnover ratios to have grown less strongly in non-participants than in continuing and phase II Factor f participants. On the other hand, the IC (1996, pp. 284–5) found that there were no discernible differences in trends of turnover, production value added and R&D — the main targets of the program — by continuing participants and non-participants. It found that:

> … for the most directly comparable data, that of PBS-type production value added, it appears that the Factor f scheme has made little difference to the relative size of the two group's [participants and non-participants] activities. (p. 287)

The IC speculated that the program may have had some effects on non-participants. The IC concluded that a precise estimate of inducement was impossible, but judged that:

> most of the activity conducted under Phase II of the scheme would not have occurred in the absence of the scheme (p. 288).

On the basis of discussions with firms, the BIE's (1991, p. 85) original evaluation suggested very high inducement rates, especially for value added:

> … the BIE's perception is that probably around 90 per cent of the proposed additional value added on export activity and a similar proportion of value added on domestic sales was induced by the scheme, but possibly only 50 per cent of the expenditure on R&D.

It was acknowledged that assessment of inducement rates was based on a 'series of brave judgments'.

The subsequent BIE review (1995, pp. 72–3) judged inducement rates on the basis of perceptions of participants and apparent growth rates of activity of phase I participants over end-of-phase II activity levels. The results were comparable with

those of the earlier review, but essentially the parameter values were assumed, rather than estimated.[19]

It is important to note that the IC and BIE estimates are based on qualitative rather than empirical assessments, reflecting the difficulties in estimating inducement rates. They cannot readily be compared with the results obtained in sections 5.3 and 5.4.

Evidence from studies of the effectiveness of policy measures aimed at stimulating activities in industries are also illuminating. A particularly rich vein of literature exists for R&D and has been summarised recently by Hall and Reenen (2000).[20] It suggests that the bang for a buck from R&D programs around the world are usually around unity, but have been as high as 2 and as a low as 0.3.

In the case of the PIIP, the estimate of the bang for a buck are five times the inducement rates.[21] Using the inducement rate of 0.73 from the 'forecast' regression approach, the bang for a buck for R&D in the PIIP is 3.65. Even if the lowest of the inducement rates is used — the estimate of 0.25 from using the longer period analysis over 1996-2002 — the bang for a buck is 1.25. Thus, the estimates from the empirical analysis of the PIIP suggest a very high bang for the buck for R&D relative to that found around the world (table 5.3).[22]

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[19] The BIE (1995, p. 73) assumed inducement rates of 90 per cent for all new participants (in contrast, the IC assumed an inducement rate of 70 per cent for domestic value added). The BIE used growth rates of activity for phase II participants over end of phase I levels as the estimate of inducement rates for continuing participants. For foreign-owned participants, this gave inducement rates of 54 per cent and 43 per cent for export value added and R&D activity respectively. For domestically-owned participants, this gave inducement rates of 60 per cent and 67 per cent for export value added and R&D activity respectively.

[20] Information on empirical estimates of the bang for a buck associated with programs aimed at increasing value added have been subject to less review, but the most important consideration will be long run supply elasticities. If firms are highly responsive to changes in the costs of supply, then value added subsidies should generate significant supply responses.

[21] This follows from the fact that the bang for a buck divided by the subsidy rate is the inducement rate (and in the PIIP, the subsidy rate is 20 per cent).

[22] Eli Lilly commented that the 45 per cent inducement rate used by the Commission in its cost-benefit analysis in the draft report was a 'low' one. With an implied bang for a buck of 2.25, it exceeds any of the estimates found in the survey article of Hall and Van Reenan (2000).

Table 5.3 **Summary of 'bang for buck' estimates for R&D from the international literature**

Country of study	Low	High	Mean
US	1.00	1.00	1.00
US	0.30	0.60	0.45
US	1.74	1.74	1.74
US	1.30	1.30	1.30
US	2.00	2.00	2.00
US	0.29	0.35	0.32
US	1.30	2.00	1.65
Canada	0.60	0.60	0.60
Canada	0.38	0.67	0.53
Sweden	0.30	0.40	0.35
Canada	0.83	1.73	1.28
Australia	0.60	1.00	0.80
Canada	0.98	0.98	0.98
All studies	0.89	1.11	1.00

Source: Hall and Van Reenan (2000).

5.7 Conclusions

Mixed signals about the effectiveness of the PIIP emerge from the analysis of the survey and administrative data and from case studies provided by firms. Comparisons of production levels between participants and non-participants from 1998-99 to 2001-02 suggest that value added has been strongly stimulated by the program, as does evidence on the changing structure of production.

Against this, analysis of unsuccessful applicants' forecast errors suggests a relatively modest inducement rate of 10 per cent, while that based on comparing the activity in the three years of the PIIP with the activity in the three preceding years suggests no effect at all. The rough average of the three empirical approaches suggests an inducement rate of around 30 per cent. Comparisons of the employment, investment and export trends suggest weak overall effects of the PIIP so far on productive capability. However, confounding factors such as outliers in the data and the prevalence of outsourcing have probably underestimated the real short run response of firms in these areas.

In any case, as pointed out by some participants in the review (for example, Sheehan sub. 15, p. 9), the effects of PIIP on some activities — such as investment (and future value added) — can be expected to take some time, and indeed to extend beyond the life of the program. So, for example, if the PIIP enables firms to use capacity at a higher level earlier in the program, this can be expected to

stimulate investment later. From that longer term perspective, it is likely the program will make a further difference to productive capability. This suggests that the estimated inducement rates for value added need to be increased somewhat. Rather than use the average of the empirical results (a 30 per cent inducement rate), the estimate has been increased by 50 per cent to a 45 per cent inducement rate in the base case for empirical modelling in chapter 6. Given the fact that none of the estimates are statistically significant, a wide range has been used for considering alternative scenarios.

It also appears that R&D has been stimulated by the program, once some confounding variables have been taken into account. Indeed, the evidence on R&D is more consistent and persuasive than is the case for value added — with all three empirical approaches suggesting positive non-trivial inducement rates (of around 60 per cent using the 1998-99 to 2001-02 data, 25 per cent using the longer span of data and 73 per cent using the forecast approach — an average of around 53 per cent). As with value added, a higher longer run effect could be expected. However, given that R&D is already an investment expenditure, the difference between the long run and short run effect for R&D should be less than for value added. The average inducement rate has been increased to 60 per cent to capture these long run effects (and this is used as the base case for modelling in chapter 6). This is a very high inducement rate relative to that usually found in the economic literature on R&D incentives.

In addition to its apparent effects on R&D expenditure, the program appears to have increased the relative importance of phase I and II clinical trials and to have increased R&D employment. Its effect on collaborative R&D is uncertain.

FINDING 5.1

While the empirical results are mixed, on balance the analysis suggests that the PIIP has induced a significant amount of new R&D and, to a lesser extent, value added activity among participants, and has strengthened the capabilities of participants in diverse ways.

6   Economic efficiency of the PIIP

The terms of reference ask the Commission to examine the efficiency of the PIIP and whether the PIIP is producing net benefits for the Australian economy as a whole. This chapter addresses these matters:

- section 6.1 explores the meaning of efficiency for the purposes of this evaluation, and dispels some common misunderstandings about what constitutes a benefit and cost for the Australian economy of an industry subsidy;

- section 6.2 identifies the parameters required to quantify the benefits and costs, and suggests some values for the parameters;

- section 6.3 presents estimates of the possible benefits and costs of the PIIP, including an examination of the sensitivity of the results to parameter changes; and

- Section 6.4 concludes with a perspective on the likely long-run, economy-wide efficiency effects of the PIIP, in its current form.

6.1   The meaning of efficiency and net benefit

Care is required in determining what constitutes a benefit to Australia from additional pharmaceutical activity resulting from government intervention. As discussed in chapter 1, the distinction between the *effectiveness* of a government program and its *efficiency* is important.

Industries (and companies) are often judged according to increases in value added, employment, investment, exports, R&D expenditure and productivity. Where these occur as a result of the entrepreneurial drive of firms and through grasping opportunities for better returns in an economy, any such increases are (absent other distortions) regarded as beneficial for Australia. By many standards, the historical performance of the Australian pharmaceutical industry has been impressive in this regard.

But the story is usually different where the increased activities arise from government interventions.[1] In that case, such measures of increased activity are relevant to assessing

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[1] In general, while multiplier analysis that attempts to measure the contribution of the industry to the economy may be useful in understanding linkages, it cannot, except in rare circumstances, be

the effectiveness of government interventions, such as the PIIP, but not necessarily their efficiency. Intuitively, it may appear that any gross increases in pharmaceutical activity (with apparent associated increases in the use of Australian inputs, such as labour, capital and land) are the amount by which the PIIP makes Australians better off. However, the amount of induced activity (or increases in other 'headline' variables) is not the appropriate measure of the *net benefit* to Australia.[2]

A more appropriate framework for measuring the net benefit is one based on the efficiency of economy-wide resource allocation. In an economy where resources have alternate uses, the *economic* well-being of society will be maximised if the resources are used in their most productive way. Generally, market prices of goods, services and inputs provide the best indicator of what these most productive or efficient allocations may be. If resources are already allocated in the best way a subsidy cannot improve this any further, and indeed reduces efficiency as it shifts resources away from their most productive uses.

In determining the efficiency of the PIIP, the central issues are whether the existing allocation of resources to pharmaceutical activity (production and R&D) is already efficient and whether the PIIP makes a net improvement.

There are (at least) two general circumstances in which the existing market allocation of resources in pharmaceutical activity may not be efficient.[3] One circumstance is where 'artificial' interventions (such as patents, registration and listing of drugs, and prescribing regulations) change market incentives (demand and supply) by too much or too little.

Another circumstance is where market prices (private values) do not reflect social values — that is, if external benefits or costs of the activity are not priced. A common example used to illustrate this point is where activities — such as R&D — produce positive benefits for others that are not mediated through market transactions ('spillovers'). These spillovers can have broader benefits to Australia through increased technological diffusion, enhanced innovation capacity, greater retention of IP and improved commercialisation rates of Australian ideas. Some of the strategic and new growth theories also provide explanations about why resources in uninhibited markets may not be allocated — at least in a dynamic sense — to their most efficient uses (Sheehan sub. 15, p. 2). (However, unlike the spillover literature, existing empirical and policy modelling in this area provides a weak basis for policy prescriptions).

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used to assess the effect on efficiency from government intervention. This issue was addressed in greater detail in the draft report (for example, box 6.1 in the draft report).

[2] Access Economics confirmed this "The Commission correctly points out that increases in value added, employment, investment, exports and R&D expenditure in a particular industry are not a good indicator of the net economic benefit to Australia" (Medicines Australia sub. 10, appendix 1, p. 4).

[3] A non-optimal allocation can be too much or too little.

In principle, therefore, if there was 'too little' pharmaceutical activity and the PIIP induced more, there would be a gross gain to society.

The costs of the PIIP need to be weighed against any such gross gains. There are administration costs for the Government and compliance costs for firms from applying and reporting. (These can be used to examine the narrower concept of program efficiency — that of administrative efficiency.) There is also a financing cost, not the nominal cost of the subsidy itself, but the adverse effect on resource efficiency from extracting funds from taxpayers. This so-called 'marginal excess burden' (MEB) is separate from any gross gains arising from the subsidised activities. Another cost to Australia is any leakage to foreign shareholders of PIIP payments that represent pure transfers (that is, payments that do not induce pharmaceutical activity in Australia).

The remainder of this chapter is concerned with providing (quantitative) guidance on the relative magnitude of the potential benefits and costs.

Two key points emerge from these introductory comments. First, the task is about assessing a government program, not the pharmaceutical industry as such. Secondly, the efficiency or net benefit of the PIIP involves an economy-wide assessment that takes account of the fact that resources have alternate uses, rather than an examination of the benefits to the pharmaceutical sector alone.[4]

6.2 Net benefit methodology

In quantifying the overall efficiency (the net social benefit) of the PIIP and drawing robust conclusions, three steps have been followed. First, the potential benefits and costs have been combined into a net equation (box 6.1).[5] Secondly, the parameters required to

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[4] The advantage of adopting a broader, economy-wide benefit-cost approach becomes more obvious in attempting to answer three questions. First, if PIIP generates net benefits, is there a point at which further increases in support deliver less incremental benefits than incremental costs, such that the net result turns negative? Second, if increases in activity underpinned by PIIP are good for the economy, could the same work for other sectors? Third, if a choice about the provision of a subsidy has to be made between sectors, which sector generates the largest net-benefit?

[5] Access Economics (Medicines Australia sub. 10, appendix 1, p. 5) explains that the social efficiency of the PIIP could be assessed using a general equilibrium model or a cost-benefit (partial equilibrium) approach, such as adopted by the Commission. Access Economics favour the general equilibrium approach, on the basis that additional pharmaceutical activity would be significant enough to influence variables, such as the exchange rate, thereby resulting in changes in other sectors. Previous general equilibrium modelling of the effects of changes in pharmaceutical activity (IC 1996; Econtech Pty Ltd 2002) suggest negligible effects on GDP. As Access Economics note, if such effects are negligible then the cost-benefit approach and the general equilibrium approach provide essentially the same answer to the question of whether

estimate the equation have been specified. Thirdly, sensitivity testing, using ranges for parameters was conducted.

The elements of the cost-benefit equation and the parameter values are discussed below.

Only induced activity is attributed as a benefit of the PIIP

Activity that would have taken place without PIIP is not relevant for evaluating the possible beneficial spillovers and improvements in resource usage associated with the program because the benefits from that activity would have been generated anyway.

Chapter 5 concluded that PIIP had been effective in inducing additional activity, but also that some of the observed increase in the value added and R&D was likely to have occurred in the absence of the PIIP. Empirical estimates were obtained using several approaches, but the overall view was that for the base case analysis, inducement rates of 45 per cent for the value added and 60 per cent for the R&D are appropriate. The sensitivity of the net benefit estimates are examined over a range from 10 to 80 per cent for the value added and 40 to 80 per cent for the research and development.

The efficiency margin on induced activity

MARGIN accounts for any gain (or loss) to society arising from a difference between the value from pharmaceutical companies using additional resources (that is, the induced value added and R&D) and the value that would arise from the alternative use of those additional resources.

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aggregate efficiency has improved or not. The general equilibrium approach would be the appropriate method for measuring the distributional differences across sectors, for example, sectors that may be adversely affected by a possible appreciation of the exchange rate. Access Economics confirm that 'each of the terms in the Commission's net benefit equation (box 6.2) [in the draft report] seeks to measure an appropriate concept' (p. 7).

| Box 6.1 | **Cost-benefit framework** |

The net benefit (NB) to Australia of the PIIP can be broken into components as follows:

NB = MARGIN + HEALTH + SPILLOVER - LEAK - FINANCING – ADMIN – COMPLIANCE + OTHER

where,

MARGIN is the difference, if any, between the private post PIIP rate of return on induced activity compared with alternative uses of those resources. It has been calculated as m*(IVA+IRD) where m represents any difference in the rates of return, IVA is induced value added and IRD is induced R&D expenditure.

HEALTH is the incremental health benefit from any drugs listed *only* because the PIIP subsidy allows the notional price to meet a company's global floor price.

SPILLOVERS are benefits from pharmaceutical activity accruing to third parties (such as R&D collaborators, suppliers and other pharmaceutical firms) that do not pay for these.

LEAK is any pure transfer of PIIP payments to foreign shareholders. To the extent that some PIIP payments to foreign owned firms do not induce activity there is a loss to Australia. LEAK can be calculated as $PIIPF*(1-\tau_f)*(1-i)$ where PIIPF is the actual payments to foreign owned firms, τ_f is the rate of Australian company tax for foreign owned firms, and i is the inducement rate by foreign owned firms.

FINANCING is the adverse efficiency effect arising from the distortionary impacts of raising funds for the PIIP. Since PIIP payments are assessable income, the net amount of public funds needed is less than the notional budget of the program. FINANCING is calculated as $meb*[PIIPF(1-\tau_f)+PIIPD(1-\tau_d)]$ where meb is the marginal excess burden per dollar of public revenue, PIIPD is the actual payments to domestic owned firms, and τ_d is the effective tax rate for domestic owned firms.

ADMIN is the government administrative cost of the program, covering both the one-off costs of establishing the scheme (such as the selection process) and the ongoing costs of monitoring, payment and management of the program.

COMPLIANCE measures the business compliance costs, covering both the one-off application costs for both successful and unsuccessful applicants and the ongoing reporting costs for participants.

OTHER represents other benefits and costs not identified above. One such potential benefit is any inducement effect of the PIIP on expenditures such as health education programs and sponsorship, as part of Broad Activity Commitments. Any other benefits and costs are likely to be of second order and/or less amenable to quantification. They can be incorporated into the analysis by surmising whether they are positive or negative.

The same framework can be used to divide the overall NB into the NB for PIIP payments to foreign or domestic firms and the NB for PIIP payments for the VA and R&D.

As explained in section 6.1, this margin depends upon the starting point — whether, without PIIP there would be too few or too many resources in pharmaceutical activity from an efficiency perspective. Chapter 3 specifically deals with the issue of whether efficient pharmaceutical activity is lost because of PBS prices. It concludes that PBS pricing could have (generally weak) effects on activity levels, but also noted that because of other distortions in the pharmaceutical market it is unclear whether the balance of effects is positive or negative. On this basis, the MARGIN in the base case was set at zero — a neutral value — since there are forces working both ways. In other words, the margin of zero in the base case assumes that the value from using the additional resources in the pharmaceutical sector is the same as the value from alternative use of those resources.[6]

In the sensitivity testing, a range of –5 to 10 per cent for MARGIN is examined. These values are not drawn from empirical estimates, though evidence about the likely distortions arising from lowered activity discussed in chapter 3 point to low rates.[7] The key interest is whether the overall conclusions about the net benefit of the PIIP are affected by moderate changes from the base case. An average rate significantly higher than 10 per cent would be difficult to justify.[8] The minus 5 per cent rate reflects the possibility that, given all the distortions in the pharmaceutical 'market', the existing allocation of resources is already greater than optimal or that PIIP 'overshoots' and induces too great an increase in activity relative to the distortion it is seeking to address. (This was seen as an important issue in the IC's (1996, p. 309) evaluation of the Factor f scheme.)

Access Economics (Medicines Australia sub. 10, appendix 1, p. 8) questioned the Commission's base case assumption that the opportunity cost of resources used for induced production is approximately equal to the private return — that is, the MARGIN of zero. It noted that in the draft report the Commission had found little or no inducement of employment and physical investment, which implies that companies were able to earn

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[6] It does not mean, for example, that the average wage for all current employment in the pharmaceutical sector is the same as in other sectors. The focus is on the marginal returns on resources shifted through government intervention.

[7] Chapter 3 estimated that even were there to be a reasonable degree of price suppression and lost activity, economic welfare losses would be relatively small. This draws on Econtech's (2002) results, which modelled PBS effects as implicit production taxes. Chapter 3 noted that even with a 10 per cent reduction in the pharmaceutical sector (as defined in Econtech's model), economic welfare losses could be of the order of around $16 million a year. The Econtech modelling relates to the non-veterinary segment of ABS's ANZSIC code 2543, and will include non-PBS human-use pharmaceuticals, such as over the counter products. The estimates of the welfare costs of implicit production taxes on this sector overstate those that would apply to the narrower PBS-related pharmaceutical industry. A margin of 10 per cent in the cost-benefit analysis that follows, results in a benefit of around $33 million over the first three years of the PIIP. This is commensurate with the implications of appropriately modified Econtech results.

[8] Although there may be particular examples where rates of return diverge more — for example, it was suggested to us during visits that statisticians recruited to the pharmaceutical sector are earning much more than in previous employment.

profit from induced production without drawing resources away from other sectors. As such a benefit appears to arise for the three year period 1999-00 to 2001-02, provided some of the extra profit accrues to domestic firms and/or foreign owned firms pay tax on the profits. Access Economics estimated this benefit at around $50 million.

On both quantitative and conceptual grounds, there are questions about the validity and policy relevance of this estimate.

At the quantitative level, pharmaceutical firms generally argued that employment and investment had increased as a result of the PIIP and gave reasons why this would not be detected readily by comparing PIIP participants and non-participants (chapter 5). This suggests that the $50 million benefit would be a considerable overestimate. It could not be of sufficient magnitude to establish a robust, positive net-benefit for the first three years of the PIIP associated with stimulating value added (once the costs of taxation and leakage were accounted for).

A further forceful point made by some participants in this review is that some of the effects of the PIIP are delayed. In particular, this implies that any short-run capacity under-utilisation would be expected to elicit longer run investment, which might not be visible during the three years of the PIIP that have so far elapsed. On this basis, while there might be some gains from better utilisation of capital during the first three years of the PIIP, this cannot be a long run condition (firms do not make investments with long-run inefficient capacity utilisation in mind).[9]

At the conceptual level, there is a fundamental issue about how to undertake *policy-relevant* cost-benefit analysis. Cost-benefit analysis is intended as a tool to help guide whether a policy should be continued, terminated or adapted. Care needs to be taken when there have been adverse or beneficial effects that are *accidental* to that policy. For example, few would argue for abandonment of compulsory superannuation on the basis that there has been a recent downturn in earnings from equity investments. Nor should the PIIP be abandoned if accidentally a drug listed as a result of supplementation by PIIP funds turned out to have severe long run health consequences.

The surplus arising from output produced at 'low' opportunity cost due to temporary capacity under-utilisation is of a similar nature. Capacity under-utilisation cannot systematically and permanently characterise the Australian pharmaceutical industry (nor was it ever conceived as a basis for intervention in the industry by the Government). Any

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[9] To the extent that using a government program increases capacity utilisation beyond the level suggested by free markets and thereby stimulates future investment levels, this future investment would conventionally be regarded as generating a welfare cost. In effect, by raising the long run returns to the activity, the subsidy would entrench resources in an activity where market signals (under-utilisation) have indicated returns are low. However, such costs have not been included in the base case (due to the assumption that MARGIN=0).

surplus is a short run, fortuitous social benefit and not a predictable and enduring benefit relevant to the policy decision to continue or adapt the current program. Accordingly, it is not included in this cost-benefit assessment, which is intended to best inform policy makers.

Consumer health benefits — do PIIP funds serve to facilitate listing of pharmaceutical products that otherwise would not be listed?

It was put to the Commission that, were it not for the notional price increases available through the PIIP, some drugs would not have been listed. The mechanism by which this was thought to arise is as follows. Pharmaceutical company headquarters set global floor prices, below which subsidiaries are instructed not to sell products. In some cases the Government is not willing to list at a price at, or above, this floor. The company may still be able to list the drug by using PIIP income to supplement the below floor price.

This is important because if some PIIP funds were used in this fashion, an added benefit from disbursing PIIP funds is any benefit associated with the listing of affected drugs. For this to be a substantial benefit, it would have to be the case that:

- a sizeable proportion of PIIP funds was used in this fashion; and/or

- that the listing of drugs as a result of the PIIP have substantial net benefits.

On the first point, the Commission asked PIIP participants to provide a list of drugs that would not have been listed were it not for the PIIP. Among the nine participants, one firm had employed PIIP funds to achieve a drug listing. Pfizer submitted that its leading hypertension drug, Norvasc:

> … was under consideration for listing but the price offered by the Pharmaceutical Benefits Pricing Authority (PBPA) at the time was substantially under the world floor price, to the extent that it would not have been listed in Australia. Once the opportunity emerged for Pfizer Australia to participate in the second phase of Factor f based on Pfizer Australia's R&D and production activities, this provided a means through the scheme to raise the price of Norvasc to a level that was acceptable to the Pfizer Head Office … [This continued under the PIIP]. Without the PIIP scheme, Norvasc in Australia would not reach the world floor price and its presence in the Australian market would certainly be in jeopardy (sub. 12, p. 20-1).

On the second point, it would appear that if the Government were listing all drugs whose health and other benefits exceeded the costs, then there would be no gains from listing drugs that would not have been listed in the absence of the PIIP. However, as discussed in chapter 3, due to budget constraint considerations, it is possible that some drugs are not being listed, although the benefits of listing at a price offered by the pharmaceutical firms exceeds their costs. A further reason for which the Government may not, at the margin, list a drug even when it appears to have net therapeutic benefits, is that the Government is

engaged in a repeat bargaining game with pharmaceutical companies over the allocation of the surplus available from listing drugs.

From the perspective of policy relevant cost-benefit analysis, the challenge is not to precisely estimate the incremental health benefit for the one case identified under the PIIP. Rather, the relevant matters are the general likelihood of such listings and the associated expected additional benefits.[10] While in theory, listing of drugs that would otherwise have been unavailable on the PBS could yield significant benefits, overall, it is unlikely that a breakthrough drug would be in this position, so that only drugs with incremental benefits would be relevant.[11] While the availability of alternative treatment options has benefits in its own right, when substitute possibilities are great, benefits are typically small.

Drawing on features of the single case and the considerations above, a ballpark estimate of the incremental benefits of listing such drugs was used (with a value of $7.5 million on a three year basis used in the base case). Given the considerable uncertainty over this estimate, the sensitivity analysis considers a range from $2 million to $13 million.

Spillover benefits

Chapter 4 suggests that spillovers may be associated with pharmaceutical R&D.[12] Empirical estimates of the spillover rates of pharmaceutical R&D in Australia appears not

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[10] For example, the incremental benefits of particular listed drugs would vary depending on the drug concerned, and could in some cases even be negative, where subsequent clinical studies or other research found unanticipated side effects. But it would be clearly inappropriate for a cost-benefit analysis of the PIIP to attribute such an incidental outcome to the PIIP. This is why the expected benefits across a portfolio of such drugs is a more appropriate measure of their benefits.

[11] Norvasc appears to fall in this category and illustrates the potential difficulties of valuing listings. On the one hand, Norvasc is the most widespread drug used for hypertension worldwide, which suggests that it has therapeutic benefits over its rivals. On the other hand, there is debate about this, with many claims that competing drugs and diuretics are just as good or even better, while being cheaper (ALLHAT 2002, Parra et al. 2000, Jai 1999). Notwithstanding the specifics of the Norvasc case, on which we wish to make no judgment, on balance, it would appear that a margin for listing can usually be anticipated. This reflects the fact that the PBPA has to take account of budget and strategic considerations and thus tends to insist on prices below those recommended by the PBAC on the basis of economic evaluation.

[12] Given the definition of spillovers in an efficiency framework and the mechanisms by which such spillovers are generated, it is likely that increases in value added produce no such spillovers (*above* those that are generally apparent in the economy more generally — which is the requirement for policy relevance). This does not mean that raw material suppliers gain no benefits from their supply relationships, but the test for such gains to be genuine spillovers are demanding. For example, foreseen benefits could be expected to affect pricing — and would not constitute a spillover. Even where genuine spillovers arise it would have to be demonstrated that they exceeded the 'background' level of spillovers that arise everywhere in a society.

to be available, so that more general estimates must be applied (with possible modification for the circumstances at hand).

In its wide-ranging inquiry into R&D in Australia, the IC (1995, appendix QB) estimated the *average* social rate of return to R&D spending in Australia to be in the range from a conservative 25 per cent to a generous 90 per cent. This means that, on average, for every dollar of R&D expenditure, society benefits by an additional $0.25 to $0.90. It suggested that a reasonable estimate could be 50 per cent and also noted that the estimates could be biased up for technical (estimation) reasons.

While these empirical estimates provide a useful guide to those that can be used in modelling the effects of government programs that stimulate R&D, some other factors should also be considered:

- These spillover estimates are *average* returns, not *marginal* ones. Spillover rates from incremental R&D can be expected to decline once the most promising R&D opportunities in an industry have been taken up. A rule of thumb for program evaluators is to use an average spillover rate where either a core R&D support program is under consideration or where few other R&D programs are available to the particular industry, but to use a lower spillover rate for a program that is an add-on to the existing suite of R&D measures. The PIIP is not designed principally as an R&D support measure. This would suggest that a spillover rate lower than the average should be used to evaluate the R&D component of the program. However, as discussed in chapter 4, pharmaceutical MNEs have only limited access to the R&D Tax Concession. Nor are there any other schemes providing significant support to pharmaceutical R&D (as distinct from the biotechnology sector). Given this situation, an average or general level of spillover rate may be the appropriate starting point to evaluate the benefits from the pre-clinical R&D component of activity under the PIIP.

- Spillover rates associated with R&D induced by the PIIP are unlikely to be higher than occurs for R&D in other industries, and may be lower (chapter 4). This reflects evidence that patents (and thus appropriability) are greater in the pharmaceutical industry and that the benefits of spillovers may be disproportionately favouring MNEs, given their prominence in the Australian industry.

- Different types of R&D may generate different spillover rates. In particular, clinical trials are less likely to generate high spillover rates, reflecting two features of such trials. First, in the absence of Australia undertaking the trials, they will proceed elsewhere, leaving open the possibility of diffusion of some of the spillover gains from abroad.[13] Secondly, while clinical trials may generate benefits associated with

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[13] Whereas, at least in some cases of more basic R&D, such as that based on Australia's unique flora or particular research capabilities, the prospects for a world-first discovery exists.

introducing new technologies and methods to clinicians, these benefits are likely to be greatest for the first of a set of trials, rather than all trials.

For induced basic and pre-clinical R&D the midpoint (57.5 per cent) of the IC's estimated range has been used for the base case, with sensitivity analysis using the range from 25 to 90 per cent. For induced clinical and other R&D, the IC's lower value (25 per cent) has been used for the base case, with sensitivity analysis conducted using a range from 0 to 50 per cent.

These spillover rates were also used in the draft report analysis, responses to which included the following:

- Pfizer (sub. 12, p. 33) argued that the spillover effects for pre-clinical and clinical R&D should be set at the most optimistic level identified by the Commission, namely 90 per cent and 50 per cent, respectively;

- Eli Lilly (sub. 9, p. 3) estimated a spillover rate of 37 per cent for its clinical R&D activity compared with the average of 25 per cent used by the Commission;

- Merck Sharp & Dohme (sub. 11, p. 14) argued for higher spillover benefits on the basis that the pharmaceutical industry is considered to be one of the most high technology, R&D intensive industries in Australia;

- Medicines Australia (sub. 10, p. 23) suggested how R&D support from the PIIP may have helped address 'problems' such as lack of venture capital for, and commercialisation skills within, start-up biotechnology firms, concluding that the benefits of PIIP funded collaborative R&D investments by MNEs were undervalued by the Commission in the spillover analysis; and

- ITR (sub. 8, p. 5) was '… concerned that the report understates the spillovers from the pharmaceutical industry in Australia'. In particular, they took issue with the spillover rate for clinical trials.

It was also suggested that possible dynamic spillover benefits have not been accounted for. However, dynamic considerations may have possible positive or negative effects on empirical estimates and it is best to adopt a neutral stance in relation to the above estimates.[14]

As discussed in chapter 5, participants provided valuable insights into how spillover benefits may arise from clinical and other research. However, these insights and the specific comments above on the spillover rates do not provide a reasonable basis on which

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[14] A given stock of R&D could have spillover benefits that endure for some years. Most estimates of spillovers do not measure this precisely, because they cannot measure all future benefits. On the other hand, to the extent that such studies do not account for such benefits, they will tend to attribute to current R&D the spillovers arising from past R&D. In that sense, spillover rates measure dynamic benefits, albeit with possible positive or negative biases.

to revise the rates. While specific mechanisms and examples have been brought to the Commission's attention, these should not be seen as additional spillovers to add to the Commission's estimates. It should be emphasised that the rates chosen by the Commission allowed for the possibility that there are a wide variety of such mechanisms and very favourable outcomes in certain cases and for some firms.

It is also very important to bear in mind the concept of a spillover that is being estimated in the efficiency framework. It does not include the (hoped for) direct benefits of the R&D investment, nor the longer term private benefits that pharmaceutical companies and research collaborators thought they may derive when entering an R&D relationship. To the extent that participants have a broader view of spillovers than those under-pinning social efficiency analysis, it is understandable they have called for higher rates to be simulated.[15]

The indicative spillover rates of 57.5 per cent for basic and pre-clinical R&D and 25 per cent for clinical and other R&D continue to be used for the base case. However, other cases that allow for higher (and lower) rates are also explored in the sensitivity analysis.

Benefits from induced educational and sponsorship support

Under the Broad Activity Commitment (BAC) requirement,[16] most of the PIIP participants included support of health education programs, fellowships, training and sponsorships in their PIIP applications.[17] Pharmaceutical companies not in the PIIP also

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[15] It also appears that some participants are thinking in terms of absolute spillover benefits rather than spillover benefit per dollar of R&D. Thus, a sector with large R&D expenditures with a moderate spillover benefit may generate greater absolute spillover benefits than a sector that conducts less R&D, but which has relatively high spillover rates.

[16] As described in Chapter 2, entry to the PIIP was competitive, based on the relative merits of the program commitments by applicants. Program commitments comprised two elements: activity targets (production value added and research and development) and Broad Activity Commitments (BACs). BACs were defined as 'broad activities which are of strategic importance to the company and of benefit to Australia, including those which contribute to PVA and/or R&D activity targets' (*Guidelines* p. 3). Examples of BACs 'include investment in plant and/or equipment, collaborative links with Australian research or medical institutes, development of R&D infrastructure, improvements in productivity, increases in employment, workplace reforms, or the location of regional headquarters in Australia' (*Guidelines*, p. 3). In addition to these specific types of BACs. most of the PIIP participants outlined their anticipated support of health education programs, fellowships, training and sponsorships (in varying detail).

[17] The benefits of other types of BACs are incorporated elsewhere in the benefit-cost framework: the investment commitments and location of regional headquarters in Australia underpin the capacity to increase and attract additional activity and thus are already counted in the induced activity estimates; the benefits of BACs relating to establishing R&D collaborative links constitute part of the spillover benefit ascribed to induced R&D; and the benefits of the employment commitments are taken into account in determining the MARGIN benefit.

make similar expenditures, so the question arises of how much of such BACs are truly additional. Only the induced component of such expenditure should be counted as a benefit of the PIIP.

An examination of the PIIP applications and regular monitoring reports reveals:

- Two companies did not refer to such programs in their BACs.

- Four of the nine PIIP participants included quantitative information. The detail and nature of this information varied widely, which gives a possible insight into additionality. Imprecise commitments are non-verifiable and therefore not genuinely binding — additionality is likely to be low for such commitments. And where no explicit commitment was made, but subsequently an expenditure is recorded as a BAC, it is more likely firms are recording activities that they would have undertaken anyway. In examining the various statements about BACs:

  - a minority was in the form of clear, explicit BAC commitments to be upheld under PIIP and which have been costed and monitored. Over the three years (1999-00 to 2001-02) upwards of $1 million was identified;

  - around another $2.5 million could be said to be in the form of 'targets', but the descriptive and financial information about such commitments is more vague compared to the commitments described above;

  - about another $3 million is mentioned, relating to existing forward commitments made prior to the PIIP; and

  - about another $8 million was referred to in monitoring reports, but which was not identified in applications as intended BACs.

It is clearly difficult to give a precise measure of induced activity from BACs, but given the nature of the commitments — and the tendency for non-participants to engage in similar activities — it is likely to be only a proportion of the amounts given in applications. In the cost-benefit analysis, an estimate of 50 per cent of the $3.5 million of the reasonably explicit commitments has been used to indicate the potential social benefit. A range from zero to $3.5 million is included in the sensitivity analysis.

Leakage to foreign shareholders of payments for non induced activity

If inducement by foreign owned firms is less than 100 per cent, then some part of the PIIP payments are a pure transfer from taxpayers to foreign shareholders.[18] This constitutes a

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[18] If the domestic firms (AMRAD, CSL and Mayne Pharma) have foreign shareholders there may be additional leakage overseas.

loss to Australia.[19] Leakage is calculated net of company and withholding tax. The effective company tax rate on profits of foreign owned firms is assumed to be the statutory nominal rate of 30 per cent. No withholding tax has been included as a 'clawback' benefit to Australia as it is assumed that any dividends are paid out of after tax profits — that is, they are fully franked and exempt from withholding tax.

It also needs to be considered whether the amount of apparent leakage of transfers abroad may be overstated because of some bidding away of the transfer element of PIIP payments during price bargaining between government and firms. That is, it might be argued that the Government may be able to extract some of the transfer element of the PIIP by negotiating lower prices than they could in the absence of the PIIP. However, PIIP funds are given to firms independently of listing prices for *specific* drugs,[20] so any transfer on non-induced activity can be regarded as a windfall to the firm. It is doubtful that the Government has a capacity to get a lower price because of windfall gains to a firm. To posit this would suggest that they would be able to secure such price reductions no matter the source of the windfall — such as an unexpected exchange rate change or greater success by the company on another drug. As well, in most cases, the PIIP money is small relative to the amounts being bargained about.

The marginal cost of raising public funds

It is not always understood that the net budget cost of the PIIP ($300 million less the tax paid on the subsidy payment) is not itself a cost when looked at in an efficiency framework. Rather, it is a transfer — an income benefit to PIIP recipients matched by an income loss to taxpayers.

However, the transfer is not frictionless. To fund the $300 million, taxes need to be higher than otherwise. In most circumstances these financing options reduce the efficiency with which the economy's resources are used. For example:

- labour income taxes change the relative price of work and leisure and create a disincentive to work; and

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[19] This cost is independent of whether payments for non-induced activity are repatriated or form part of retained earnings. What matters in determining benefits and costs is inducement and who has claims over the wealth. This subset of PIIP payments does not induce additional value added and foreign shareholders have claims to these PIIP payments. Although retained earnings may be re-invested in Australia there is no additional benefit as the inducement rate already takes account of this benefit.

[20] Other than in the very unlikely event that prices achieved for all drugs by a firm are too close to the EU average to accommodate notional price increases. But in all cases so far, firms have had many drugs they could use for notional price increases under the PIIP — by no means is price suppression exhausted by PIIP payments.

- taxation of the income of foreign corporations domiciled in Australia can create disincentives for 'footloose' capital.

The efficiency cost of raising the PIIP funds is quite separate from any potential benefit in applying it to the pharmaceutical industry. Financing can be costly, yet the application can still be beneficial.

While the precise magnitude of the financing burden depends on the manner in which the program funds are raised, the social cost is non-zero except in some 'unusual' circumstances[21] and which are not currently a reflection of the Australian situation. The normal assumption in program evaluations is to assume that funds are financed from income taxes. There are many empirical estimates of the marginal excess burden covering a variety of taxes, scenarios and countries. Having regard to this literature, the BIE (1995) used an estimate of 20 per cent to evaluate Factor f, while the IC (1996) simulated both a 20 per cent and 33 per cent rate, the latter rate having been used by the Industry Commission in its inquiry into R&D (IC 1995). Lattimore (1997) used a base case of 27.5 cents per dollar and a range of 15 to 40 cents to analyse the R&D tax concession. For current purposes, the same values as Lattimore have been adopted.

Some participants suggested that company and personal tax on additional activity should be included as a benefit and viewed as an offset against the marginal cost of raising public funds and leakage of transfers abroad.

However, such taxation receipts are not an additional benefit when measuring *efficiency*. To count any increase in tax would involve double counting. A better allocation of resources means higher earnings by Australian owned land, labour and capital. Taxation is a mechanism for transferring these earnings (economic wealth) between Australians, either in cash or public goods and services. A more efficient allocation of resources increases the tax base — more gross earnings for Australian owned resources. Once earned, taxation does not increase or decrease this stock of wealth, it merely re-allocates it. If the PIIP improves resource allocation this will be measured by the MARGIN benefit above. Any additional economy-wide taxation receipts associated with the improved allocation of resources does not further increase the aggregate economic wealth of Australia as a whole.[22]

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[21] Freebairn (1995) identifies the case where downwardly sticky wages are unresponsive to changes in taxation. Drawing on Campbell and Bond (1997), it is conceptually possible to change the progressive or regressive profile of tax schedules such that the same amount of revenue can be raised with less distortion to work-leisure trade-offs, or more revenue without further distortion — a type of Ramsay pricing approach. Another case would be if the PIIP funds were raised by a hypothecated tax and where such tax was in the form of a 'correction' to a negative externality, for arguments sake, a pollution tax.

[22] It should also be noted that participants have focused only on the gross increase in tax from induced pharmaceutical activity. In an economy-wide framework, with opportunity costs, and

Administration costs

A breakdown of the administration costs of the PIIP are shown in table 6.1.

The program establishment costs — preparing guidelines and conducting the selection process — included legal expenses of around $40 000 and $26 000 for the ANAO probity evaluation. The establishment salary costs reflects the involvement of six Departmental staff for six months. An average cost of $100 000 each per annum on a fully distributed cost basis has been assumed.

In 1999-00 'other administration' costs were much higher than in subsequent years because they include some first year expenses, such as building the PIIP database ($59 000) and legal expenses ($11 000).

Table 6.1   **Administration costs of the PIIP, 1999-00 to 2001-02**

Cost item	1999-00	2000-01	2001-02 (est.)
	$	$	$
PIIP establishment (salary)	300 000		
PIIP establishment (non-salary)	140 000		
Ongoing salary	72 058	98 514	145 000
PBPA travel, allowances, meeting expenses etc.	7 300	5 335	10 000
Property and IT overheads	49 500	50 000 [a]	50 000 [a]
Other administration	70 068	28 809	30 000
Post-PIIP development			20 000

[a]   While $49 500 was included in the 1999-00 costs of the PBPA similar property and IT overheads were not included in 2000-01.

Source: PBPA (2000a, p. 4), PBPA (2001a, p. 6) and ITR estimates.

A full account of administration costs should include departmental work that investigates possible replacements to the PIIP after its sunset in 2004. An amount of $20 000 has been estimated by ITR.

Overall, administration costs to date are less than 1 per cent of program payments. During consultation, companies generally made favourable comments about the helpfulness of the Department staff. Good client service may manifest itself as marginally higher

distortion costs from raising public funds for a subsidy, any net increase in taxation from improved resource allocation will be (much) less than the additional gross receipts from pharmaceutical activity.

administration costs, but lower compliance cost for companies (see next section). No adverse comments were made about Departmental services.

Compliance costs

We did not systematically investigate the compliance costs of each PIIP company or unsuccessful applicant, since early indications were that these were modest. The information provided by companies included that:

- it takes an estimated two to three days full-time for one person to prepare data for quarterly reports, which are required three times per year, plus two days to write and clear each report. For the PIIP annual report, it takes an estimated three to five days for preparation of the data, plus a further two days to write the report;

- the initial bid took an estimated two months to prepare and the re-bid following a merger similarly took two months; and

- the annual compliance costs were estimated to be up to $50 000 for one company.

On the basis of this information, the annual recurrent preparation costs for the nine participating companies (in aggregate) could range from $80 000[23] to $450 000. The lower estimate of recurrent costs represents normal direct preparation costs. Additional efforts to deal with merger implications and under-performance will add to these costs.[24] The higher estimate of recurrent costs, based on $50 000 per company, should be sufficient to allow for the compliance costs for the merger cases, or of costs beyond the preparation of reports (such as attendance by senior management at meetings with the PBPA). For the base case, we have used an estimate of $265 000 for recurrent costs — the mid-point of the range — and $370 000 for the one-off preparation costs for 22 bids.[25] No allowance has been made for head office involvement in the bid process (as only compliance costs incurred using Australian resources constitute a cost to Australia).[26]

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[23] This is based on the assumption that, for each company, one person takes five days for the quarterly reports and six days for the annual report. With three quarterly reports and the one annual report, this suggests an annual resource cost of 21 person days per participating company and 189 person days for all participating firms. Assuming a salary plus overheads of $100 000, this equates to a cost of 189/240 *$100 000 or around $80 000.

[24] A number of companies also noted the degree of human capital residing with its PIIP reporting staff and the risks that this entails, the implication being that future compliance costs may be higher if such staff were unavailable.

[25] This is based on the assumption of 40 person days preparation per applicant and the same salary/overhead costs as for ongoing administration. This yields 3.7 person years at $100 000 per year.

[26] Sometimes what appear to be compliance costs would have been incurred anyway or had some other benefits for the firm (for example, this is an important issue in considering taxation compliance costs). However, this did not appear to be an important issue in the PIIP. In any case,

Other potential benefits and costs

Two potential costs that have not been modelled explicitly are:

- while the PIIP stimulates pharmaceutical activity for participants, it may displace activity among non-participants (chapter 5). This could include clinical trials (reflecting mounting cost pressures), and a reduction of capacity or closure of facilities; and

- there may be broader compliance costs that are related to efforts expended in seeking to maintain or expand arrangements for government-funded industry development in pharmaceuticals or in meeting the evaluation requirements of the program. For example, firms have worked towards a new scheme through the Action Agenda. They have also faced compliance burdens associated with this review through their meetings with the Commission and in responding to our survey and data requests. (The Commission's own costs in running this review are also relevant costs.) While, in some cases of industry and regulatory policy, substantial resources can be spent by firms trying to lobby for a better operating environment, the Commission's judgment is that such costs are likely to be small in the case of the PIIP.

Other comments on methodology

The analysis has been conducted in nominal terms. No account has been taken of the time profile of the potential benefits and costs. Conceptually, the R&D spillover benefits are likely to accrue later than the costs. Building this into the estimates of net benefits would be less favourable to the assessment of PIIP, but not by much.

6.3 Results

The base case

The base case data and parameters are summarised in table 6.2 and the estimated benefits and costs are shown in table 6.3.[27] The results indicate that, under the current scheme, the benefits are significantly outweighed by the costs. The benefits arise principally from spillover benefits. Around half of the costs relate to the distorting effects of raising public funds and the administration and compliance costs of the program. The other half of the

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even large errors in estimating compliance costs make no appreciable difference to the net benefits of the program.

[27] While the cost-benefit analysis is based on the PIIP payments realised for the first three years, it should be emphasised that the goal of the analysis is not to pinpoint an historical estimate of net benefits, but rather to give a guide to policy makers about the kind and magnitude of net benefits that can be expected from the existing design of the PIIP.

costs relate to the inability to design a perfectly targeted scheme so that there are transfers (leakages) from taxpayers to foreign shareholders of subsidies on non-induced activity. The numbers in table 6.3 are indicative rather than precise measures of the cost-benefit outcome; it is the broad messages that are important.

The sources of the benefits and costs have implications for the results according to the type of activity supported. In particular, payments for value added are estimated to result in a significant net cost, while payments for R&D are estimated to generate a net benefit.

Table 6.2　Base case data and parameters

Variable/parameter	Base case
PIIP payments, foreign owned, first 3 years for value added	$77.7 million
Payments, Australian owned, first 3 years for value added	$35.5 million
Payments, foreign owned, first 3 years for R&D	$19.0 million
Payments, Australian owned, first 3 years for R&D	$7.8 million
Inducement rate VA	45 per cent
Inducement rate R&D	60 per cent
Additional rate of return on resources in induced activity (efficiency margin)	0 per cent
Spillover social rate of return on induced basic and pre-clinical R&D	57.5 per cent
Spillover social rate of return on induced clinical and process R&D	25 per cent
Share of induced R&D — basic and pre-clinical research	25 per cent
Effective company tax rate (domestic)	20 per cent
Company tax rate (foreign)	30 per cent
Marginal social cost per dollar of public funds	27.5 per cent
Induced commitments for health education programs and sponsorship	$1.75 million
Incremental health benefit of drugs listed only because of PIIP subsidy	$7.5 million
Administration cost, recurrent	$200 000
Administration costs, one-off.	$460 000
Compliance costs, recurrent	$265 000
Compliance costs, one-off	$370 000

Table 6.3　Estimated benefits and costs, first 3 years of the program
Base case parameters

Net benefit (NB) components and total	Benefits and costs
	$m
EFFICIENCY MARGIN	0.0
SPILLOVER BENEFITS	26.6
HEALTH BENEFITS	7.5
OTHER BENEFITS	1.8
LEAKAGE OVERSEAS	-35.2
FINANCE COST	-28.1
ADMINISTRATION COST	-1.1
COMPLIANCE COST	-1.2
Net benefit (NB)	**-29.7**
NB by type of payment:	
To foreign owned firms	-30.1
To domestic owned firms	0.4
For value added	-47.0
For R&D	17.3

The sensitivity of the results

The terms of reference for this review ask for an indication of the robustness of the results. This reflects the fact that the base case parameters are not known with certainty. The sensitivity of the results has been explored in several ways.

First, the effect of changing one parameter at a time has been examined (table 6.4). The results show that changing the inducement rate for R&D (higher or lower) had the most effect on the estimated net outcome, followed very closely by the efficiency margin parameter. The two least influential parameters were the spillover rates on R&D — as outlined above there is much debate about these parameters but resolving this would appear to be of less practical concern. Importantly, using a 50 per cent more favourable parameter for *any* factor still does not generate a net benefit for the PIIP.

Table 6.4 **Sensitivity of base case to 'equal' changes in each key parameter**

Parameter description	50 per cent favourable change		50 per cent unfavourable change	
	Parameter values	Revised overall NB for PIIP	Parameter values	Revised overall NB for PIIP
	%	$m	%	$m
VA inducement rate	67.5	-17.5	22.5	-42.0
R&D inducement rate	90.0	-12.4	30.0	-47.0
Pre-clinical R&D spillover rate of return	86.25	-23.9	28.75	-35.5
Clinical R&D spillover rate of return	37.5	-22.2	12.5	-37.3
Additional rate of return on resources in induced activity	5 [a]	-13.0	-5 [a]	-46.5
Efficiency cost per dollar of public funds	13.75	-15.7	41.25	-43.8

[a] Since the base case value is zero a 50 per cent change from the base case is not possible. Instead we have set the favourable change as 50 per cent of the difference between the base case and the upper value used in the sensitivity testing (10 per cent). For the unfavourable case we maintain the symmetry evident for the other parameters.

Secondly, the effect of changing all key parameters simultaneously under the most pessimistic and optimistic scenarios was investigated (table 6.5). These extremes are very unlikely, as the chances of all the key parameters simultaneously taking on their most favourable or unfavourable values is very low.

Table 6.5   **Net benefit for least and most favourable scenarios**
First 3 years of the program

	Base Case scenario	Most favourable scenario	Least favourable scenario
	%	%	%
VA inducement rate	45	80	10
R&D inducement rate	60	80	40
Pre-clinical R&D spillover rate of return	57.5	90	25
Clinical R&D spillover rate of return	25	50	0
Additional rate of return on induced activity	0	10	-5
Efficiency cost per dollar of public funds	27.5	15	40
Net benefit	**-$29.7 m**	**$105.7 m**	**-$100.2 m**

Thirdly, recognising that the base case parameters are not known with certainty, the net benefit result was estimated 100 000 times, based on relatively wide variations in parameters (figure 6.1)

This probability approach allows an estimate of the probability that the program generates a positive net benefit. It also indicates confidence intervals around the base case estimates. The results suggest there is only about a 13 per cent chance of a positive (net benefit) outcome. There is an 80 per cent chance that the net benefit is between a $60 million dollar loss and a $5 million gain (table 6.6).

However, were the scheme to be re-oriented to R&D only, there is a stronger likelihood of a net benefit. In that case, the results suggest there is about a 92 per cent chance of a positive (net benefit) outcome. The expected value of the net benefit per subsidy would be 65 per cent (compared with around minus 20 per cent with the current scheme under the base case). In such a scheme, the net benefits to Australia from R&D activities by both domestic and foreign firms are likely to be positive (unlike under the present PIIP design that has an estimated net cost for payments to foreign firms).

Figure 6.1   **Distribution of net benefit [a]**
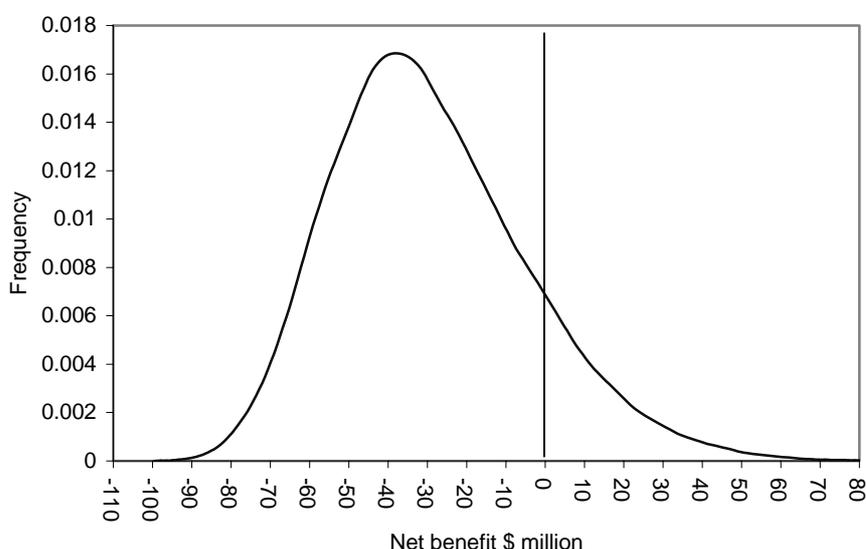
[a] The distribution was derived by randomly drawing the value of each of the twelve parameters from their underlying distributions and estimating the net benefit. This was repeated for 100 000 random combinations. The twelve parameters were assumed to be distributed as follows: the inducement rate for value added was distributed normally with mean 0.45 and standard deviation 0.281, that is as $N(0.55, 0.281)$; the inducement rate for R&D was distributed as $N(0.60, 0.204)$; the spillover rate of return for basic and pre-clinical R&D was distributed as $N(0.575, 0.166)$; the spillover rate of return for clinical R&D was distributed as $N(0.25, 0.127)$; the marginal social cost per dollar of raising public funds was distributed as $N(0.275, 0.089)$; the additional rate of return (efficiency margin) on pharmaceutical activity was distributed as $N(0, 0.051)$; recurrent administration costs per year was distributed as $N(0.2, 0.026)$; one-off administration costs was distributed as $N(0.46, 0.051)$; recurrent compliance costs per year was distributed as $N(0.265, 0.084)$; one-off compliance costs was distributed as $N(0.37, 0.051)$, benefits from BACs were distributed as $N(1.75, 0.893)$ and health benefits from PIIP-related listed drugs were distributed as $N(7.5, 2.81)$. The distributions were truncated so that in no case a random variable was outside the 95 per cent confidence interval (this being done to ensure reasonable boundaries on all variables).

Table 6.6   **Estimated 80 per cent confidence interval for PIIP net benefit[a]**

	10 per cent lower bound	*10 per cent upper bound*
Total net benefit (NB) $m	-59.2	4.6
NB from PIIP payments to[b]:		
Foreign ($m)	-54.2	-2.7
Domestic ($m)	-7.9	8.8
Value added ($m)	-68.4	-20.1
R&D ($m)	1.0	35.6
Net benefit rate (net benefits per PIIP subsidy $) (%)	-42.3	3.3

[a] Based on the 100 000 simulations described in figure 6.1. [b] Components do not add to total because each of the 80 per cent confident intervals are derived separately from the 'middle' 80 000 outcomes for that component. An 'exact' match would be achieved if the 10 000th lowest and 10 000th highest total net benefit was divided into its components.

6.4   Conclusions regarding efficiency

The PIIP generates benefits and imposes costs for the Australian economy as a whole. The principal benefits are spillover effects from R&D, although there are some benefits also from particular Broad Activity Commitments and consumer health benefits from listing drugs that would otherwise not be available on the PBS. The main costs are distortions from raising the public funds for PIIP subsidies and the transfer of subsidies on non-induced activity to foreign shareholders.

It is highly likely that, under the current design, overall the costs of the PIIP have exceeded the benefits and would continue to do so. This is a robust result that could only be overturned with highly optimistic and unrealistic scenarios for key parameters.

At a more detailed level, payments for R&D are likely to have generated benefits that exceed the costs, while subsidies for value added activity are likely to involve a net loss.

FINDING 6.1

While there are some benefits from the PIIP, inefficiencies in raising funds for PIIP subsidies and the inability to perfectly target the scheme make it more likely than not that the program produces net costs for the Australian economy as a whole. However, the R&D component of the scheme appears to generate net benefits.

7   A modified PIIP

The terms of reference for the evaluation ask the Commission to examine — if government intervention in the industry is justified — whether alternative policy and program measures would be better than the PIIP.

As discussed in previous chapters, there are some significant limitations with the existing PIIP:

- the stated rationale for the scheme, PBS price suppression, is not as strong as is generally claimed;

- the scheme has been effective in inducing new R&D and production, but there are some design features of the scheme that reduce its effectiveness; and

- while precise measurement is very difficult, it is likely that the program in its current form is not generating a net gain for Australia overall.

Despite these limitations in the current program, there remains a case for government intervention. Previous chapters identified several factors at work that, in aggregate, provide a rationale for industry assistance arrangements for the pharmaceutical industry. First, the global nature of the industry and associated arrangements for determining the location of IP ownership make it difficult for pharmaceutical MNEs to gain access to the existing R&D Tax Concession. Secondly, while the impact of PBS pricing on activity is likely to be less than commonly claimed, negative head-office perceptions created by the pricing arrangements more generally may have some effects on the activities of MNEs in Australia. Thirdly, for domestic firms that are not yet large global entities, PBS pricing arrangements may have an impact on R&D activity and investment through a reduced capacity to recoup the costs of R&D.

This chapter assesses possible intervention in the pharmaceutical sector against these rationales, with the over-riding objective of broadly designing an industry program that would generate net benefits for Australia overall. Section 7.1 discusses issues in relation to the R&D tax concession. Section 7.2 assesses modifications to the PIIP to improve effectiveness, while section 7.3 concludes the chapter with a recommendation for a modified PIIP.

7.1　Access to the R&D Tax Concession

The existing 'beneficial owner' requirements of the *Income Tax Assessment Act* and the *IR&D Act* effectively limit access to the R&D Tax Concession by foreign MNE subsidiaries in Australia (chapter 4).[1] The preponderance of MNEs in the pharmaceutical industry and their inability to access the concession is, without offsetting policies, likely to distort the level of pharmaceutical R&D taking place in Australia *vis a vis* other industries. *Prima facie,* this provides a basis for action. A direct response to this would be to remove the 'beneficial owner' rule. This could garner some spillover benefits on induced R&D undertaken by pharmaceutical MNEs, but the potential wider implications of such a change are significant and therefore require careful analysis.

The rule could be relaxed in two forms. The R&D Tax Concession could be changed for all firms, regardless of sector, or just pharmaceutical firms. These changes have different implications.

Making a general change to the R&D Tax Concession

The advantage of this approach is that there are MNEs in other sectors where the IP ownership rule may also stifle R&D and spillovers. On economic and administrative grounds, generally available programs that do not discriminate between industries are usually preferred to those that treat each industry differently. General programs minimise distortions between industries, tend to reduce the incentives for rent-seeking by firms claiming a need for special assistance and generally involve lower administrative and compliance costs. Some participants are in favour of a change to enable access to the R&D Tax Concession.[2]

Because of these advantages it might seem that a general reform in the R&D Tax Concession is warranted. However, there are several considerations that suggest caution.

Were the 'beneficial owner' requirement to be relaxed, then some, or possibly many, MNEs that currently own their IP in Australia in order to access the R&D Tax Concession may instead switch ownership abroad. This could then threaten tax revenue associated with license income. ITR, for example, argued:

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[1] Australian firms, by definition, are not constrained from accessing the R&D Tax Concession as the IP is held in Australia.

[2] For example, Servier (sub. 7, p. 1) was supportive of a change to the beneficial owner requirement in the Tax Concession, indicating that it seemed to be a 'much simpler and more flexible approach than PIIP.'

A general relaxation would enable foreign-owned multinationals companies in other sectors currently meeting these requirements [the 'beneficial owner' requirement] to exploit IP-related benefits elsewhere than in Australia, potentially leading to a leakage of national benefits overseas without commensurate returns to the Australian economy. (sub. 8, p. 3).

This concern would have a basis if two conditions simultaneously held.

First, a foreign MNE's decision to own IP in Australia would have to be responsive to the availability of the R&D Tax Concession. In the case of the pharmaceutical sector, most foreign MNEs have revealed their preference for owning IP abroad, notwithstanding its adverse implications for accessing the concession. Such firms clearly do not base their IP ownership decisions on the existing R&D Tax Concession. But many Australian subsidiaries of foreign MNEs outside the pharmaceutical sector have established holding companies that own the IP in Australia and, accordingly, are able to access the R&D Tax Concession. Whether these firms would shift ownership offshore if that no longer endangered access to the concession is unknown. Their IP ownership decision would depend on how specific to Australia their research was, the nature of their mechanisms for disseminating non-Australia-specific IP among the various global arms of the MNEs, the relative strengths of IP protection in different jurisdictions, and the taxation advantages from shifting ownership. Detailed assessment of such firms' responsiveness to the provisions of the R&D Tax Concession is outside the scope of this evaluation, but would need to be undertaken before making a policy change.

Secondly, tax revenue would need to be lost if the IP were held abroad. This is not as clearcut as it might appear at first blush. Even when the IP is held overseas and the Australian-based subsidiary is reimbursed for its R&D, the ATO grosses up the R&D expense by a margin to reflect a 'profit' on the provision of intra-group services. This 'profit' is subject to tax. In other cases — for example, the collaborative development of a drug — IP ownership by the foreign MNE does not rule out tax benefits on other income flows. For example, Pfizer (2002, pp. 4–5) noted:

> If… the IP relates to proof of concept for a potential drug substance, a joint development program (eg the development of Relenza by GlaxoSmithKline and Australian biotechnology company Biota) may be more appropriate where both the parties contribute their respective expertise and development costs, risk and profits are shared equitably. In none of these cases could it be argued that ownership of the IP needed to remain local in order for Australia to benefit financially. In the case of Relenza, Biota profited substantially from the transaction.

While changes to the jurisdiction of IP ownership would not have tax revenue implications as extreme as might be thought, it appears likely that the taxation

returns from a stream of royalties associated with Australian-owned IP would exceed that applied on a profit margin for reimbursed research undertaken on behalf of a foreign parent.

Thus, the argument that the concession has to have its current form to preserve taxable income flows has some validity for firms outside the pharmaceutical sector. It has little weight for the pharmaceutical industry since they hold so little IP in Australia.

ITR also raise the question of whether the returns from commercialisation could also be diminished by a change to the beneficial owner requirement:

> … relaxing the IP rules for all sectors is likely to compromise … commercialisation outcomes (sub. 8, p. 3).

However, it would be expected that the returns to IP from commercialisation — which are private benefits — would be enjoyed by the MNE regardless of whether the change in the R&D Tax Concession was made or not. This is because the IP is still owned by a foreign entity no matter where the IP is held.

Moreover, the premise that commercialisation is affected by IP ownership is questionable. In many cases, it could be expected that decisions about the best location to commercialise technologies will be based on hard-headed assessment, regardless of the location of IP ownership. For example, many foreign MNEs in the mining industry undertake R&D in Australia, where it is developed and commercialised because of Australia's comparative advantage in this industry. It seems improbable that commercialisation would shift to other locations even if the IP ownership were to move abroad.

However, were there to be a link between IP ownership and commercialisation, then relaxing the IP ownership rule would be akin to eliminating an investment distortion — which would usually enhance economic efficiency. If firms decided to commercialise elsewhere if the IP rules were relaxed, this presumably would reflect their judgments about comparative returns. The gains from free trade apply — in conventional circumstances — as much to investments in commercialisation as they do to other productive activities.

A possible caveat is that ownership of IP abroad might involve a different decision-making process about further commercialisation, with implications for the some of the dynamic gains from commercialisation. For example, decisions about how and where to commercialise might be made by a group of global R&D directors, instead of in the Australian subsidiary. That might mean that, in some cases, decisions would be made to commercialise abroad rather than in Australia. This could involve some forgone gains in local capability, lost knowledge transfers and weaker

collaborative arrangements between Australian subsidiaries of foreign MNEs and Australian-owned companies (thus weakening a conduit for spillovers).

A further concern about removing the 'beneficial owner' requirement is that it would have to be undertaken in a way that did not unintentionally permit what ITR (sub. 8, p. 3) has referred to as 'aggressive tax planning'. Similarly, the IR&D Board noted the potential for the change to:

> … undermine the integrity of the concession … [and to] encourage behaviour that seeks to exploit the special terms of access (ITR sub. 8, p. 8).

Were section 73B(9) of the Income Tax Assessment Act to be removed it would, for example, pave the way for tax exempt bodies to use the tax concession by contracting out R&D to taxable companies. This problem could be overcome by adding an exception clause to the existing section 73B(9) that specifically allowed a concessionary R&D deduction to a taxable subsidiary of a foreign MNE, even if the IP is owned overseas by its parent.

A final concern about making a general change to the R&D Tax Concession at this time is that such changes create uncertainty for applicants about the future nature of the scheme. Clearly, it is important to quickly remove loopholes that have been used for tax minimisation, and to review and improve the effectiveness of concession every so often. However, too frequent cycles of change mean that businesses intending to make longer term strategic R&D investments have little certainty about how their investments might be treated over the horizon of those investments. This uncertainty would be factored in as a risk margin and would reduce the likely extent to which the concession induced new activity — and reduce the overall benefits of the scheme. This suggests that any consideration of a *broad* change to the IP ownership rules of the R&D Tax Concession should be part of the next major review of the concession, rather than undertaken now.

It is clear that there are some risks associated with making a broad change to the 'beneficial owner' requirements of the R&D Tax Concession. These implications warrant substantive and detailed consideration before any implementation. The Commission's inquiry into automotive assistance (PC 2002, pp. 84–86) indicated the desirability of an independent review of Australia's general support measures for R&D around 2005. Part of any such review could reconsider whether general changes in the beneficial owner requirements would be warranted, taking account of the issues raised above.[3]

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[3] The introduction of any change to the beneficial owner requirements stemming from a review in 2005 need not have any implication for the Commission's recommendation for a modified PIIP (recommendation 7.1). For example, firms would only be able to claim subsidies for given R&D from one source. Alternatively, to the extent that the IP ownership problem mainly affects the

Ring-fencing the change to the R&D Tax Concession to the pharmaceutical industry

While a general change to the R&D Tax Concession is not warranted at this stage, another possibility is a more narrow and targeted change to the concession that relaxes the beneficial owner rule only in the pharmaceutical industry.

Unlike a general change to the concession, this is unlikely to adversely affect commercialisation or taxation revenue on royalties, since most foreign pharmaceutical firms do not hold IP in Australia anyway. And the change would not produce program uncertainty for firms outside the pharmaceutical industry. However, the ring-fenced approach still has major drawbacks.

A ring-fenced R&D Tax Concession would mainly address the incapacity of many foreign pharmaceutical MNEs to access the existing R&D Tax Concession. At best, it deals only partially with the two other rationales noted above:

- An R&D Tax Concession would only weakly address the problems arising from MNE perceptions about the environment for the pharmaceutical industry in Australia. In particular, the concession is partially hidden in their accounts as part of firms' tax calculations and getting access to the tax measure would not signal that any weight was being given to the impacts of the PBS.

- It does not address the fact that price suppression could affect the capacity of domestically-exposed firms to recoup their investments in R&D. (Notably, such firms will typically already be able to access the R&D Tax Concession, so an amendment to the existing measure would make no effective difference to them).

The ring-fencing option has some other potential drawbacks and uncertainties.

First, the pharmaceutical industry would have to be clearly defined. As its boundaries have become blurred with biotechnology, this could be difficult at the margin. As noted by ITR (sub. 8, p. 3):

> A ring fence option may not be sustainable in the medium to long term. ITR's general experience has been that ring fencing tax concessions to one sector is inherently problematic for a range of reasons. For example, in this sector, what would be the natural border line between pharmaceuticals and some bio-technology companies?

Moreover, some areas of R&D — for example in bioinformatics — might be regarded as straddling the information technology and pharmaceutical industries – presenting a dilemma for the IR&D Board about whether these activities would be eligible. These definitional issues are not unique to a pharmaceutical-specific R&D

pharmaceutical industry, any general change to the beneficial ownership requirement could be deferred until after expiry of the modified PIIP.

Tax Concession. They also apply, to some degree, to any industry-specific program. It is likely that any definitional difficulties could be overcome. However, in the case of an entitlement-based measure such as the R&D Tax Concession, this could involve administrative costs if appeals were mounted over the IR&D Board's decisions about the boundaries of the industry.

Secondly, the ring-fencing option would highlight the fact that other firms, potentially with an equally valid individual claim, were unable to get equivalent treatment under the R&D Tax Concession as pharmaceutical firms. This would create pressure for a more broadly adopted change — which, as noted above, may not be beneficial for Australia. ITR (sub. 8, p. 3) commented that 'there are already calls from some sectors for a relaxation of these rules.'

Thirdly, it is difficult to flexibly design a pharmaceutical-specific tax concession without creating too great a gulf between it and the general tax concession.[4] The more a ring-fenced measure diverges from the generic measure, the less economies there are from having the two measures linked.[5]

Finally, notwithstanding the potential that a ring-fenced concession might involve initially lower compliance costs for firms than the PIIP, several firms indicated that there would remain significant uncertainty over the approach taken by the ATO when considering deductions under the R&D Tax Concession. They considered this would still hold even were the beneficial owner rules to be modified for the pharmaceutical industry. This uncertainty was seen as offsetting any immediate gain from lowered compliance burdens.

Overall, the disadvantages of a ring-fenced R&D Tax Concession outweigh its advantages. This suggests that the problems associated with accessing the Tax Concession and the other identified rationales for intervention provide a prima facie case for some other form of direct industry assistance, oriented to R&D.

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[4] Such differential treatment is administratively feasible, albeit it adds to complexity. For example, in 2002, the UK Government proposed additional tax credit benefits above those for other R&D activities for vaccine research in TB, HIV/AIDs and malaria (http://www.inlandrevenue. gov.uk/r&d/).

[5] For example, increased fiscal certainty for government could be introduced to the ring-fenced tax concession by having a 'first-come first-served' scheme until a funding cap were reached. It would be possible to have different rates of subsidies for different R&D activities, based on views about their relative spillover rates. But both of these features would be at odds with the design of the general tax concession and would reduce ease of administration of the program. The IR&D Board might have to apply different standards to applications from the pharmaceutical industry, and were capping to be applied to one and not the other, the Board would need to have separate administrative and funding management for the two streams of R&D.

7.2 Modifications to improve the effectiveness of the PIIP

The PIIP in its current form has been assessed as not being the appropriate form of government assistance for the pharmaceutical sector. In addition, its design features do not make it well placed to address the rationales for intervention that have been identified.

Design limitations and inflexibilities associated with the current arrangements include that:

- entry is a 'one shot' game, in which participants are determined at the start of the program. There is limited scope, if any, for entry by other firms in later years, even if their bids appear attractive at that stage;

- the program involves significant penalties for forecast errors — which are common given the exigencies of world demand for drugs and technological change; and

- after the program commenced, it contains no incentive to undertake additional activity beyond that specified in the original application. Thus there is no continuing 'inducement incentive' in the PIIP.

The industry has drawn attention to a number of these and other perceived inadequacies. The Pharmaceutical Industry Action Agenda proposes design changes to address these (box 7.1).

Key program elements that need to be considered in designing an improved program include:

- eligible activities;
- eligible companies;
- capped or uncapped funding;
- subsidy rates;
- competitive entry; and
- the timeframe for any new program.

Although participants did not endorse all the elements of the modified program presented in the draft report, comments were generally supportive of the Commission's suggested design changes.

Box 7.1   The Pharmaceutical Industry Action Agenda and the industry's views

The Pharmaceutical Industry Action Agenda agreed that:

> The Commonwealth Department of Industry Tourism and Resources (ITR), in consultation with industry [would] develop a proposal for an industry development program as a successor to the Pharmaceutical Industry Investment Program that expires in 2004. (ITR 2002a, p. 55)

The Action Agenda noted a number of issues relating to the design of the current PIIP that had been raised during the consultation process. These include that:

- only nine out of thirty-odd firms that supply the PBS participate;
- funding is fully committed up front;
- there is no funding for capital investment;
- only suppliers to the PBS could apply; and
- the same rate of subsidy is paid for all activity, whether it comprises high or low value activity.

Reflecting these limitations, in an appendix to the Action Agenda, the industry has put forward criteria that it considers should govern a new industry program. It considers a new program should:

- be available to all firms that meet the eligibility criteria;
- accept applications for new funding annually;
- allow payments received by a firm to be taken either as actual price increases or as a lump sum;
- reward companies for:
    – replacement of value adding activity for products and/or pharmaceutical-specific services that are regionally or globally significant and that meet certain criteria, for example, increased export intensity and increased local value-added content for a company as a whole;
    – additional value-adding activity in R&D and manufacturing; and
    – formation of linkages and partnerships along various parts of the value chain. (R&D is to be defined in the same way as under the PIIP. In addition, R&D that has a demonstrated link to the development and/or registration, including bio-equivalence studies and clinical comparative studies, of new generic medicines should also be eligible.)
- apply different rates of subsidy to different activities. For example, R&D would receive a higher subsidy rate than replacement manufacturing.

Source: ITR 2002a.

Eligible activities

The PIIP supports manufacturing (production value added) and R&D. Around 75 per cent of funding over the life of the PIIP is to be paid for manufacturing, with the remaining 25 per cent for R&D activity.

The industry proposes that subsidies should be continued for each of these activities, although it suggests that different activities could be subsidised at different rates (box 7.2). The Pharmaceutical Industry Action Agenda also suggests that there should be funding available for capital investment. The Action Agenda proposals are aimed at addressing the traditional PBS price suppression rationale and promoting industry development. The design features are being assessed here against a different rationale, and one with a particular focus on R&D.

Box 7.2   **Pharmaceutical industry proposal for eligible activity**

The industry's broad outline of a new IDP would fund different activities at different rates depending on the contribution they would make to Australia. For illustrative purposes they propose three rates X, Y and Z where Y is greater than X and Z is greater than Y.

Funded at the lowest **X** rate would be:

- *Replacement* local value-adding activity for products and/or pharmaceutical-specific services that are regionally or globally significant and meet certain other criteria; and

- *Replacement* R&D activity not involving local partnership and participation.

Funded at the higher **Y** rate would be:

- *Additional* local value adding activity predominantly for the domestic market; and

- *Additional* R&D not involving partnership.

Funded at the highest **Z** rate would be:

- Additional local value-adding activity that is regionally or globally significant; and

- Additional R&D activity involving local partnership and participation.

Source: ITR 2002a, p. 83.

Support for R&D

A program providing assistance to R&D would clearly be consistent with the identified rationales. It directly addresses the inability of MNEs in the pharmaceutical sector to access the R&D Tax Concession.

Such support could also address negative head office perceptions caused by PBS pricing. Indeed, pharmaceutical companies suggest that by paying lower than world average prices for medicines, Australia — as a developed country — is not funding its 'proper' share of drug development costs. To the extent that location of R&D spending by companies is not solely based on a country's research strengths, such a perception could have a minor effect on the level of domestic R&D activity. A program that explicitly supported pharmaceutical R&D could go some way to counteracting any effect of this sort. Also, R&D subsidies for domestic firms would offset any impact on R&D activity of PBS pricing arrangements.

From an effectiveness perspective, a reorientation of the program towards R&D could also increase overall additionality and garner the high spillovers associated with this activity. An R&D only focussed program increases significantly the likelihood of the intervention generating a net benefit for Australia as a whole. Eli Lilly (sub. 9, p. 4) was broadly supportive of refocussing the PIIP on R&D.

Support for production value added (PVA)

A number of participants also argued that PVA should be retained as part of any future program. For example, Merck Sharp & Dohme (sub. 11, p. 19) questioned:

> … whether a PIIP which focusses on R&D alone will provide sufficient incentive to retain a sustainable industry in Australia. … [And] recommends that the PC revisit its conclusion on manufacturing activity.

Medicines Australia (sub. 10, p. 10) reiterated the industry's proposal in the Action Agenda that support be provided to PVA.

However, against the identified rationales for intervention (which have an R&D focus) there is not a clear case for including PVA. Moreover, and critically, the collateral efficiency costs — leakages abroad and tax distortions — are likely to be too high relative to the benefits for the intervention to generate a net benefit for Australia.

The case for funding replacement activity is particularly weak:

- it would raise questions about the long term sustainability of the industry if manufacturing activity required assistance to be viable; and

- more pragmatically, widening the eligible activities risks diluting whatever funds would be available for the program.

Finally, removing PVA from a future pharmaceutical industry program is unlikely to raise significant concerns on adjustment grounds — see appendix E.

Support for capital investment

Using capital investment by pharmaceutical companies as a basis for payments would overcome some of the problems associated with PVA. For example, increases in investment represent real increases in capacity, whereas over the short term value added is often just related to the extent of use of existing capacity.

However, assisting capital investment suffers the other limitations of subsidising value added. Moreover, subsidising *incremental* investment might be difficult to calibrate. To the extent that the PBS affects perceptions, there could be a minor reduction in investment by some firms. But, as noted in both chapters 3 and 4, rational decision making by head offices of MNEs suggest that large scale investment decisions are typically affected by more hard-headed attributes than perception. This suggests that measures to increase investment would need to be finely nuanced so as not to excessively subsidise investment, thus distorting flows of capital.[6] However, it is unclear whether such a carefully calibrated approach is practical. In particular, the lumpy and somewhat irregular nature of capital expenditure would make it difficult to determine an appropriate base on which subsidised investment would be calculated, while it would take some time to estimate the extent to which investment genuinely responded to a given subsidy rate. Inevitably, the recurring problem of subsidising investment that would have occurred anyway would re-appear (with welfare costs from transfers where foreign companies are involved).

Company eligibility

The current PIIP is confined to companies that have price suppressed products listed on the PBS.

A key issue for any new scheme is what types of companies should be eligible to apply for access. For example, should a future program include biotechnology companies, or should it be limited to pharmaceutical companies? Pharmaceutical companies generally supported having the scheme accessible to companies with products on the PBS. On the other hand, ITR (sub. 8, p. 4) suggested that biotechnology companies should be included in any future scheme.

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[6] Moreover, if a program provides greater assistance than is warranted, subsidising investment would have negative impacts on economic efficiency, whereas, in the case of R&D, there is at least the potential for some incidental spillovers.

On the basis of the identified rationales for the program, there are strong grounds for restricting eligibility to pharmaceutical firms with products listed on the PBS. This reflects:

- the inability of many PBS-supplying pharmaceutical firms to effectively access the R&D Tax Concession;

- any adverse impact of the PBS on head office perceptions of the business environment in Australia; and

- the possible adverse effect of the PBS on domestically-exposed firms.

The rationales suggest that biotechnology companies and domestic pharmaceutical firms without PBS products should not be eligible for the scheme. As discussed in box 7.3, there are a range of other design considerations, some of which form arguments for including biotechnology companies, while others suggest they should be excluded from the PIIP.

Box 7.3   Other considerations affecting eligibility

There are a number of factors, in addition to the identified rationales for assistance, influencing the determination of appropriate eligibility conditions, some favouring wider eligibility and others maintenance of the existing narrower conditions.

As discussed in the Action Agenda and by ITR (sub. 8, p. 4), change within the pharmaceutical and bio-medical sectors is rapid. Pharmaceutical companies are refocusing on external collaboration rather than in-house research, and the bio-medical sector already plays a key role in the drug development pipeline. In this situation, subsidised R&D activity in biotechnology firms may directly substitute for R&D activity that would be lost as a result of disincentives to invest in R&D in Australia by foreign pharmaceutical MNEs. To the extent that this substitution occurs, the nature of Australian biotechnology firms (their small size, domestic ownership and susceptibility to liquidity constraints) are likely to increase inducement and reduce leakages abroad. All other things being equal, this increases the probability of a net benefit from a modified program — a point also noted by ITR (sub. 8, p. 4).

- But the similarities between the industries should not be exaggerated. Pharmaceutical R&D is heavily tilted towards clinical trials, which is not true for the biotechnology sector. Additional R&D by the biotechnology sector would not be a panacea for any efficiency costs associated with clinical trials lost as a consequence of disincentives to invest by foreign MNEs.

Excluding biotechnology firms may create an incentive for strategic behaviour in order to be eligible for PIIP funding. The PIIP provides an incentive for research companies to distribute PBS products for other pharmaceutical companies in order to gain access to payments under the program. There is some evidence of this occurring under the Factor f program and the PIIP.

<div align="right">Box continued</div>

Box 7.3   continued

A further basis for wider eligibility is that once a merit-based approach is adopted it is often preferable to select the best R&D projects from the widest possible range of companies.

ITR (sub. 8, p. 4) also argued that biotechnology companies should be included in any further scheme to encourage partnerships between pharmaceutical companies and biotechnology companies. This could reinforce a conduit for knowledge spillovers and assist commercialisation of Australian innovation.

- But it is not necessarily the case that including biotechnology firms in a modified program would encourage greater collaboration. Access to the program would provide an independent source of R&D finance, which would reduce one of the major imperatives behind seeking collaboration for early stage R&D with foreign pharmaceutical MNEs.

There are also practical factors that suggest that companies without products on the PBS should be excluded:

- Spreading the payments among a greater range of companies would dilute the funding available to the primary targets of the scheme, given its rationales, and thereby reduce its effectiveness;

- with respect to the PBS rationale, PIIP payments can be internally allocated to particular new drugs in order to increase the apparent price received to a level above the global floor established by head office. This may allow some drugs to be listed that would otherwise not be on the PBS (as exemplified by the case of Norvasc — chapter 6). However, if all links with the PBS were removed, as they would need to be if non-PBS supplying firms were admitted to the program, this strategy would probably be untenable;

- the small size of biotechnology companies could complicate and increase the administrative costs of the PIIP. And including biotechnology companies could raise complex definitional issues about which companies and research were eligible since biotechnology covers a range of research areas beyond those linked directly to pharmaceuticals. In contrast, identification of price suppressed pharmaceutical firms is straightforward; and

- biotechnology companies have access to a range of other R&D support programs. Access to further subsidies through a modified PIIP could risk tilting the assistance playing field towards them. Some participants noted that were PIIP to exclude biotechnology firms, then the situation could arise that a pharmaceutical and a biotechnology firm could be engaged in similar research, yet only the former would be subsidised. However, once other mechanisms for assisting the biotechnology sector are taken into account, this apparent anomaly disappears.

However, widening eligibility beyond firms with products listed on the PBS could risk the effectiveness of the scheme by diluting any available funding among firms that are not the primary targets of the program.

Moreover, there are a range of other government support mechanisms available to the biotechnology industry. These include the Biotechnology Innovation Fund (BIF), R&D Start Grants, the R&D Tax Concession, various forms of State Government Assistance, as well as direct Commonwealth funding of public infrastructure (ITR (2002a, p. 12) reported that 70 per cent of biomedical companies formed in 2001 were spin-offs from research institutions).

In any case, an R&D scheme for pharmaceutical firms is likely to be of significant benefit to the biotechnology sector, both directly through collaborations, as well as indirectly. Ausbiotech (sub. 14, p. 4) stated that:

> A common route for commercialisation for a research project with in a university/research institution is through partnerships with an interested strategic partner, such as a multinational pharmaceutical company (MNC). … Consequently, a vibrant, sustainable pharmaceutical industry in Australia is important … for the continued growth of Australia's fledgling biotechnology industry.

Participation in any modified PIIP should, therefore, be restricted to firms supplying the PBS.

A capped or uncapped program?

Another issue for the design of a future program is whether the total cost to government of the program is capped or uncapped. The PIIP was capped at a total of $300 million over its five year life. The Pharmaceutical Industry Action Agenda recommended that upon the expiry of the PIIP there be an entitlement program available to all firms that meet the specified eligibility criteria. This effectively would be an uncapped program.

By being generally available to firms with products on the PBS, an entitlement program would mimic the uncapped nature of the current R&D Tax Concession and could be seen to comprehensively address negative perceptions arising from the PBS. If the criteria were clearly established, such a program would also be relatively easy to administer — participants would submit annual returns outlining audited performance against the criteria, and an entitlement calculated accordingly.

Against this, the strong disadvantage associated with entitlement programs is that total expenditure is unknown in advance. Actual cost to government could significantly exceed the estimated cost — the experience with the Factor f program being a case in point. From a fiscal policy and budgetary planning perspective it is

obviously desirable that the total amount of assistance to be devoted to the pharmaceutical industry be broadly known in advance. For this reason, capped programs are generally preferable whenever capping does not fundamentally conflict with the program's objectives.

From a policy design perspective, capped assistance requires entry criteria to the program to ensure that entitlements remain within the cap. The issue of who gets the assistance under a capped program can be resolved in two broad ways.

First, as in the case of the PIIP, the program could be subject to competitive entry. Such a program effectively involves two sets of eligibility criteria:

- criteria that firms bid against to gain entry into the program; and

- criteria that then govern how much they would receive once entry has been achieved.

(Aside from its relationship to capping of entitlements, there are other considerations relating to the desirability or otherwise of competitive entry to a government program. These are discussed in a later section.)

Second, there are various possible hybrid approaches that combine caps and entitlements. Three such possibilities are:

- a first-come first-served approach where specified entitlements are paid to firms until the money runs out;

- an entitlement program in which the amount available to any one firm is capped. With a relatively small number of large players in the industry, this could provide some measure of certainty that payments would not blow out;

- another suggestion made by one company would be to combine a cap with an entitlement program and vary the subsidy rate according to the level of activity. For example, the government may nominate a subsidy rate of 20 per cent based on the expected level of activity. If actual activity at the end of a given year was double this amount the subsidy rate would be reduced accordingly (to 10 per cent in this case) so that the total amount paid remained within the cap. Such an arrangement would allow a relatively simple program design and meet the government's requirement for budget certainty. A cap of this type would allow all eligible firms to access the program. However it is not clear whether it would meet the participants' need for certainty. For instance, a firm may undertake a project on the expectation of a 20 per cent subsidy rate, only to have that rate reduced.

Prudent program design and risk management strongly suggests some form of capping of total funding to any future pharmaceutical industry program.

Subsidy rate(s)

A major determinant of any future subsidy rate would be the total available funds. This would be a matter for government consideration given other budget priorities. Determining a subsidy rate in any successor to the PIIP would also depend on a range of factors, including:

- how a base level of activity is determined — a base that increases each year, all things being equal, would allow a higher subsidy rate for a given amount of funding than a fixed base;

- the scope and value of activity that is eligible — the wider the activity base, the lower the subsidy rate; and

- striking a balance between providing a reasonable incentive to increase activity and raising the subsidy rate too high. Too low a subsidy would not address the underlying rationales for intervention, would reduce the administrative efficiency of the program and, given compliance costs associated with applications, attract little interest by firms. Too high a subsidy rate creates an incentive for firms to engage in strategic behaviour and reclassify activities to maximise payments. It would also risk 'over-compensation' — attracting too many resources to the subsidised activity.

The incentives created by the program will also be affected by whether there is a single subsidy for all eligible activity or whether there are different rates for different types of activity.

The additional administrative costs, both for firms and government, are one factor that can determine whether differential subsidy rates are feasible. In the case of the PIIP, administrative costs do not appear to be a significant constraint. Indeed, a number of participants suggested that greater complexity within the program, and higher compliance costs, would be a trade-off worth making for greater flexibility.

In this light, different subsidy rates could apply to different types of R&D. R&D can be categorised in a number of ways, including:

- basic and pre-clinical research versus clinical trials and process R&D;

- collaborative research versus in-house research; and

- 'new' research and 'replacement' research as referred to in the industry's proposal in the Pharmaceutical Industry Action Agenda.

There is a strong argument for subsidising basic and pre-clinical research at a higher rate than clinical trials. As suggested in chapter 4, pre-clinical research is likely to

lead to significantly greater spillover benefits to Australia than clinical trials. The boundaries between clinical trials and other research are also relatively clear cut.

On the same argument, there would also appear to be a case for providing a higher rate for collaborative research than in-house research — collaborative research may generate a greater knowledge transfer to Australia than in-house research. However, there are several likely problems with such an approach:

- Treating collaborative research more generously than in-house research would create an incentive for companies to artificially structure projects to provide the appearance of collaboration. It would be difficult for a program administrator to distinguish genuine collaboration from projects with the appearance of collaboration.

- It would also be administratively difficult to handle projects where part of the research was done by the company and part was collaborative.

- More fundamentally, it may not be appropriate to create a bias against doing in-house research. For example, such a program could work against MNEs building up their own research expertise in Australia.

If different subsidy rates were to be employed, like *types* of research projects should be treated in the same manner, whether or not they involve collaboration with public institutions or other Australian firms.

The division of research into 'new' and 'replacement' that is used in the Pharmaceutical Industry Action Agenda raises a number of issues. Whether 'new' and 'replacement' have meaning depends on how the other elements of program are designed — whether there is a base, how the base is constructed, or whether projects are approved on a case by case basis. A key objective of any program is to induce activity that would not otherwise occur. Depending on the pattern of activity levels of the company, this could be 'new' (an increase in total research spending) or 'replacement' research (research that maintains current spending, but would not occur without program funding).

Competitive entry

Competitive entry is a related but separate issue to that of capping entitlements. For example, it would be possible to have competitive entry to a program, but not cap entitlements for successful firms — payments could be made for all activity above a base level.

Entry to the PIIP was based on competitive entry. Each applicant's bid was assessed by an expert panel against the four guiding PIIP principles (chapter 2). Bids were

ranked and firms were admitted sequentially until claimed entitlements exhausted the funding cap. At the time, nine companies were accepted from a total of 22 bids. There are 30 or so companies with products listed on the PBS.)

As noted above, competitive entry to a program can be an effective rationing device, but it also has other advantages and disadvantages.

The main advantage is that it may be more likely to induce new activity than an entitlement program. Offering a subsidy for certain activity under an entitlement program will induce activity by raising the returns available to that activity. Adding the additional element of competition for access to that subsidy is more likely to induce the maximum possible level of activity for a given level of subsidy as each company attempts to ensure that its bid is attractive. Competition could thereby magnify the effect of the subsidy.[7]

The major drawback from competitive entry is that, by definition, some companies, undertaking what would otherwise be eligible activity, would miss out. However, by confining the scope of the program to R&D activity, competitive entry could operate to eliminate only poor applications rather than impose a cut-off for entry at a point where sound applications miss out.

Once-only competitive entry to a five year program also has the potential to arbitrarily discriminate against firms based on where they are in their business cycle when the program begins. Companies rarely remain in a steady-state for long. The PIIP favours companies on a steady growth path at the time the program starts. For example, if a company has just completed restructuring it could be advantaged both in presenting a credible bid and in generating entitlements through a growing base. On the other hand, if it were just embarking on a period of restructuring (that may ultimately yield strong growth), or facing a period of uncertainty (positive or negative), it is placed in a more difficult position to develop an attractive application. That company may be in a much stronger position to bid in one to two years' time.

Servier also suggested that excluding firms (that were unsuccessful or did not initially apply) through the competitive entry process from participating in the program for the full five years reduced the program's effectiveness:

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[7] Where additionality is not that easily observable, but growth rates above a base are used as a proxy, competition also tends to select the highest growing firms, which will only imperfectly equate with additionality – box 5.1. This form of selection bias negates the advantage of competitive entry.

During such five year periods investment decisions continue on a global basis and Australia may not be as well placed as other countries to maximise its case (Correspondence September 2002).

However, these problems arise because of the one-shot nature of the competitive entry to the PIIP, rather than because of competition *per se*. For example, if there were an annual or bi-annual competitive assessment of projects for entry to the program, failure to secure funding in any one year would not have such a dramatic effect on individual firms. Nor would success be tied to the business cycle of particular firms.

With this in mind, the Pharmaceutical Industry Action Agenda has suggested that there be multiple entry and exit points for applicants, which would be consistent with an annual allocation of funds.

Overall, if a modified PIIP were to operate there would be merit in having multiple entry and exit points for participants. Under such arrangements the benefits of competitive entry are likely to outweigh any costs.

Entry criteria

A key to the success of competitive entry into any program is having clear and transparent entry criteria. There were few criticisms of the PIIP in this regard among applicants. The process has also been endorsed as meeting probity requirements by the Auditor General.

However, improvements to the criteria are possible in any future program. The PIIP set out four guiding principles (chapter 2). While the intent of the principles is clear, they are not readily measurable. Just as importantly, the weighting to be accorded to each principle was not specified. For example, there is evidence that the single most important indicator of a successful application was the size of the R&D of the applying firm, though this was not an explicit criterion. Also, tradeoffs between different types of activity in competing applications were not clear. Thus, there was an element of subjectivity or, as some participants noted, a 'beauty contest', to the assessment process.

In addition, the less clearly specified the assessment criteria, the more likely companies will misinterpret the criteria or question the fairness of the process. For example, one successful firm subsequently found out, when it later cancelled one of its many research projects, that the project had been pivotal to its success. Notwithstanding the potential problems with qualitative criteria, as previously discussed, they should not be completely ruled out. One of the main aims of assistance programs is to induce activity that would not otherwise occur and to

encourage R&D that has high spillovers for the Australian economy. As noted, such requirements are inherently difficult to specify in measurable terms. Hence, assessing proposals according to qualitative criteria may have a role in meeting the objectives of a program that cannot be met with a quantitatively specified element of program design.

While it is unlikely to be possible to eliminate all subjectivity from the assessment process, the potential for misinterpretation of the criteria by bidders would be minimised if the number of assessment criteria were kept to a minimum. Thus, a key criterion in any future program should be that beneficial activity would not be likely to occur in Australia without the incentive. Guidelines could be developed to try to give this criterion greater practicability.

Timing issues

As alluded to above, the Pharmaceutical Industry Action Agenda raised a number of issues concerning the timing of the PIIP. First, related to competitive entry, is the problem of forecasting for the entire five years of the program. Secondly, is the question of how long a new program should run for.

Problems with forecasting for five years

The PIIP required forecasts five years in advance, which determined the company's base and hence the entitlements for each firm. Multiple entry and exit points to a future program would relieve the problems caused by the all-or-nothing approach to whether a firm could participate in the PIIP. It would also overcome some, though not all, of the other problems for successful participants arising from the five-year nature of the program.

In a rapidly changing industry, forecasting levels of future activity, particularly at the project level, is very difficult. In the case of R&D, new and unexpected opportunities continually emerge, while seemingly promising avenues of research can fail to deliver results. At the industry level, the significant number of mergers and acquisitions between PIIP and non-PIIP companies that have occurred over the course of the PIIP to date (chapter 2) is indicative of the difficulty of predicting the future.

There is some flexibility as to when a company earns its entitlement under the PIIP. But if it fails to meet its targets early in the program, lost entitlement cannot be recovered in full, unless the shortfall is made up the following year.

This lack of flexibility in the carryover arrangements, combined with the requirement to forecast activity, is likely to result in a lower effective subsidy rate than the nominal rate of 20 per cent. When bidding, companies would realise that there was a significant probability that unanticipated events would cause annual levels of activity to vary (positively or negatively) relative to its forecast. Implicitly they would discount their expected entitlement to take account of the probability of a relative decline in activity in a particular year that could not be fully recovered the following year.

Another manifestation of a lower effective subsidy rate could be companies adopting a conservative approach to forecasting their level of PVA and R&D in order to avoid the perception of under-performance. This would cap their entitlement at a conservative level — less than they thought they would actually be able to achieve. Once entitlement is allocated, there is then little incentive under the program to undertake additional projects. The case of one applicant represents an acute example of this problem. The applicant was initially successful but, owing to impending changes in its business environment, withdrew from the program rather than risk the possibility of significant under-performance.

While multiple entry points will partly solve this problem, more flexible carryover provisions could also be desirable.

How long should a program run for?

Longer time frames have the advantage that they often tie in better with firms' planning horizons. For example, a repeated criticism of the R&D Tax Concession has been that recipient firms have little certainty that subsidies will be available in a few years' time. Without reasonable certainty, firms may not commit to lumpy investments that require some years of subsidy for a payback.

The Pharmaceutical Industry Action Agenda suggested that a program with longer time frames would be appropriate to provide greater certainty to the industry. For example, Singapore's ten year horizon is cited in the Action Agenda as being broadly appropriate. The industry's proposal suggests that the Government make a firm commitment for another five year program and an in-principle commitment for a further five years.

While certainty assists industry decision making, certainty beyond a five year period is difficult to achieve within a government program. The industry's proposal itself reflects the reality that governments are understandably reluctant to lock-in budget funds for a long period in advance. In this environment, an in-principle

commitment may not guarantee significant certainty, particularly given that the program could span several electoral cycles.

More fundamentally, the industry is significantly different today from what it was ten years ago. It is not clear that the objectives of a program established in 2004 would remain relevant in 2010 or 2014. It may not be sensible to commit to funding for an extended period.

The appropriate length of any future modified PIIP would be a tradeoff between a number of competing factors. A five to six year program would allow for, say, three entry points (one every one and half to two years).

7.3   Conclusion

A modified PIIP providing incentives for pharmaceutical industry R&D projects would most likely be effective in generating a net benefit to Australia as a whole.

A competitive selection process and the fully incremental design of the program suggests that it would involve higher additionality and lower leakages and, in all likelihood, greater welfare outcomes than the alternative policy option, a ring-fenced R&D Tax Concession (see Appendix F).

A focus on R&D and its commercialisation would allow a program that provided a 'big splash in a small pond'. This approach may have a greater chance of changing any perceptions about the business environment in Australia than a program that provided small amounts over a wider range of activities.

RECOMMENDATION 7.1

Upon the expiry of the PIIP in 2004 the Government should put in place an R&D-only subsidy program for the pharmaceutical sector. The program should:

- *provide subsidies for R&D;*

- *be open only to pharmaceutical companies with products on the PBS;*

- *have its total funding capped;*

- *have entry based on competitive criteria that emphasise undertaking beneficial activity that would not otherwise occur;*

- *include more than one entry point; and*

- *have a duration of five to six years (six years would allow three entry tranches).*

8 Other measures

This chapter examines the following three matters related to the PIIP and the pharmaceutical industry environment:

- clause (f) of the Pharmaceutical Benefits Pricing Authority's (PBPA's) guidelines that refers to pharmaceutical activity in Australia;

- industry concerns about the Pharmaceutical Benefits Scheme; and

- the effects of the pharmaceutical patent extension on generic manufacturers.

8.1   Clause (f) of the PBPA guidelines

The PBPA, when setting prices, is required under clause (f) of the its guidelines to take account of:

> … the level of activity being undertaken in Australia, including new investment, production, research and development (PBPA 2002, p. 4).

However, the PBPA states that it does not currently take this clause into account when setting prices:

> Factor f is presently not taken into consideration in determining prices. It is however, in part, taken into consideration under the Pharmaceutical Industry Investment Program. The Pricing Authority is presently seeking advice on this matter (PBPA 2002, p. 4).

Thus, it would seem that the PBPA's assessment is that the objectives of clause (f) are achieved through the PIIP (that is, subsidising activity in Australia for some firms facing suppressed prices). However, there also appears to be some unease within the PBPA about whether this is the case. In particular, many pharmaceutical firms facing apparent price suppression are unable to access the program because of its competitive entry requirements and capping. Given that the structure of the PIIP militates against it effectively fulfilling clause (f), it is unclear how to interpret and act on the clause.

Pharmaceutical companies, including Merck Sharp & Dohme (sub. 11, p. 21) and Pfizer (sub. 12), strongly supported the retention of clause (f) in some form, although they acknowledged that it was not being fully implemented at present.

There are a number of ways of potentially fulfilling clause (f). However, as discussed below, each is at best problematic and somewhat unrealistic.

Price increases for Australian drugs

One option would be to pay the average world price only for drugs that are manufactured in Australia and listed on the PBS. This approach would almost certainly increase domestic pharmaceutical activity significantly, as MNEs would shift packaging and formulation activities to benefit from higher prices. However, it would have significant costs for the budget and/or patients. In effect, such a measure would be like an ad valorem subsidy for domestic production, with the subsidy paid for by Australian patients or by the taxpayers more generally. As such it would:

- be discriminatory in respect of imports, creating a large wedge between the price of imported and domestically produced drugs;

- increase local production by far more than price suppression could conceivably have reduced domestic activity;

- be likely to engender costly resource allocation effects of the kind created by other trade barriers; and

- almost certainly conflict with WTO obligations.

Paying world prices

In the light of the difficulties posed by discriminatory treatment of Australian-produced pharmaceuticals, a second option would be to pay full 'world' prices for drugs, regardless of their origin. However, the increased cost to the budget and/or patients make this prohibitive:

- Paying (say) EU level prices would be administratively easy, but it presumes price suppression is equivalent to price differences. In fact, as noted in chapter 3, not all of the observed price differences can be traced to price suppression *per se*. Paying EU prices would go beyond compensating for price suppression.

- Even were actual price suppression to be countered by such a measure, the cost would be very high. For example, in 2001, sales of PBS benefit-paid pharmaceuticals were around $4.8 billion and would be around $6.9 billion were prices to be at world levels (at existing quantities). If 50 per cent of the difference between world and Australian prices can be ascribed to price suppression, then suppression would aggregate to around $1 billion a year.

Accordingly, neither of the options for directly dealing with activity impacts by eliminating price suppression is realistic or desirable.

Adoption of rate of return regulations

A third option, suggested by Sheehan (sub. 15, p. 12), was to adopt a rate of return approach as used in the UK. The UK Government allows 'free' pricing by pharmaceutical firms, but constrained by a profit cap. The mechanism is complex, so complex that the relevant UK Minister noted that: 'the Pharmaceutical Price Regulation Scheme is inordinately complicated and I make it clear to the Committee that I would never take it as my question on Mastermind' (cited in Bloom and van Reenan 1998, p. 6).

Like other rate of return regulations, it also has the potential to reduce incentives for efficiency and to lead to biases in capital allocation. The administration of the scheme also lacks transparency.

Nevertheless, Bloom and van Reenan indicate that, among a range of contenders, it is probably the preferred measure for pharmaceutical pricing. However, that is in a UK context, in which the effects of uninhibited price suppression may be more problematic, especially given the widespread referencing to UK prices in other jurisdictions. In an Australian context, the activity effects of price suppression are not as significant. The application here of rate of return regulations of the UK type would have severe budgetary implications and very uncertain benefits.

Distribution of assistance in proportion to the level of price suppression?

Some participants and non-participants in the PIIP have suggested that, in the absence of general PBS price increases, any funding available under a future arrangement should be distributed *in proportion* to the price suppression under the PBS. These participants and non-participants have criticised the current arrangements on the basis that the firms that are subject to the greatest level of price suppression do not necessarily gain the most out of the program. The option of paying subsidies in proportion to the level of price suppression would be seen to partially compensate for price suppression, could be perceived by the industry to be fair, and could be consistent with clause (f).

However, as with the option of raising drug prices directly, it is not clear that such an approach would induce significant levels of additional activity. If the Government accepted that low PBS prices have some effect on activity, with limited funding, the objective of a pharmaceutical sector program should be to increase the level of activity to the maximum extent for each dollar of funding — that is,

achieving the 'biggest bang for the buck'. Some firms are likely to undertake more activity in response to a subsidy than others. Hence, as the distribution of funding under the PIIP suggests, this could lead to a different pattern of funding from providing assistance in proportion to the level of price suppression suffered by each firm.

In Conclusion …

Given that clause (f) is not being applied at the present, that its objectives are not really being achieved through the PIIP and that each of the options to implement the clause (f) objective would be inappropriate, the clause is redundant and at worst detrimental to the interests of the community. Clause (f) is one Gordian knot that can safely be cut.

RECOMMENDATION 8.1

Clause (f) should be deleted from the guidelines issued to the Pharmaceutical Benefits Pricing Authority by the Commonwealth Government.

8.2   PBS processes

Chapter 3 examined in some detail price suppression through the PBS and its possible adverse effects on the pharmaceutical industry. However, there are widespread concerns within the industry about other aspects of the PBS listing and assessment processes, which it claims also affects industry investment and activity in Australia.

To release a new drug in Australia, a pharmaceutical company first applies to the Therapeutic Goods Administration (TGA) for registration of the drug. The company then submits an application to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the PBS. To gain listing a company must provide clinical and economic data that demonstrate that a new drug is cost-effective. The test for cost-effectiveness is related to the price of the drug:

- if the applicant is seeking a higher price than for alternative drugs on the PBS, it must demonstrate that the new drug is more effective than alternatives; and

- if the applicant is seeking listing at the same or lower price as alternatives on the PBS it must demonstrate that the drug has at least the same effectiveness as those alternatives.

If the PBAC advises that listing should take place, the company negotiates a price, and possibly a price/volume agreement with the PBPA. Where the annual cost to

the PBS is likely to be over $5 million, Ministerial approval is required. If the cost is likely to exceed $10 million, Cabinet approval is necessary before the drug is listed.

The pharmaceutical industry has suggested that TGA registration processes are now 'world class'. It also supports the broad 'evidence-based' approach to listing. However, the industry has expressed wide-ranging concerns with the application of PBAC and PBPA processes. Specific claims with respect to the PBAC and PBPA are noted below.

The industry contends that many of their concerns arise because of what they consider to be a distortion to the cost-effectiveness framework by a desire to minimise the total costs of the PBS. For example, Pfizer (sub. 12) noted Departmental statements that the forward estimates project a 6 per cent annual growth rather than the 10 per cent growth that has prevailed over the last decade, and suggested that a 'soft cap' operates with respect to PBS expenditure. Medicines Australia cited the listing and pricing of the drug Symbicort as indicative of this approach (box 8.1).

Box 8.1   Medicines Australia's discussion of the listing of Symbicort

Symbicort is an inhaled Asthma treatment combining a corticosterioid, budesonide, and a long acting beta agonist. Medicines Australia provided the following commentary on the listing of Symbicort

> An application to have this combination available on the PBS was made in December 2001, for consideration at the March 2002 PBAC meeting from which Astra Zeneca expected listing on 1 August 2002. The individual components in separate devices (as Pulmicort and and Oxis) were already available on the PBS.

> The PBAC recommended the product for listing but provided special advice to the PBPA such that the price of Sybicort was to be less than the sum of the actual components and based on a weighting of prices of other (less expensive) strengths of the components. Subsequently, the price offer from PBPA, based on the PBAC advice, was too low for the company to proceed with listing.

> Subsequent meetings with the Branch and PBAC Chairman, and written submissions to the PBAC and PBPA, led to a better price offer from the PBPA which the company was able to accept (albeit the lowest in the world, being less than than 60 per cent of the average price in other markets).

> The product is to be listed from 1 February 2003, a delay of 6 months.

Medicines Australia claims that had there not been agreement to list the drug it would have led to the demise of the company's respiratory portfolio. It suggested this would have resulted in no further local R&D investment in the respiratory therapy area by AstraZeneca, including clinical trial activity.

Source: Medicines Australia (sub. 10, p. 21)

PBAC issues

The industry alleges that there are overly stringent demands on types of data for assessing *clinical effectiveness*, which hamper the ability of companies to demonstrate effectiveness. The industry claims that world wide clinical data are often discounted by the PBAC in its deliberations because the studies do not use a comparator drug that the PBAC considers appropriate for Australia; and that the PBAC's demand for high level randomised trials — which, it is claimed, is not always possible to conduct for the relatively small market in Australia — is higher than in other countries. MSD (sub. 11, p. 6) suggested that:

> The PBAC's conception of relevant data is not consistent in its emphasis on information such as: treatment changes measured in the laboratory as distinct from clinical outcomes; subjective adverse effects; and definition of treatment endpoints.

The industry also claims that there are flaws in some of the methodologies used to assess *cost-effectiveness*, particularly relating to estimating the impact of a new therapy on time in hospital and workplace productivity. It claims that drugs are approved by the PBAC only with overly stringent restrictions on their therapeutic uses. For example, the industry claims that the treatment guidelines for osteoporosis published in the *Medical Journal of Australia* suggests that women who have osteoporosis, but no fracture, should be treated. However, it also claims that 'under the PBS, bisphosphonate and other medicine classes are available on an authority basis only for the treatment of patients who have suffered fracture' (Medicines Australia 2002, p. 27).

Medicines Australia (2002) also suggest that workload placed on PBAC members is too high given the number of applications, the detail in the material presented and the importance of listing decisions. It further claimed that the decisions of the PBAC lack transparency, compounded by a lack of review provisions for PBAC decisions.

Eli Lilly, (sub. 9, p. 18) while criticising the process, acknowledged that there were some recent improvements:

> Progress is being made in improving the PBAC process and also in innovative approaches to risk management for new PBS listings.

According to the PBAC, the Government has requested that, from June 2003, the PBAC publish reasons for its decisions (Schubert 2003). This will increase the transparency of the PBAC process.

PBPA and Ministerial approval

With respect to the PBPA, the industry alleges that price/volume agreements place all risk and responsibility on the pharmaceutical company for a higher than expected number of prescriptions. It argues that while 'leakage' of prescriptions into indications not endorsed under the PBS is an issue, the volume of prescriptions can also rise for legitimate reasons, such as higher effectiveness than initially estimated, or a greater number of people who could benefit from the drug. An example suggested by one company was a drug for a terminal illness whose demand exceeded initial volume projections because of longer life expectancy under treatment than originally estimated. The manufacturer was apparently penalised under a volume agreement despite the fact that the drug was only used for the appropriate indication.

In addition, of significant concern to the industry are the delays caused by the recent requirement for ministerial and cabinet approval. For example, Avandia — a drug to treat type II diabetes — received a positive recommendation from the PBAC on cost-effectiveness grounds for listing on the PBS in March 2001. However, Avandia has not been listed as at January 2003.

The industry's concerns with respect to listing processes are not new. In 1996, the Productivity Commission's predecessor, the Industry Commission found that:

> delays, volume restrictions, complex administration processes and the current application of the main pricing tool, cost-effectiveness analysis, are reducing the welfare of consumers by denying them timely access to some drugs and by rationing the use of others. While these problems are not severe at the moment they appear to be worsening. (IC 1996, pp. LIV-LV)

While there have been a number of improvements since 1996, the industry alleges that a drive for cost containment within the PBS has intensified over the past two years, with adverse implications for their perceptions about the environment for pharmaceutical activity in Australia. An assessment of these issues is beyond the scope of this inquiry. However, to the extent that the problems are serious and sustained, the appropriate response would be to review the PBS's listing processes to identify improvements that would promote the community's interest in having cost-effective access to safe and effective drugs, as well as address negative industry perceptions. Several submissions from the industry to this evaluation have called for an inquiry into the PBS listing processes.

8.3   Patent extension and the effect on generic pharmaceutical manufacturers

Generic drug manufacturers have indicated that the 1998 amendments to Australia's patent protection regime for pharmaceuticals place them at a competitive disadvantage in export markets relative to foreign-based generic manufacturers. Generic firms consulted by the Commission raised the issue as an important obstacle to domestic activity levels in the Australian pharmaceutical industry — potentially of a much greater magnitude for generic manufacturers than price suppression under the PBS.

(This matter has been examined by an Interdepartmental Committee on springboarding and patent extension being chaired by ITR. A report has been completed and recommendations put to Government. The Commission has not seen the report.)

In 1998 the Government amended the Patents Act 1990 to provide an extension of pharmaceutical patents of up to five years, allowing a maximum effective patent life of 15 years from the date of first regulatory approval. This was intended to bring Australia's patents regime into line with other advanced countries. However, because Australian patents often expire later than elsewhere, an unintended consequence of the patent extension requirements has been to impede Australian exports of generic products, and favour foreign-based generic manufacturers.[1] According to ITR (2002c, p. 1):

> Australian patent law prevents the manufacture and export of generic drugs while a patent remains in force here. This means that generic pharmaceutical manufacturers are unable to use Australia as a base to access export opportunities in markets where a patent has expired, but remains in force in Australia.

Australian generic drug manufacturers have argued that a key to their competitive position compared with foreign generic manufacturers is having products ready for launch in new export markets as soon as the patent expires. Later entry to foreign markets has several effects:

- Sales are lost that could have been made during the patent extension period in Australia to foreign markets *where patents have expired*.

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[1] Australia's system is geared to a maximum 15 year effective patent life, while the US maximum is 14 years. Further, the method of calculating extensions is different and will commonly result in later expiry in Australia. The changes have resulted in a majority of pharmaceutical patents (up to 70 per cent) expiring later in Australia than they do in comparable countries. For example, the patent on a drug priority filed in the US and Australia in June 1980 would expire in June 2003 in the US, but not until June 2006 in Australia (ITR 2002c, p. 5).

- Delayed access may mean it is never worthwhile to penetrate the foreign market with the given molecule. This arises for two reasons. First, entry to a foreign market involves upfront and continued investments[2] that have to be recovered over the diminished economic life of the particular molecule. If that life is sufficiently reduced because of delayed market access, the revenue stream may not be sufficient to warrant such investments. Secondly, while less important than for originator brands, brand recognition and associated marketing also affects the sales potential of a particular generic drug.[3] Developing such recognition depends on being quick to market, ie there are first mover advantages that are lost if market access is not possible during the patent extension period.

ITR estimates from information supplied by local generic drug producers that export revenue of $2.2 billion over the period 2001 to 2009 could be lost if the current system is maintained. Generic producers have argued for an amendment to Australia's IP regime that permits exports during the patent extension period. They argue that being able to export from Australia to markets where there is no patent in force cannot harm the interests of patent holders.

Against this, patented manufacturers have claimed that such a change would allow Australian generic manufacturers to enter the Australian market more quickly when the patent expired here. They argue that this would infringe upon a normal period of *de facto* market exclusivity, enjoyed by all patent holders, created by the time taken by other producers to begin production.

However, this exclusivity is more apparent than real. Under current arrangements, generic producers can enter the market almost immediately the patent expires. The existing Australian patent provisions (in accordance with TRIPS[4]) allow generic manufacturers to meet regulatory compliance requirements for any generic product prior to patent cessation (so that production processes can be developed, samples can be produced and any clinical trials to confirm bioavailability or other therapeutic features of the generic drug can be conducted). Upon expiry of the patent, the active ingredient can be imported immediately, and formulation can rapidly commence. Indeed, a generic producer suggested production could

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[2] In regulatory compliance, possible development of new manufacturing processes and packaging, and marketing costs.

[3] This is evidenced in the Australian case by the prominence of the Alphapharm brand (which has around a 70 per cent share of the Australian generics market).

[4] The WTO Panel Case (WT/DS114/R) brought by the EU against Canada claimed that conducting development work before patent expiry on the originator drug was against WTO legislation. In March 2000 the WTO ruled that this was not true and that such clinical trials, production testing and sample provision was in accord with TRIPS.

commence within a matter of days after a patent expires. Even quicker entry could occur if the generic company imported the final product, or imported the product in bulk and packaged it in Australia. Thus the export provision would have virtually no effect on access to the domestic market by generic producers.

Moreover, the provision would not contravene the prohibition on stockpiling as production undertaken prior to the expiry of the extended patent would have to be directed to export markets, and not sold on the domestic market.

Nor do there appear to be any other broader offsetting benefits to Australia from the current restriction. It has been argued that the changed treatment of patents could raise adverse perceptions about the commitment of Australia to protection of intellectual property; but even with the change, Australia's intellectual property regime for pharmaceuticals would still be one of the most stringent in the world.

Overall, there is a compelling economic case to allow generic drug manufacturers in Australia to export to countries where patents have expired during the period of patent extension granted in Australia.

Notwithstanding the economic case, some participants have suggested that such a change would not be consistent with Australia's obligations under the WTO's Trade-related Aspects of Intellectual Property Rights (TRIPS) Agreement (box 8.2 contains selected Articles of the Agreement). While the Commission has not examined all of the legal complexities of the TRIPS agreement, it makes the following observations.

First, the change would be consistent with and would reinforce the objectives of TRIPS set out in Article 7 of the Agreement. It would remove a distortion in investment flows and global production patterns that arises from the present anomalous situation. A less efficient overseas generic manufacturer can displace a more efficient Australian-located one because of privileged market access. Removing the distortion would improve dynamic and static economic benefits globally. The realisation of such economic benefits is an explicit goal under Article 7 of TRIPS, while Article 8 recognises that measures may sometimes be required to ensure that intellectual property rights do not unreasonably restrain trade.

Economic and social arguments may be accorded greater standing under TRIPS than they are within some national intellectual property systems, which combine a 'rights' based approach with an economic approach. The TRIPS Agreement is not an all encompassing global intellectual property agreement. As its title indicates, its focus is on *trade related aspects* of intellectual property. It deals with a subset of intellectual property law. Its protection of intellectual property is directed at

balancing the static social and economic benefits of the wide availability of new knowledge against the economic benefits of ensuring that innovators have strong incentives to innovate. The proposed amendment furthers the former without damaging the latter.

Box 8.2   Selected Articles of the TRIPS Agreement

Article 1 Nature and Scope of Obligations

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

Article 7 Objectives

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology to the mutual advantage of producers and consumers of technological knowledge conducive to social and economic welfare, and to a balance of rights and obligations.

Article 8(2) Principles

Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Article 30 Exceptions to rights conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Source: WTO 2003

Second, the limited WTO consideration of disputes under the Agreement to date suggests that it does not take a position on patent extensions for pharmaceuticals. For example the WTO dispute resolution panel report on *Canada — Patent Protection for Pharmaceuticals* noted that:

> Notwithstanding the number of governments that had responded positively on that claimed interest [in whether regulatory processes for pharmaceuticals provided patent holders with a legitimate interest in a period of exclusivity after the patent expired] by granting compensatory patent term extensions, **the issue itself was of relatively recent standing, and the community of governments was obviously still divided over the merits of such claims**. … The panel believed that Article 30's 'legitimate interest'

concept should not be used to decide, through adjudication, **a normative policy issue that is still obviously a matter of unresolved political debate** [emphasis added]. (WTO 2000, pp. 168-69).

If the legitimacy of a period of exclusivity after the normal patent expiry for pharmaceuticals is 'a normative issue that is still obviously a matter of unresolved political debate', then the manner in which that period is recognised (that is, patent extensions) is also a matter of unresolved political debate. If interpretation of the TRIPS is silent or neutral on the patent extension issue, it is also silent on the precise manner in which the extension is implemented.

Third, if the suggested change were determined not to be consistent with TRIPS it would create a strong disincentive for countries to ever go beyond the minimum requirements of TRIPS, no matter how justified further action may be. Doing so would raise the bar for that country, and for that country only. Patent extensions in pharmaceuticals are intended to take account of the diminution of patent life that arises from regulatory delays in the approval of new drugs. Such extensions bolster intellectual protection. But the generic export anomaly has the effect of considerably weakening the incentives for a country to grant such exemptions.

Fourth, some have interpreted the ruling of the WTO in respect of the case (WT/DS114/R) brought by the European Union against Canada (quoted above) as suggesting that, on legal grounds, the 'limited exception' provision in TRIPS Article 30 could not be used as the basis for allowing generic exports. Without discussing the legal issues in any detail:

- Even if the provision was judged to fall within the scope of TRIPS, it would be a 'limited exception' within the meaning of Article 30. As noted, patent extensions for pharmaceuticals do not fall within the core requirements of the Agreement. They are a voluntary extension to the agreement adopted by some countries and not by others. A change to patent law that only affects a non-core or voluntary aspect of the agreement is, therefore, narrow and limited in scope. Hence it is a 'limited exception' under article 30.

- There is not a well developed basis on which to interpret the TRIPS agreement. Precedent does not play as crucial role in the WTO as it does within national legal systems. And to the extent it is important, there is not a large body of cases on which to base interpretations.

This suggests that there is a case to be made that the proposed change would promote the interests of the community and is consistent with the objectives of Agreement, and thus that it would (if necessary) qualify as an exception to the rights conferred in the Agreement as envisaged under Article 30.

There are strong economic grounds for Australia's intellectual property legislation to be amended to allow generic drug manufacturers in Australia to export to countries where patents have expired during the period of the Australian patent extension.

The Commission has not examined the possible legislative changes that would be required to effect this.

A   Meetings, submissions and survey respondents

This appendix lists the parties that formally participated, through meetings, submissions, responses to the survey and the roundtable discussions on the draft report. The Commission gratefully acknowledges these contributions.

Table A.1   **Meetings**

Program participants (9)	
AMRAD	Merck Sharp & Dohme
Bristol-Myers Squibb	Novartis
CSL	Novo Nordisk
Eli Lilly	Organon
GlaxoSmithKline	Prima Biomed
Janssen-Cilag	Schering-Plough
Mayne Pharma	Servier
Pfizer	Sigma
Pharmacia	Wyeth

Other companies (16)	*Government agencies (3)*
	Commonwealth Department of Industry, Tourism and Resources
3M	
Alphapharm	Commonwealth Department of Health and Ageing
AMGEN	Commonwealth Treasury
AstraZeneca	
Boehringer-Ingelheim	*Other organisations (3)*
Institute of Drug Technologies	Medicines Australia
Kendle	AusBiotech
	Association of Australian Medical Research Institutes

Submissions (18)

ANSTO Radiopharmaceuticals and Industrials (ARI)

Association of Australian Medical Research Institutes

AusBiotech

Bristol-Myers Squibb Australia Pty Ltd

CSL Limited

Eli Lilly Australia Pty Limited

Commonwealth Department of Industry Tourism and Resources

Mayne Pharma (Australia)

Medicines Australia

Merck Sharp and Dohme (Australia) Pty Limited (2 submissions)

New South Wales Department of State and Regional Development

Peter Sheehan

Pfizer Australia

Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee

Queensland Government

Servier Laboratories (Australia) Pty Ltd

Victorian Department of Innovation, Industry and Regional Development

Table A.2   **Survey respondents**

Program participants (8)	
Bristol-Myers Squibb	
CSL	Aventis Pasteur
Eli Lilly	Merck Sharp & Dohme
GlaxoSmithKline	Novartis
Janssen-Cilag	Organon
Mayne Pharma	Roche
Pfizer	Sanofi-Synthelabo
Pharmacia	Schering-Plough
	Serono
Other companies (19)	Servier
3M	Wyeth
Allegan	Boehringer-Ingelheim
Alphapharm	Boots Healthcare
AstraZeneca	Ferring
Aventis	Lundbeck

Table A.3   **Participants at Sydney and Melbourne roundtables**

Sydney 9 December 2002	*Melbourne 11 December 2002*
3M	Access Economics
Alphapharm	AMRAD
AMRAD	AusBiotech
AstraZeneca	Bristol-Myers Squibb
AusBiotech	Centre for Strategic Economic Studies
Aventis	CSL
Commonwealth Dept Industry, Technology & Resources	Commonwealth Dept Industry, Technology & Resources
Eli Lilly	GlaxoSmithKline
Generic Medicines Association	Institute of Drug Technologies
GlaxoSmithKline	Kendle
Janssen-Cilag	Mayne Pharma
Medicines Australia	Medicines Australia
Merck Sharp & Dohme	Merck Sharp & Dohme
Novartis	Servier
Pfizer	Victorian Government
Pharmacia	
Schering-Plough	
Wyeth	

B Relationships between price and activity

This appendix examines (the relatively sparse) evidence on links between pricing and activity in the pharmaceutical industry that is at the heart of the claims made about the distorting effects of price suppression.

Table B.1 presents some data on activity and prices — consistent with the methodology employed by the BIE (1991).

Table B.1 **International data on prices and pharmaceutical activity**

	Net exports to sales 1991[a]	Export/import ratio 1991	Price relative to Australia 1990[b]	Price trend (1980-1995)[c]	Export trend (1980-1995)[d]
Australia	-0.169	0.407	1.00	0.033	0.160
Austria	-0.126	0.729	1.90	0.063	0.135
Belgium	0.051	1.132	1.56	0.064	0.131
Canada	-0.196	0.224	2.85	0.063	0.100
Finland	-0.261	0.426	2.50	0.080	0.088
France	0.041	1.280	1.48	..	..
Germany	0.116	1.475	3.23	..	..
Greece	-0.332	0.194	1.65	..	..
Italy	-0.098	0.583	0.85	..	..
Japan	-0.036	0.502	2.56	0.086	0.111
Netherlands	-0.026	0.925	2.50	0.044	0.120
Portugal	-0.251	0.237	1.52	..	..
Spain	-0.045	0.653	1.00	..	..
United Kingdom	0.140	1.700	2.06	..	..
United States	0.011	1.164	4.40	0.068	0.078
New Zealand	..	0.165	1.00	..	..
Denmark	..	..	..	0.059	0.133
Sweden	..	..	..	0.024	0.161

a The import, export, and domestic production data are from OECD Health Data (OECD 2002b). Sales are defined as domestic production plus imports. Data for 1991 are used because it is presumed that production activity is likely to respond to prices with some lag. **b** These data are from the BIE (1991, p. 37) and are based on the unweighted average price for 20 of the 24 largest selling products in Australia. Prices are expressed relative to Australia (with Australia = 1.0). **c** The trend price growth rate over 1980 to 1995 was estimated by regressing the price index for expenditure on pharmaceuticals and other medical non-durables (which the OECD notes typically only picked up prescription drug prices) against a time trend. Prior to estimation, the price indexes were converted to a common currency (the US dollar). **d** The trend export growth rate over 1980 to 1995 was estimated by regressing the value of pharmaceutical exports (in US dollars) against a time trend.

Source: OECD Health Statistics 4th edition (2002) and BIE (1991).

Figure B.1 shows the relationship between pharmaceutical prices and 'net export to sales' and 'export to import' ratios. Figure B.2 graphs the trend in export growth against the trend growth in pharmaceutical prices. None of these relationships provide strong support for the hypothesis that price suppression hurts activity.
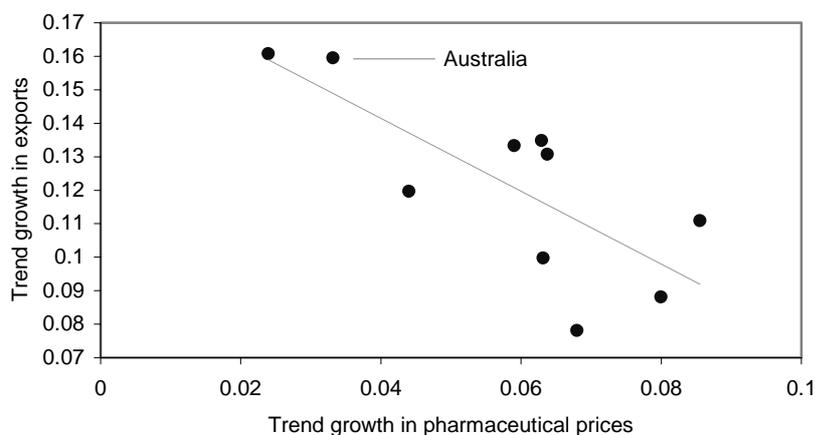
Figure B.1   **Relationship between activity and pharmaceutical prices**
1991
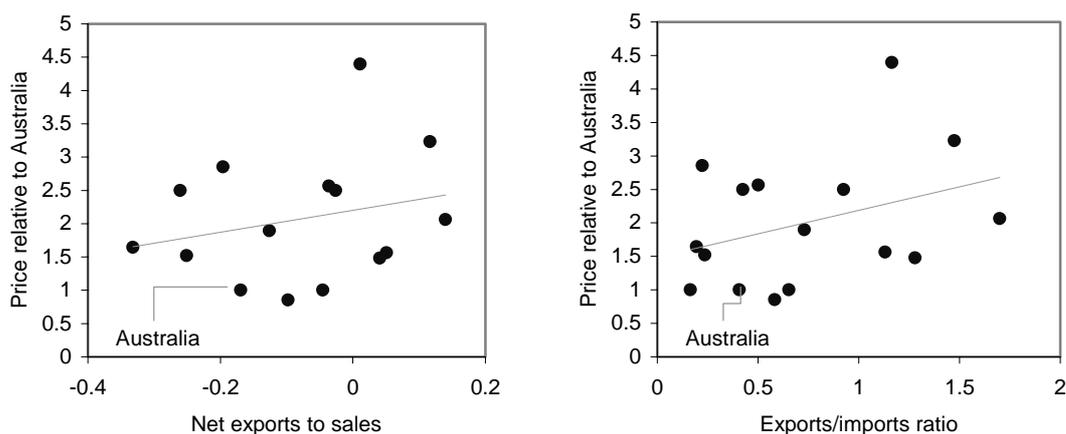
a See table B.1 for a description of the data and its sources.

Data source: BIE (1991) and OECD (2002b).

Figure B.2   **Relationship between export trends and pharmaceutical price trends**
1980–1995

a See table B.1 for a description of the data and its sources.

Data source: OECD (2002b).

In order to examine the link between prices and activity with greater precision, a number of simple regressions were run. These revealed the following:

(Exports- imports) /sales = - 0.154 + 0.036 Price ratio; R^2=0.06; N=15
$\qquad$ (-1.7)   (0.9)

Exports/imports = 0.378 + 0.179 Price ratio; R^2=0.13, N=16
$\qquad$ (1.4)   (1.4)

Trend growth in exports = 0.185 - 1.09 Trend growth in prices; R^2=0.58, N=10
$\qquad$ (9.2)   (-3.3)

The figures in parentheses are t statistics, N refers to the number of observations on which the regression is based and R^2 (the coefficient of determination) is a measure of the extent of the variation in the relevant activity variable explained by the relevant price variable.

The regressions are simple and do not control for other possible factors that might be associated with growing activity, such as industry policy, the share of MNEs in domestic production and input costs. Nevertheless, were there to be a strong positive association between pharmaceutical prices and activity it would be expected to show up in these regressions.

In the first two regressions, the sign is positive, but the estimates are not statistically significant, nor very substantive in an economic sense. Thus, the first regression implies that the expected shift in the net exports to sales ratio from doubling relative prices from 1 to 2 is only 0.036 (this would see the ratio move from -0.118 on average to -0.082). Moreover, the regressions explain very little of the variations in activity between different countries (between 6 and 13 per cent).

In contrast, the third regression suggests that there is a statistically significant *negative* association between export activity trends[1] and price trends. This simple model explains nearly 60 per cent of the variation in export growth trends. To the extent that prices reflect domestic costs — such as wage costs — then the association is consistent with standard economic theory. As costs and prices rise the competitiveness of a country's pharmaceutical industry declines and export growth is reduced. These results provide further support for the notion that international price differences reflect underlying cost variations as well as differential contributions to sunk R&D. This further underlines the difficulty in measuring the amount of price suppression in any market.

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[1] Export activity was selected as the activity variable because it should be invariant to domestic population numbers or age structures, which would be confounding variables were value added to be used as the activity variable.

The findings do not necessarily refute a connection between increased pharmaceutical profits — arising from price increases *not* stemming from cost increases — and increased exports. Unfortunately, it is difficult to obtain consistent international pharmaceutical profit data that could be used to directly test the link between increased profits and activity levels (partly reflecting general data inadequacies and in part due to transfer pricing). That said, trends in value added less wage costs (VALWC) may be an adequate proxy for trends in profits. This is because the other major component of costs — plant and equipment — could be expected to follow similar trends in all locations. Accordingly, the variations between countries in trend VALWC may be reasonably correlated with trend profits (though variations in domestic demand will also affect the estimates). However, a regression found no statistically significant relationship between trend VALWC and trend exports (and indeed the coefficient was negative). While this might reflect problems with VALWC as a proxy, it casts further doubt on the strength of the link between activity levels and financial returns that is claimed to be the central source of the distortions arising from price suppression.

C Existing assistance measures for R&D

Currently, most of Australia's basic research is conducted in public universities or through government programs such as NHMRC and the Australian Research Council (ARC). Also, much of the infrastructure for clinical trials is in the public health system. Further programs to assist R&D relevant to the pharmaceutical industry include:

- R&D start[1] — makes available approximately $180 million per annum to fund specific R&D projects. It awards grants and/or loans of up to 50 per cent of project costs. Projects can range from those costing less than $100 000 to many millions of dollars. For example, it offered a total of $31 million to innovative companies in the biomedical industries through its R&D Start grants and loans program.

- R&D Tax Concession — the Commonwealth Government's principal support scheme to encourage innovation. It provides tax concessions of 125 per cent and up to 175 per cent on eligible expenditure (chapter 4).

- Pre-seed Fund — funds early stage commercialisation of R&D from publicly funded institutions.

- Innovation Investment Fund — a venture capital program that provides funds to nine private venture capital funds to promote the commercialisation of Australian R&D, through the provision of venture capital to small, high-tech companies at the seed, start up or early expansion stages of their development.

- Pooled Development Funds (PDF) program — designed to increase the supply of equity capital for growing Australian small and medium-sized enterprises. PDFs are private sector investment companies established under the PDF Act which raise capital from investors and use it to invest in Australian companies. 10 out of the 122 PDFs specialise in biotechnology and most others are open to all applicants.

- Cooperative Research Centre (CRC) grants — facilitate cooperation between researchers from universities, CSIRO and other government laboratories, and

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[1] New applications for the R&D Start program were temporarily suspended by the Government on 8 May 2002 and recommenced on 28 November 2002.

private industry or public sector agencies. An average of $20.5 million per year are devoted to medical sciences and technology (Table C.1).

Table C.1   **CRCs in medical sciences and technology**

Cooperative Research Centres for	*CRC funding over 7 years (millions of 2001/2002 dollars)*
Aboriginal and Tropical Health	14.4
Asthma	11.5
Cellular Growth Factors	17.1
Chronic Inflammatory Diseases	16.5
Cochlear Implant and Hearing Aid Innovation	14.2
Diagnostics	16.3
Discovery of Genes for Common Human Diseases	13.5
Eye research and Technology	17.7
Tissue Growth and Repair	8.9
Vaccine Technology	13.4
Total	**143.5**

Source: 2002 CRC Compendum [http://www.crc.gov.au/Docs/pdf/Compendium%202002.pdf].

- Biotechnology Innovation Fund (BIF) — commencing in the 2001-2002 financial year, funding for the program was doubled to $40 million under the $2.9 billion Backing Australia's Ability initiative. BIF was designed to fund the gap between the initial research stage of a biotechnology project and the early stage of its commercialisation.

- Centre for Stem Cells and Tissue Repair — recently announced as the successful applicant for the Biotechnology Centre of Excellence program. This is part of the Commonwealth's Innovation Statement 'Backing Australia's Ability', with joint funding of $46.5 million over five years, provided by Biotechnology Australia and the ARC.

Various state government programs are also available and have been targeting biotechnology in particular (for example the NSW Government's BioFirst Strategy, the QLD Government's BioIndustries Strategy, and the VIC government's Biotechnology Strategy Plan). Programs are also in place to facilitate clustering, for example the Bio21 program in Victoria and the Thebarton Precinct in Adelaide. Some of these have funded significant infrastructure. For example the Victorian Government has committed $100 million to the construction of a Synchrotron — a complex machine that produces fine beams of extremely bright light that can be used to investigate the structure of molecules and matter.

A number of pharmaceutical companies are benefiting from these various schemes. For example, AMRAD — a PIIP participant — has received State government assistance. Mayne Pharma and CSL, among others, have been eligible for the R&D Tax Concession. Mayne Pharma has received a small R&D Start grant.

Pharmaceutical companies are also important participants in a number of Cooperative Research Centres:

- AstraZeneca is the sole industry participant in the new CRC for chronic inflammatory diseases;

- AstraZeneca, GlaxoSmithKline, Merck Sharp & Dohme, Aventis Pharma, 3M Pharmaceuticals and Boehringer Ingelheim participate in the CRC for Asthma;

- CSL participates in the new CRC for vaccine technology; and

- AMRAD participates in the CRC for cellular growth factors.

D Explaining international price variations

As discussed in chapter 3, a major determinant of price variation is likely to be various systems of price and other regulation of pharmaceuticals used in different countries. Evidence from Sheehan (sub. 15, p. 7) also suggests this is likely. However, other factors are also likely to be at work, complicating the interpretation of international price differences.

Some of the other factors that may be relevant to international price differences are marketing costs and national income differences. Marketing costs (typically relating to marketing to doctors[1]) represent a substantial and growing share of costs for pharmaceutical firms.[2] These costs must be recovered from drug prices. For example, OTA (1993, p. 90, pp. 303–4) found marketing costs amounted to around 23 per cent of total costs over the commercial life of a drug, while a more recent study based on company accounts claimed that marketing, advertising and administrative costs accounted for around 27 per cent of pharmaceutical sales revenue for major US pharmaceutical companies in 2001 (Families USA 2002, p. 3). PhRMA (2002, p. 91) has estimated that marketing personnel accounted for 35 per cent of pharmaceutical firms' personnel in 2000 (and administration, another 12 per cent).[3] Despite uncertainty about their precise magnitude, marketing costs clearly comprise a large share of total costs. Labour costs (the main element of total marketing costs) vary significantly by country and can therefore be expected to

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[1] Many countries, including Australia, do not allow direct marketing of prescription pharmaceuticals to consumers, though this does occur in New Zealand and the US. Pharmacists may also be the target of marketing where their decisions affect the make of the product sold (as in generic substitution in Australia).

[2] For example, see OECD (2001, p. 22, pp. 30–31) for a broad discussion of their significance.

[3] Harris (2000) estimated that, by 2000, marketing costs were US $7 billion and indicated these were around double that of R&D expenses. PhRMA (2002, p. 18), the major US pharmaceutical industry association, found much higher marketing costs (of US$15.71 billion in 2000), but also indicated that such costs were still only 60 per cent of total R&D costs (which were US $26.03 billion). Families USA (2002) estimated marketing, advertising and administrative costs of US $45 billion for the top nine pharmaceutical companies in the US and R&D costs of US $19 billion in 2001. It is possible that some of the differences stem from the differing definitions of the industry (such as the inclusion of OTC and other business lines in the Families USA study).

contribute to international differences in marketing costs and, in turn, wholesale drug costs.

Relative national incomes (on a purchasing-power parity basis) may also affect the price charged by firms and/or shift the budget constraints applying to public purchases of drugs (Getzen 2001). In general, health care expenditure is relatively responsive to increases in aggregate national income (with income elasticities typically reported above unity[4]) — with the implication that profit maximising prices determined by negotiation with an insurer or government representing the interests of its 'policy holders' will tend to be lower in countries with lower incomes.

Using the seven comparator countries examined by the Productivity Commission (2001), it seems that there is a strong association between pricing differentials and income relativities (figure D.1). Some 92 per cent of the variation in relative pharmaceutical prices is 'explained' by variations in relative per capita income.

While the data suggest the importance of income effects in explaining international pharmaceutical price differences, it should not be seen as implying that there is no price suppression. First, one interpretation of the pattern is that lower relative income countries are more willing to ration supply and pursue cost-containment strategies to keep a cap on government or insurance budgets.[5] Second, were countries to have identical PPP income to Australia, the relationship suggests that prices would still be around 30 per cent lower in Australia, which, among other influences, will reflect price suppression.[6]

---

[4] Kanavos and Mossialos (1996) summarise the broader literature on estimating health expenditure income elasticities (which are usually above one), while Getzen (2001) examines the literature on aggregate pharmaceutical expenditure income elasticities. However, income elasticities at the individual level are often not statistically different from zero. This striking difference in the elasticity estimates may well reflect Getzen's view that the budget constraint is generally the relevant determinant of health care costs at the national level, while insurance, public and charitable provision, and financial pooling within families stops personal income from being a constraint on health care spending at the individual level. Jacobzone (1999, pp. 10–11) makes the complementary point that aggregate income elasticities are really picking up institutional features of health care systems.

[5] Another is that the relative income measures may also be picking up differences in marketing costs, which will be correlated with relative wage rates.

[6] That is, if relative incomes were equal then using the regression results below table 3.1, relative price $=-0.53+1.24 = 0.71$.

Figure D.1   **Pharmaceutical price differences and income differences, 2001[a]**
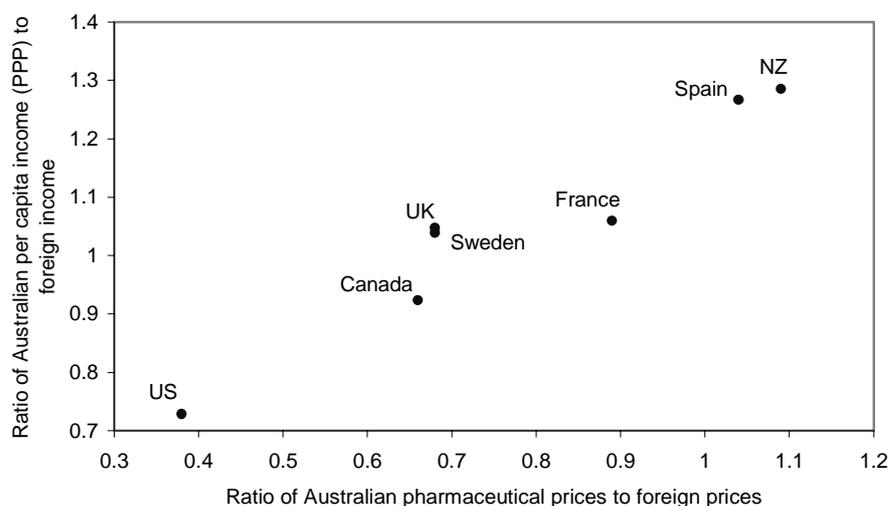
a The pharmaceutical price differences are for the lowest 'all' category from table 3.1 while the income ratios were calculated from income per capita ($US) at purchasing power parity from OECD (2002, pp. 12–13). The linear relationship between relative prices and relative income was (with t statistics in parentheses):

Relative price = −0.53 + 1.24 Relative income; R^2= 0.924.
                    (3.1)   (7.8)

The pattern of international pricing differences apparent for generic drugs also suggests that factors other than price suppression are at work. There is a substantial degree of variation in international prices for generic drugs, notwithstanding that patents have expired for these drugs. This suggests that other factors, such as non-competitive industry structures and cost differences, are important determinants of international price variations (box D.1).

Finally, some survey evidence emerged in past evaluations of the Factor f scheme (the predecessor to PIIP) about the important, but incomplete effects of the PBS buying arrangements in explaining international drug price differentials. Australian pharmaceutical companies claimed that, were pricing to be liberalised, prices would rise, but would remain below world prices and probably still below average European prices (BIE 1991, pp. 38–39). In its 1995 repeat survey of the industry, the BIE (1995, p. 13) found similar results.[7]

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[7] Several participants in the review questioned the relevance of the BIE's estimates, claiming that recent measures, such as therapeutic reference pricing, had deepened price suppression or that the global pharmaceutical market had changed. It is not clear that price suppression has changed fundamentally over this period, though further volume controls appear to have been introduced. For example, the PBPA found that popular products were 67 per cent of the UK price in 1996 (IC 1996, p. 198). These estimates are comparable to those found in the PC's price study (2001). In any case, the relevance of the BIE study is not the exact number, but the conceptual point that price suppression and price difference are not the same.

> **Box D.1   The puzzling story of generic drugs**
>
> The relative price differences across countries for the lowest estimate for generic drugs (which will be copies, not originator drugs) — are very close to those of branded drugs (table 3.1). On first sight, this is surprising:
>
> - the patents have expired, so that the main source of market power has vanished;
> - there is a global market for the active ingredients that are used to manufacture and package generics;
> - trade barriers and transport costs are negligible;
> - the R&D costs required to confirm bioequivalence are very low relative to the original R&D costs involved in bringing the molecule to market. (One firm said it cost around 1/500th of the original cost);
> - there are relatively low entry barriers in establishing formulation and packaging plants for generics;
> - there are some costs in registering a drug, but outside the US these processes are not that prolonged, expensive or elaborate;[8] and
> - there is stiff competition between rival generic manufacturers for the same drug.
>
> In these circumstances, it would be expected that competition would erode any differences in profit margins between different countries, and that averaged over a few years, exchange-rate corrected wholesale prices would be nearly identical across countries. This is not what is observed (even when originator out-of patent drugs are excluded from the analysis).
>
> There are several hypotheses about why this may be so:
>
> - marketing and administrative costs — while usually regarded as less in absolute size for out-of-patent drugs — may still be important as a *share* of total costs (especially given the low value of R&D). This could drive some international differences; and/or
> - there may be residual market power derived from some entry barriers that leads to some above-normal returns to pharmaceutical firms. Differences across countries could then be ascribed to the different intensities of countervailing power used by buyers and market structures for generic production. For example, Sheehan (sub. 15, p. 6) argues that generic drugs are not priced in competitive markets.
>
> Both hypotheses have implications for the existence and nature of price suppression more generally. If either holds, then they must clearly also hold for branded drugs. They reduce the claim that international price differences only stem from differential buyer bargaining power, but could reflect differences in entry barriers and costs.

---

[8] And while the US has relatively complex arrangements — which sometimes have been exploited by brand drug manufacturers — generics have a substantial market share and many firms compete in their supply.

E Adjustment issues

In some industries, most notably the passenger motor vehicle (PMV) and textile, clothing and footwear (TCF) sectors, transitional arrangements have been an important feature of the move to lower assistance levels. Transitional arrangements give the industry and workforce time to adjust to the withdrawal of government support and, thereby, smooth adjustment costs.

Consistent with the approach for these industries, it could be argued that transitional arrangements should be considered for the pharmaceutical industry in circumstances of a significant change to the PIIP.

However, the Commission's recommendation for a modified R&D-only program would continue industry-specific assistance to the pharmaceutical industry.

In addition, there are significant differences between arrangements for the pharmaceutical sector and the PMV and TCF industries that are relevant to the consideration of transitional arrangements:

- subsidy arrangements for the pharmaceutical sector have not been as entrenched as in some other industries (the Factor f program commenced in the late 1980s);

- the PIIP has significantly scaled down subsidies relative to its predecessor, Factor f;

- only a small proportion of firms in the pharmaceutical industry receive PIIP assistance;

- for the firms that do receive PIIP assistance, the rate of assistance is significantly lower than in the PMV and TCF industries (the PIIP provides an average subsidy rate to total industry activity of around three per cent);

- the pharmaceutical industry has been growing substantially over the last ten years; and

- the pharmaceutical workforce is highly skilled and mobile. Indeed, retaining skills in the industry, or within Australia, is generally more of a concern than the impact on the workforce of restructuring.

For these reasons, there does not appear to be a case for transitional arrangements on industry adjustment or other grounds from the withdrawal of subsidies to PVA from any future assistance arrangements.

Nor is withdrawal of support for PVA likely to have a significantly adverse impact on the industry. The industry is built on Australia's comparative advantage in certain niches, such as clinical trials and as a flexible manufacturer of short runs for local and regional markets. This advantage will persist in the absence of the program.

F   A ring-fenced R&D Tax Concession versus a modified PIIP

The model developed in chapter 6 to assess the efficiency of the existing PIIP can be extended to a ring-fenced pharmaceutical R&D Tax Concession. Consideration of the key parameters underlying the model suggests that a modified R&D-only PIIP is likely to generate larger benefits.

Inducement rates — a major key to the size of the benefits — are likely to be greater in a modified PIIP than the concession for two reasons. First, the R&D Tax Concession is a hybrid of an incremental scheme and a base assistance package. Much of the subsidies flowing from the concession is at the 125 per cent level. Lattimore (1997) used data from the BIE to examine inducement rates for the tax concession and found that with a concessional rate of 25 per cent, the program induced around 10 per cent additional R&D for foreign-owned firms (with a bang for a buck of around 1.21). The overall inducement rate with the current hybrid scheme should be higher than this, but is unlikely to be higher than that generated by a pure incremental scheme, as used in the PIIP (chapter 5). Second, the ring-fenced R&D Tax Concession would increase R&D by foreign MNEs only, yet estimates of inducement rates are usually lower for such firms than for domestically-owned firms, as noted by Lattimore (1997) and BIE(1993).

A major obstacle to the efficiency of any industry policy that assists foreign firms are leakages of transfers abroad. As noted in chapter 6, there are several ways in which these leakages may be partly offset under a PIIP-like scheme that may not be replicated by a Tax Concession:

- firms may partly compete away leakages by offering broad activity commitments — such as funding for university degrees;

- grants under the PIIP are sometimes represented by the Australian subsidiary of a foreign MNE as a 'top up' on the listed price of a drug to get above a minimum floor price imposed by head office. In some cases this has allowed a product that would otherwise not be listed to be listed, with consumer (and potentially some production) benefits. This can only occur if receipt of assistance is contingent on price suppression, as is the case with the current PIIP.

A possible factor favouring the R&D Taxation Concession is that as it is uncapped, the total benefits could be higher than a capped PIIP, even if the net benefit per dollar (N) of any subsidised R&D (S) is lower. That is, it is possible that $N_{TC} \times S_{TC} > N_{PIIP} \times S_{PIIP}$ even if $N_{TC} < N_{PIIP}$ (where the TC and PIIP subscripts relate to the type of policy intervention used). However, this could only be true if the net benefit per dollar associated with the tax concession for *this class of firms* is sufficiently positive. Back of the envelope calculations suggest that this is unlikely.

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