MEDICINES Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

Medicines Australia Submission to the Productivity Commission

Evaluation of the Pharmaceutical Industry Investment Program

15 January 2003

Contents

About this Report
This report is the Medicines Australia Submission to the Productivity Commission in response to the Productivity Commission Draft Research Report – Evaluation of the Pharmaceutical Industry Investment Program – released Tuesday 3 December 2002.

Medicines Australia
Level 1
16 Napier Close
Deakin ACT 2600
Ph: 02 6282 6888
Fx: 02 6282 6299
www.medicinesaustralia.com.au

MEDICINES AUSTRALIA: SUBMISSION TO THE PRODUCTIVITY COMMISSION

Executive Summary

1. PIIP has been of benefit to Australia (see Section 1):

   (a) On its own as an investment incentive program to create additional activity;

   (b) In partially addressing the continually worsening operating environment, notably price suppression;

   (c) As part of a much wider impact of Industry development packages (phases I and II of Factor (f), in general; and

   (d) In addressing increasingly negative Industry perceptions of the Australian investment environment – as well as increasing Australia's competitiveness for global investment.

2. PBS arrangements are having an increasingly negative effect on the operating environment in Australia (see Section 2):

   (a) Price suppression is a significant reality;

   (b) Price suppression is compounded by increasing volume restrictions, delays in listing, non-listing, more rigorous economic and financial analysis of submissions, reference pricing and other budgetary measures; and

   (c) The deteriorating PBS environment for industry has a direct, negative impact on local activity.

3. Activities of the industry have wide economic benefits and PIIP compliments other Government innovation and research-based initiatives (e.g. NH&MRC, Biotech).

4. This submission demonstrates that the Productivity Commission has not given due weight to:

   (a) The evidence provided by the industry regarding the positive effects of PIIP;

   (b) The level of price suppression and its real impact on activity and head office perceptions; or

   (c) The impact of the wider PBS environment and how it has worsened over the last 2 years.

5. On the basis of the above points, it is the industry's view that the firm recommendations and conclusions put forward by the Productivity Commission in its draft report about the value of the PIIP are not supported by the body of evidence.

Consequently, Medicines Australia believes that the recommendation against a new program should be removed.

6. Medicines Australia strongly believes that if the Productivity Commission re-examined the evidence and assumptions underpinning its analysis, its conclusion would be that a new industry investment program is justified.

7. To fully address the impact of the worsening operating environment, increased rationalisation and global competition, an investment program of a quantum larger than PIIP would need to be implemented in line with the recommendations of the Pharmaceuticals Industry Action Agenda.

Introduction

Development of the pharmaceuticals industry should be a priority for Australia in terms of both innovation and health.

The prescription pharmaceutical industry is a knowledge intensive industry, which is critical to the Government's innovation agenda.

Changes in the global market, including increasing globalisation of this sector, will mean that Australia must make an active choice for growth, or be left behind as other competing nations benefit. Other countries are demonstrating that they are prepared to take necessary actions to strengthen their competitiveness and to make their countries a better place for doing business. This highlights the importance of a new industry program.

The industry can play a vital role in helping to commercialise the output from research scientists and institutions in Australia and leverage the benefits of the Government's extensive investment in R&D.

As a $12 billion industry, the pharmaceuticals industry is already a major contributor to the Australian economy, employing 35,000 people across at least 300 firms and institutions.

The industry is the second largest exporter of manufactured goods in Australia behind road vehicles and ahead of beverages (including wines), and has the potential to grow more.

A responsible and viable industry is a critical element of the Government's National Medicines Policy, which states:

"*…It is essential that industry policy and health policy be coordinated, providing a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines.*

International competitiveness will only be achieved if Australian industry can operate in a global environment…"

Failure to provide an environment that is perceived to be conducive to investment opportunities will result in a decline in the pharmaceuticals industry, with increased departure of researchers and their research to more attractive markets, limitations to the abilities of start-up companies to pursue drug development at home, and dissipation in manufacturing activity and exports.

Importantly, Australia would be in danger of losing not only a significant part of a $12 billion industry with all the consequential adverse impacts on employment and the trade balance, it will also be losing one of its brightest chances to build a globally competitive knowledge-intensive sector.

It is therefore exceedingly disappointing that, in assessing the industry's environment in Australia, the Productivity Commission has placed little regard on the global context in which the industry operates, or the relevance of the industry to Australia's future economic growth.

In Section 1 of this response, we highlight the positive effects of the PIIP program and the risks in not renewing an industry investment program. In Section 2, we outline the impact of the PBS environment and our concerns with the Productivity Commission's findings regarding price suppression and its impact on activity. In Section 3, we provide an analysis of the wider economic benefits of the industry and the PIIP. Section 4 addresses the economic modeling used by the Productivity Commission, Section 5 discusses the Productivity Commission recommendations for a future scheme and Section 6 provides comments on other issues.

SECTION 1

PIIP has been of benefit to Australia

PIIP has generated investment, jobs, research and development and exports. The Productivity Commission acknowledges the value that the program has delivered.

It has:

(a) Enhanced Australia's ability to compete for global investment;

(b) Created additional activity over the first 3 years;

(c) Cemented the gains achieved under the earlier industry development packages (Factor (f)); and

(d) Assisted in addressing the increasingly negative Industry perceptions of the Australian investment environment.

PIIP has also sustained an Australian-based industry during a period of industry mergers and acquisitions and consequential global industry restructuring of operations.

In many countries competing with Australia for pharmaceutical industry investment, national (and sub-national) government policies are being directed towards supporting the industry in order to attract investment.[1] This is particularly important during a period of industry rationalisation, corporate mergers and capacity underutilisation – all of which characterise the global pharmaceutical industry at present.

The removal of the PIIP and the deteriorating Australian operating environment, characterised by PBS problems, only serves to confirm negative perceptions of the degree to which this industry is valued in Australia.

The industry is disappointed that the Productivity Commission did not give due weight to the global environment in which pharmaceutical companies are operating, or consider the impact the removal of PIIP will have upon perceptions in the context of competing jurisdictions' policies to attract and develop industry activity. This is addressed in more detail in the next section.

PIIP cannot be seen in isolation from its predecessor programs.

Without Factor (f), there would have no substantial base on which PIIP could build. The report does not consider the success of the Factor (f) Program in building capacity in Australia during a period of disinvestment.

[1] See, for example, the *Pharmaceutical Industry Competitiveness Task Force* project in the United Kingdom, and the *Better Health Through Innovation* process underway in Canada.

Since the inception of Factor (f) some 15 years ago, the Australian pharmaceutical industry has gone through a major transformation in direct response to an improved policy environment for the industry. In return for the Government's investment in, and commitment to, industry development programs the industry has:

(a) Built an export base where little existed before;

(b) Stimulated innovation to secure R&D opportunities that have placed, or will place, Australia on a world platform;

(c) Embarked on major capital investment in high-tech manufacturing facilities; and

(d) Created employment opportunities for highly skilled people.

Since 1995-96 alone, more than 2000 jobs have been created, and exports have increased more than three-fold.[2]

The PIIP was put in place at a time when the industry was disinvesting, not a static environment as assumed in the analysis. As a result of this assumption, the Productivity Commission has undervalued the impact of the program in maintaining industry activity in Australia, in an environment of ongoing price suppression.

The Productivity Commission has also questioned the longer term legacy of the manufacturing component of the program saying that *"…while the program has induced some PVA that would not otherwise have taken place, it appears to have been less successful in increasing productive capacity,"*[3] and uses this as a factor to justify non-intervention.

This assessment fails to recognise that adequate plant utilisation has been and will be critical in shielding Australian facilities from rationalisation. Pfizer's experience is evidence of this as is that of BMSA (see Example Box 1.1).

Example Box 1.1

Pfizer's West Ryde production facility

Prior to 1993, Pfizer's West Ryde production facility was one of 40 worldwide. Due to global rationalisation, only 10 were to be chosen to remain open. The West Ryde site was not one of these. Based on the incentives offered by Factor (f), Australia persuaded its parent organisation to include the West Ryde site amongst the ten rationalised sites and make it a regional supplier to Asia.

The listing of Pfizer's new anti-hypertensive Norvasc with the assistance of Factor (f) allowed the facility to ramp up production and develop the capacity to undertake specialised runs as a "fast flexible" plant (one able to quickly produce new products and

[2] Pharmaceuticals Industry Action Agenda, p.7.
[3] p.7.3, PC Draft Research Report, *Evaluation of the Pharmaceutical Industry Investment Program.*

undertake large or small runs). This made it attractive as a location for the production of other products, regardless of whether they were listed in Australia or not.

BMSA in the global context

In 1989, the global merger between Bristol-Myers and ER Squibb & Sons resulted in considerable excess manufacturing capacity. This necessitated a significant rationalisation of worldwide manufacturing facilities. BMSC eventually closed down over half (34) of its manufacturing plants worldwide, including facilities in the United Kingdom, United States (2), Germany (2), France, Canada, Taiwan, South America (2) and South Africa.

However, as a direct result of the achievements and momentum generated under Factor (f), Australia was recognised as a key manufacturing location within the Company's global strategy, and was retained as one of only 32 BMS manufacturing plants worldwide.

In an industry with long lead times, the Productivity Commission's analysis of PIIP is over too short a time frame to provide meaningful findings. The outcomes of Factor (f) are still being realised some years after the cessation of Government funding e.g. the MSD/CSL collaboration and AZ's ongoing activities (see Example Box 1.2).

Example Box 1.2

Merck Sharp & Dohme (Aust) collaboration with CSL

Merck US and Merck Sharp & Dohme (Aust) have been involved in developing the HPV vaccine in Australia for more than a decade, and have exclusively licensed technology developed by CSL and Professor Ian Frazer of the University of Queensland. MSD initiated this collaboration at a time when the Factor (f) program was running. 2002 saw the start of the final Phase III studies of the vaccine in Melbourne and internationally.

AstraZeneca's ongoing activity from Factor (f)

AstraZeneca Australia (then Astra Australia) was a contracted participant during the period 1992 to 1999 (June) in Phase 2 of the Factor (f) scheme.

AstraZeneca Australia was not able to enter the original Factor (f) scheme due to fact that it had just completed substantial investment in manufacturing in the mid 1980's and when Factor (f) was announced had no planned major manufacturing investment in the immediate years. During the period 1992 – 1999, AstraZeneca Australia met or exceeded all criteria and commitments with regard to domestic value added, export value added and R&D, together with specific investment projects in manufacturing. There was further substantial investment beyond the Factor F commitment, which is outlined in more detail below.

Exports

Despite some changes in the product range exported, overall export sales have continued to grow strongly as shown in the chart below. In addition, some new markets have been added, such as Japan. Opportunities continue for further export sales in Asia Pacific and Europe. AZA will become sole global supplier of some product ranges over ensuing years (eg Polybag and PE Polyamp).

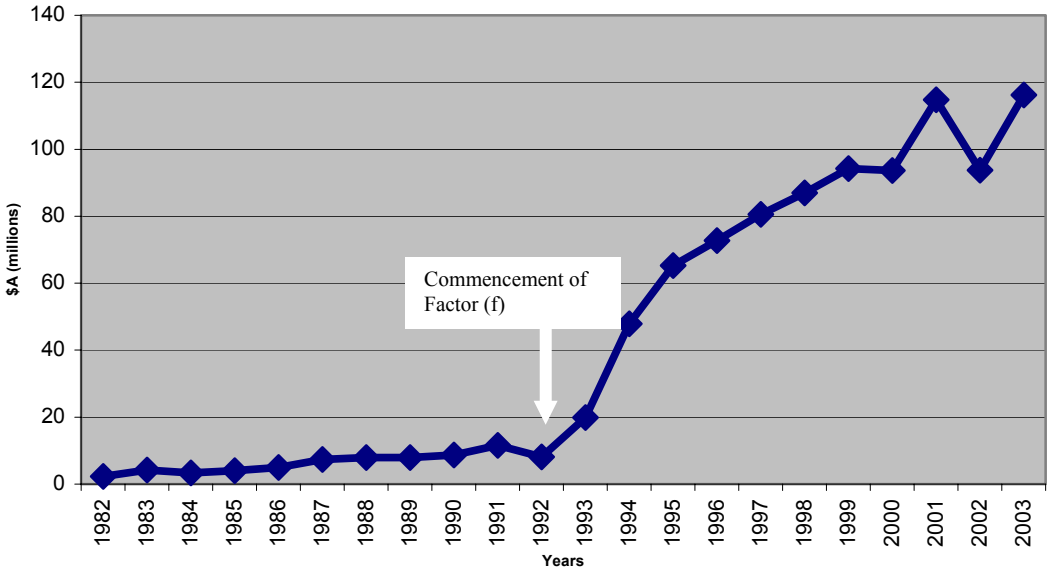


Chart 1: AstraZeneca Australia's Export sales from 1982 – 2002 (and forecasted export sales in 2003)

Manufacturing

Investment has continued in Manufacturing post-Factor (f). A new state of the art sterile manufacturing plant has been built and further investment is currently taking place in extending our building and equipment for tablet packing as well as continued additional investment to support blow filled sealed production for both local and export markets. It is doubtful that without the establishment of AZA as a viable manufacturing unit for export supply (primarily blow filled seal technology) during and as a direct result of Factor (f) that any further investment opportunities in Australia would have been sanctioned by corporate HQ following the merger of Astra and Zeneca in 2000.

Research & Development

The partnership between AstraZeneca and Griffith University was set up as a result of AstraZeneca's (then Astra's) involvement in the Factor (f) scheme. Since the conclusion of the Factor (f) scheme, AstraZeneca has continued to invest in the AZGU partnership (now called the Natural Discovery Unit at Griffith University).

As a result of this funding, the Natural Discovery Unit has been able to leverage Queensland State Government funding for specific projects and university-based funding for research infrastructure and activities.

As well as the obvious benefit of identifying new chemical compounds, which could potentially become new medicines, there are a number of other positive impacts that have resulted from the AstraZeneca and Griffith University collaboration. These include: -

- Investment in buildings and facilities e.g. $5m purpose built laboratory;
- Salary Expenditure of $18m throughout the period;
- Creation of jobs that wouldn't have existed otherwise ;
- Capital Expenditure of $15m throughout the period;
- Expenditure on consumables, repairs and maintenance, thus supporting local suppliers;
- Opportunities given to PhD candidates;
- Development of an understanding of Queensland biodiversity via the Collection Program in collaboration with the Queensland museum and the Queensland Herbarium;
- Research and Training opportunities in different areas of expertise;
- Creation of employment opportunities and career paths; and
- Enabling Griffith University to establish the Centre for Biomolecular Science and Drug Discovery.

In October 2002, it was announced that AstraZeneca would continue its investment in the Natural Discovery Unit at Griffith University. This represents a commitment from AstraZeneca of over $100m since 1993. Had AstraZeneca not been involved in the Factor (f) scheme the establishment of a partnership between AstraZeneca and Griffith University may not have taken place. In addition, AstraZeneca's ongoing commitment to this partnership has had some significant spin-off benefits in terms of infrastructure development, employment, extra funding for further research and upskilling.

The PC's statement that *"failure to renew this industry assistance measure is unlikely to have a significantly adverse impact on the industry"* (p.xxii) is not borne out by the evidence to date and is strongly refuted by industry.

There are many examples of activities which simply would not have occurred but for Factor (f) and PIIP (see Example Box 1.3).

Example Box 1.3

Activities undertaken as a direct result of Factor (f) and PIIP

Growth in research collaborations:

In the case of Pfizer's R&D collaborative program, established entirely as a result of the PIIP program, Pfizer's Global Research and Development division (PGRD) set aside $25 million over five years to spend specifically on early-stage research conducted in Australia. Prior to PIIP, Pfizer had one research collaboration with an Australian biotech company and one with an Australian academic institution. Today, Pfizer has over 45 collaborations with academic research institutions, Government bodies and biotech companies. It is possible that a very small number of these collaborations would have

gone ahead in the absence of PIIP, but certainly the majority can be directly attributable to PIIP. $26 million has already been committed for R&D collaborations, with 18 months of PIIP still to run.

Expansion of clinical research capabilities:

Eli Lilly's Global Clinical Data Management Centre (GCDMC): PIIP was instrumental in capturing this opportunity for Australia. The other location considered was Singapore, already the site of two other Lilly research investments in the past 5 years. 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.

Growth in export markets because of the ability to list a product:

Factor (f) allowed Pfizer to achieve an acceptable price for Norvasc, its leading calcium channel blocker. Norvasc was under consideration for listing but the price offered by the 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 to participate in the second phase of Factor (f) this provided a means through the scheme to raise the price of Norvasc to a level that was acceptable to the Pfizer Head Office. Norvasc is now exported to Taiwan, the Philippines, Singapore, Malaysia, Thailand, Hong Kong and Indonesia. The volume of exports exceeds the volume sold domestically.

It is important to emphasise that Pfizer's steady growth in manufacturing activity would not have occurred without participation in PIIP, and without Factor (f) initially would have been jeopardised completely.

Actives manufacturing:

The Institute of Drug Technology (IDT) has become a significant FDA-approved active pharmaceutical ingredient development and manufacturing company in Australia. It grew out of the Victorian College of Pharmacy. The company produces a diverse range of products, including parenteral grade cytotoxics, non-cytotoxics, antibiotics, veterinary products and biologics. IDT's client base includes several top 20 international pharmaceutical companies.

The impetus for its actives manufacturing originally came from a contract with Pfizer, which was a direct result of Pfizer's participation in the Factor (f) Scheme. This demonstrates that supporting one part of the value chain can have important flow on effects for other sectors.

Source: Pharmaceutical Industry Action Agenda

The Impact of PIIP on Bristol-Myers Squibb Australia (BMSA)

Research & Development

Under the terms of its PIIP contract, BMSA has committed to increase its local manufacturing and R&D activities by more than $200 million over the life of the five-year program in return for a grant payment of $39 million.

In the first three years of PIIP commencing in July 1999, BMSA has increased R&D expenditure in Australia by an average of 80% over a base of $8 million. This growth is almost double again if the final expenditure on LIPID, an exceptional clinical trial commenced during Factor (f), is removed from the base year calculation. BMSA forecasts more than doubling R&D expenditure in the last two years of the program.

PIIP has been instrumental in helping to persuade the internal global committees to involve Australia in more BMS research. Australian clinicians are now involved in more early phase trials, which gives them faster access to novel treatments and the opportunity to share information with their international colleagues.

Manufacturing

In addition to these activities under both Factor (f) and PIIP - and as a direct consequence of them - Bristol-Myers Squibb has invested $40 million in recent years to increase its Australian production capabilities, expand offices and upgrade laboratories and other facilities. As a result of these upgrades, BMSA's manufacturing plant is one of only four in Australia to have met the strict standards of the US Food and Drug Administration (FDA) for approval to export to the US. Due to development funded under Factor (f), in the first year of PIIP, BMSA was exporting to 21 countries. By the expiration of PIIP in 2004, BMSA will be exporting to 75 countries.

Other activity

Activities under the Broad Activity component of PIIP have seen the BMSA operation become a regional hub for shared financial services and information management, and a centre of excellence for the corporation's global research institute. BMSA have also committed to an increase of more than 200 new employees. In this way, given the small size of the Australian market, the local BMSA operation is able to "punch above its weight" in an effort to secure continued growth and global viability.

There are also many examples of activities which have been lost because companies have been unable to access funding from an industry program (see Example Box 1.4).

The absence of a new program will result in further lost activity and opportunity, without improvements in the PBS environment.

Example Box 1.4

Activities lost as a direct result of no PIIP funding

Loss of export markets

Australia did not become the source of supply for many Latin and Central American markets, for MSD's product for the treatment of male pattern hair loss, Propecia.

Loss of computer technology hub

MSD's proposed consolidation of computing infrastructure in Australia to provide improved IT services to other Asia Pacific markets, has now been located in Singapore. This represents a lost investment commitment of around $10 million.

Loss of research collaboration

A proposed research collaboration between MSD and the Garvan Institute did not proceed.

Activity lost due to lack of Factor (f) Phase II funding support

On the basis of the improved standing of BMSA following the implementation of Phase 1 of Factor (f), BMS headquarters gave enthusiastic support to a submission to participate in Phase 2 of the program. BMSA's application was approved but despite this, funding was not forthcoming due to the Commonwealth Government's exhaustion of funds and budgetary restrictions on further allocation. Consequently, BMSA's expansion plans were significantly curtailed.

Like the Phase 1 application, the Phase 2 submission was based on two types of initiatives; Manufacturing and Export and Research and Development:

Manufacturing and Export

Growth of manufacturing and export was to be achieved through a continuation of initiatives commenced in Phase 1, together with the addition of new products with higher value added. The additional export markets proposed were very significant – Europe (UK, Germany, Austria, The Netherlands, Norway and Switzerland), Canada and most of Latin America (excluding Brazil and Mexico). The expanded export program was designed to take exports to a total of $469 million over the 5 ½ years of the Phase 2 program. Total domestic value added for the period of Phase 2 was projected to be $250 million.

In 2003, BMSA estimates that export earnings foregone due to the non-funding of its Phase 2 submission amounts to around $400 million per annum.

Research and Development

The Phase 2 R&D strategy involved several objectives which were to be realised through a focus on a couple of key initiatives, particularly the establishment of the Asia/Pacific Centre for Oncology Research (APCOR).

Lack of funds

Without Phase 2 Factor (f) funding, the opportunity for BMSA to realise its proposed objectives was significantly diminished:

- Export opportunities to North America, Europe and some regional markets were lost or severely curtailed; and

- The opportunity to establish APCOR was lost

This unexpected outcome dealt a severe blow to the status of BMSA and its management in the eyes of the Company and led to a reduction in the credibility of Australia as an investment destination. In this context, it should be appreciated that internal competition between operations for a share of the BMSC global manufacturing and research budgets is intense, so the temporary loss of advantage by one operation may bring about a more prolonged shift in its fortunes.

It is worth noting that these lost opportunities represent lost economic benefit to Australia including lost employment opportunities. It also means that our technology base is below our potential, thereby diminishing our ability to attract and win further investment from MNEs.

Preliminary Recommendation 7.1 is also at odds with the Pharmaceuticals Industry Action Agenda, which sets a path for growth for the industry over the next 10 years.

The Action Agenda recommends the development of a successor to PIIP (Action 4) and notes (at p. 54) that a successor program can be justified on the basis that:

(a) Prices for prescription medicines under the PBS continue to be low in Australia and this use of government purchasing power discourages investment and activity in pharmaceuticals research, development, commercialisation and manufacturing;

(b) Reduced industry activity decreases the desirable spillover effects - this in turn limits the opportunities for commercialisation of Australia's basic research and high paying jobs for graduates; and

(c) Existing support programs do not drive the type of investment in R&D, manufacturing, services and partnerships that are essential to achieve sustainable growth.

In light of the above, Medicines Australia believes Preliminary Recommendation 7.1 should be removed.

The importance of perceptions of the Australian operating environment

The PIIP has played an important role in addressing the impact of negative perceptions of the Australian operating environment caused by the pricing and operating environment.

In reaching its conclusions regarding the future of the PIIP, the Productivity Commission discounts the fact that head office perceptions of the Australian pharmaceutical environment are a key factor in investment decisions.

Discounting this factor leads the Productivity Commission to conclude that no further industry support program is warranted. However, if the Productivity Commission had given due weight to this issue, the need for a successor to PIIP would be immediately apparent due to the unique environment in which the pharmaceutical industry operates within Australia.

Pages 3.27-3.29 of the Draft Report outline the input from companies on the importance and impact of 'perceptions' of the Australian operating environment on the operation of Australia MNE subsidiaries:

"Overwhelmingly, the Commission's consultations with the local subsidiaries of MNEs suggested that their overseas (head) offices had adverse perceptions of Australian pharmaceutical environment…" (p3.27); and

"This suggests that, at least for small markets, head offices may use rules of thumb for investment decision-making." (p3.28)

This section outlines a strong case regarding the problems of uncertainty, achieving PBS listing and subsequent medium and long-term pricing issues (to name a few issues) and their impact on investment decisions. Indeed, the opinion of the industry is unanimous on this issue and its experience of this is widespread.

This is then simply dismissed by the Productivity Commission with the broad statement that *"In general, however, it appears that large MNEs are deliberative and hardheaded in their investment allocation decisions, using decision-making processes that minimise long-run costs."* (Preliminary Finding 3.5).

No evidence or rationale is provided to support this dismissal of the evidence provided by the industry.

There is no modeling used or explanation of why this conclusion is reached and the substantial evidence received to the contrary is discounted or ignored.

Furthermore, evidence and comment contained in other parts of the Report seemingly contradict this finding.

Elsewhere, the Productivity Commission accepts that the operating environment may impact upon investment decisions in small markets:

"... it is conceivable that in some instances head offices may see price suppression and PBS listing problems as a sufficiently adverse signal that – without some countering influence – they require higher implicit hurdle rates for investments to take place in Australia compared with other countries." (p3.29); 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." (p4.18)

This acceptance of the role that perceptions play and the conclusion categorically discounting their importance is contradictory.

Medicines Australia believes the conclusion in Preliminary Finding 3.5 is incorrect and not supported by the evidence outlined by the Productivity Commission in the Draft Research Report. This conclusion detracts from the rigor of analysis contained in the report and should be removed or substantially qualified.

Undervaluing the impact upon R & D investment

While the Productivity Commission's finding regarding the location of production investment (finding 3.3) applies to manufacturing investment decisions, Medicines Australia is also of the opinion that the role of perceptions in siting R&D investment has also been undervalued.

R&D investment is, by its nature, more flexible in terms of its location. Therefore, the role of perceptions in siting this more 'footloose' investment is greater – it not being as subject to a simple or arbitrary model analysis based on costs. It should be noted that, in relation to R & D investment, Australia faces the disadvantages of distance from global centres as well as a lack of critical mass and clustering compared to major research centres such as Europe, Asia and the US. It should also be noted that Australia is already 'underweight' in relation to the amount of R&D that takes place here relative to market size – despite substantial increases over the past decade. Negative perceptions about the Australian operating environment only magnify the difficulties faced when seeking to rectify this.

Medicines Australia believes that the Productivity Commission has not given due weight to the impact perceptions may have on R&D investment – the Productivity Commission should specifically address R&D investment in dealing with perceptions rather than simply use those relating to manufacturing.

The role of Australian MNE subsidiaries

The Productivity Commission's report also fails to understand the environment in which Australia subsidiaries of MNEs operate globally. Australian subsidiaries operate within competitive global organisations in seeking to attract both manufacturing and R & D investment.

Within global corporations, Australian managers seek to attract the attention and support of decision-makers for smaller investments (as opposed to larger-scale investments not within the reach of Australia due to lack of large-scale taxation incentives or market size). When competing globally for such investments, Australian managers need to overcome a perception that the Australian operating environment is not supportive of the industry, and that such decisions are naturally sited in supportive environments.

It is in competing for these investments that 'rules-of-thumb' as outlined by the Productivity Commission are particularly relevant. Yet this actual Industry dynamic has not been taken into account by the Productivity Commission in reaching its conclusions in the Draft Report.

Why are perceptions so important?

The Draft Report outlines the view of the Productivity Commission that one of the problems in dealing with negative perceptions is that they cannot be precisely characterised (p.4.18). The Productivity Commission then uses this inability to measure the quantum or impact of these perceptions as a reason to justify not making a recommendation of a policy response to address them.

The Productivity Commission ignores the impact that the removal of PIIP will have on these perceptions and the longer-term impact this will have on the Australian pharmaceutical industry.

Given that global MNEs' perceptions are having a negative impact upon Australia's ability to attract investment, and the fact that the Productivity Commission has accepted that Australia is susceptible to rules-of-thumb, Medicines Australia believes the Final Report should take into account this evidence offered by the industry and accept that the PIIP scheme has assisted in partially addressing these negative perceptions.

Finally, in Preliminary Finding 4.3, the Productivity Commission contends that it is implausible that mis-perceptions of Australia capabilities are widespread.

The fact that MNEs have had a presence in Australia over several decades does not negate the fact that global decision-makers may form flawed perceptions of Australian capabilities. Indeed, the industry believes that programs such as Factor (f) and PIIP serve to provide a route to address these perceptions as supportive policies of government.

Given the lack of evidence to support Preliminary Finding 4.3, Medicines Australia believes this finding should be removed or substantially qualified accordingly.

In an environment characterised by price suppression, a deteriorating PBS process (which is discussed in Section 2), and a global industry undergoing rationalisation and witnessing increasing competition for investment, the removal of the PIIP will only compound the negative perceptions of the Australian operating environment.

SECTION 2

PBS arrangements are having an increasingly negative effect on the operating environment in Australia

(a) Price suppression is a significant reality;

(b) Price suppression is compounded by increasing volume restrictions, delays in listing, non-listing, more rigorous economic and financial analysis of submissions, reference pricing etc; and

(c) The deteriorating PBS environment for industry has a direct, negative impact on local activity.

The conclusions made by the Productivity Commission on price suppression contradict past conclusions the Commission, its predecessor and other inquiries, studies and experts have drawn.

"The Commission has 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…the Commission has found that there is a case for general Government reform to improve the PBS environment." Industry Commission, 1995, p.lvi.

The report's conclusions also continually go against the preponderance of data pointing to the existence of price suppression, whilst not outlining any strong data to support the Commission's view.

"…there is some evidence to support the view that Australia's cost-containment arrangements, particularly reference pricing, may have contributed to keeping prices relatively low".[4]

Price Suppression

The Productivity Commission understates the price suppression effects of PBS arrangements. The comparison of 1995 survey estimates of 'liberalised' prices in Australia to those of 'non-liberalised' prices in the US and UK forms a convenient base from which the Productivity Commission concludes that there is a non-suppression element of price differences between Australia and the US and UK. The argument is also somewhat academic as the terms of reference ask the Productivity Commission to examine whether the PIIP achieves its objectives of counteracting pricing outcomes under the PBS (page iv) (which have been said by the Productivity Commission to be low relative to other countries (in its 1995 Report on the Industry)). The Terms of Reference do not ask the Productivity Commission to speculate on what level of price difference they think might be attributable to price suppression.

[4] P. XVI, Productivity Commission, International Pharmaceutical Price Differences, 2001.

This finding is also counterintuitive given that the PBS is the major purchaser of pharmaceuticals in Australia (around 80% of the market) and exercises its monopsony purchasing power to impose low prices (lower than those obtained overseas) for new and innovative medicines.

Individual companies often have few options. Even when superiority of a new treatment is established, a company must often either accept a price based on that of an older less effective comparator OR not achieve listing on the PBS. As such, the company is seldom in a position of power when it comes to 'negotiating' a price.

The Productivity Commission acknowledges there is price variation, but is ambivalent regarding price suppression. The fact that new drugs are often compared with either "old" (off patent) drugs of low price, or products that are themselves the subject of price erosion via reference pricing, means that the ability to demonstrate adequate cost-effectiveness to obtain necessary price premiums for new drugs is reduced. This is price suppression via the PBS listing process.

The Productivity Commission also makes a finding that "*Volume effects are likely to significantly counter the impact that price suppression has on pharmaceutical firms' profits.*" This finding is an overstatement when compared with the conclusion in a previous paragraph that *"Such volume effects counteract the effects of price suppression, though it is still likely that the overall impact of price suppression on net revenue remains negative."*

The Productivity Commission has not understood the effects of restricted listings (including Authority Required listings) on volumes obtained via the PBS. This speaks to the claim in the report that any price suppression that may exist is minimalised because listing on the PBS provides compensatory volumes. The Productivity Commission has understood neither the increasing frequency of restricted listings, nor the comparatively restricted markets that result for a product compared to other countries.

The first point was reinforced by Professor Lloyd Sansom recently at the Medicines Australia / Pharmaceutical Benefits Advisory Committee meeting: 70% of submissions to the most recent PBAC meeting were seeking Authority or Section 100 listing. This is driven by the current preference of the PBAC for such restrictions to secure PBS listing.

The second point can be illustrated by numerous examples where the Australian listing or PBAC recommendation is much more limited that the reimbursement of the same product in the UK, western Europe etc. eg osteoporosis drugs, glitazones for Type 2 diabetes etc.

When looking at volume effects the Productivity Commission also overlooks the size of the Australian market (about 1.2% of the world market) and that companies already choose not to seek listing of some new drugs in Australia because both prices and volumes are too low.

Non-price pressures

The significantly changing dynamic of regulation and processes for listing in the past two to three years has led to growing uncertainty and a consequent lessening of confidence in PBS listing process within the industry. Industry considers that research on the impact of this recent period should be undertaken before reliable conclusions can be reached.

The Productivity Commission is reluctant to consider the wider ramifications of the PBS, despite it being pivotal to the viability of the Australian pharmaceutical industry (one of the four pillars of the National Medicines Policy) and consequently critical to the effect or success of any Industry Development Program such as PIIP.

Although one of the express purposes of PIIP was to counteract pricing outcomes under the PBS, the program was not implemented in this fashion. PIIP funding was allocated on the merit of companies' proposals to increase levels of R&D and PVA activity above that which would occur in the then PBS listing environment, not on the level of 'price suppression' incurred by these companies. As such, the PIIP implicitly addressed far more than price suppression. Arguably, the PIIP addressed the general operating environment which is predominated by the PBS process.

The impact of other important elements of the PBS process have not been taken into account in the Draft Report. There has been a significant worsening of conditions for industry over the last three years e.g. reference pricing, restrictions in populations, delayed listings, greater regulation (e.g. DoFA and Cabinet involvement, more sub-committees of the PBAC etc.), price-volume agreements etc. In the last half of 2002 the PBAC introduced additional sub-committees to undertake additional listing-related assessments. This process has become so complicated and resource intensive that it cannot continue without a complete review and restructure.

The report ignores, or fails to investigate, data that illustrates that the problems listing medicines on the PBS have increased in recent years, their impact on industry development and the importance of schemes such as PIIP in addressing these problems.

The industry questions why no new data regarding the PBS and pricing issues has been collected to take account of changes over the past 2-3 years. With the move to Cabinet approval for increasing numbers of medicines, a study of delays and trends in the data over the past 2 years is warranted.

Impact upon activity

Depressed prices and delays in achieving PBS listing (which in Australia is the only effective way to access the major market) are at the forefront of individual company decision-makers' minds. Delays in listing reduce effective patent life and, therefore, the returns on substantial R&D investment.

As the pharmaceutical industry is highly research and capital intensive, any measures that reduce effective returns undermine the ability of local subsidiaries to argue for head

office investment or to undertake discretionary local investment, which may be of particular value to the Australian medical research and biotech sectors. It should be noted that this is an area where both State and Commonwealth Governments are making substantial financial commitments.

Not getting PBS listing means denial of access to both R&D and manufacturing opportunities. For example, clinical trials are often not conducted in Australia due to the fact that PBS listing is either not achieved or substantially delayed.

The following example (Example Box 2.1) of a delay in listing for AstraZeneca highlights the problems faced by companies when this occurs and the likely effects if a listing is not obtained.

Example Box 2.1

Symbicort is a fixed dose combination product of a corticosteroid, budesonide, and a long acting beta agonist, eformoterol delivered by inhalation device (200ug and 6ug respectively delivered per puff) for the treatment of Asthma.

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 AstraZeneca expected PBS listing on 1 August 2002. The individual components in separate devices (as Pulmicort 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 Symbicort was to be less than the sum of actual components (less than the price requested by the company and considered a minimum price for the company) 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 60% of the average price in other markets).

This has enabled the product to be listed from 1 February 2003, a delay of 6 months.

Had there not been agreement on price (and this was deemed very likely), the potential consequences were real and severe, including the unviable market demise of the individual component products (Pulmicort and Oxis) and thus the demise of the company's respiratory portfolio. This would have resulted in no further local R&D investment in the respiratory therapy area by AstraZeneca, including clinical trial activity and the laying off of sales and marketing staff (a marketing manager had already been laid off as the position was seen as becoming redundant).

These consequences are in addition to the clinical consequences of disadvantaged patients and prescribers who would have been denied access to an alternative combination product for the treatment of asthma.

In summary, the draft report inadequately deals with industry concerns about the operation of the PBS by dismissing delay and market access issues. Furthermore, the draft report outlines its disagreement with previous price suppression arguments, but does not contain the data to support this and dissent from previous findings.

Medicines Australia vehemently disagrees with the Productivity Commission's conclusions regarding price suppression given:

(a) The contrary evidence in past reports and inquiries; and

(b) The Government's introduction of a suite of cost-containment measures in recent years – including Therapeutic Reference Pricing, Weighted Average Monthly Treatment Cost, Therapeutic Benchmarking, and risk sharing/price-volume agreements.

Medicines Australia believes that the Productivity Commission should have undertaken a more in-depth analysis around price suppression and listing issues, given that this is central to the conclusions drawn by the Commission.

The preliminary findings around price suppression and the preliminary recommendations of the Draft Report as a whole should be qualified pending such an analysis being undertaken.

Failing this, the Report should contain a recommendation calling for an urgent, independent review of the operation of the PBS environment (including price suppression and listing issues) and its impact upon the level of pharmaceutical industry activity in Australia.

SECTION 3

Activities of the Industry have wide economic benefits and PIIP compliments other Government innovation and research-based initiatives (eg NH&MRC, Biotech)

The Draft Report contains no discussion of innovation, nor the contribution of the industry to supporting the Government's plans in Backing Australia's Ability, NHMRC research funding, biotech priorities and strategic biotech plans at both the State and Commonwealth levels.

There is little or no discussion of the current, or potential, role of MNE pharmaceutical companies in building linkages between domestic biotech companies, researchers and the global market and the potential economic and welfare benefits this would present.

There is immense value to be realised in forging a closer relationship between the Australian research community and pharmaceutical companies. Many such alliances and collaborations have been built in direct response to the Factor (f) and PIIP industry programs and a new program will be critical to maintaining this momentum and compliment the Government's existing focus on the biotech sector.

By matching Australia's excellence in science with the industry's experience in getting products to market, the basis for a sustainable Australian biotech sector can be established.

KEY R&D COLLABORATIONS WHICH WOULD NOT BE IN EXISTENCE TODAY WITHOUT THE SUPPORT OF INDUSTRY PROGRAMS

Astrazeneca

The AZGU project between AstraZeneca and Griffith University in Brisbane is an example of a major collaborative research venture. Laboratories have been established and high technology equipment installed for over 40 researchers using High Throughput Screening technology and advanced systems for chemical isolation and structure identification of plant and marine organisms from Queensland rainforests and the Great Barrier Reef.

This represents a commitment from AstraZeneca of over $100m since 1993.

The success of the venture is due to a number of factors - a strong local champion, government assistance through the Factor (f) Scheme to open doors at the corporate headquarters and obtain Head Quarters (HQ) resourcing, and building on Australia's competitive advantage of unique flora and fauna.

Pfizer

In the case of Pfizer's R&D collaborative program, established entirely as a result of the PIIP program, Pfizer's Global Research and Development division (PGRD) set aside $25

million over five years to spend specifically on early-stage research conducted in Australia. Prior to PIIP, Pfizer had one research collaboration with an Australian biotech company and one with an Australian academic institution. Today, Pfizer has over 45collaborations with academic research institutions, Government bodies and biotech companies. It is possible that a very small number of these collaborations would have gone ahead in the absence of PIIP, but certainly the majority can be directly attributable to PIIP. $26 million has already been committed to R&D collaborations, with 18 months of PIIP still to run.

Eli Lilly

The Clinical Outcomes Research Institute (CORI) was established here as part of Eli Lilly's PIIP program with the specific aim of supporting clinical research across the Asia Pacific area. Since establishment, the scope has changed somewhat, to focus more on Phase IV trials but over a wider geography (all the world excluding US and Western Europe).

As well as expanding the quantity of clinical trial activity being conducted within Australia or supported by Australia, CORI also expanded the company's clinical research capability. This is best described as vertical integration of all clinical research activities eg protocol design, IT development, database design, data collection, data analysis, statistical services and report / publication writing.

Australian MNE subsidiaries have the unique ability to help remedy the existing gap in venture capital and skills.

Limited available venture capital for Australian innovation creates a chasm in Australia's pharmaceutical / biotech commercialisation process.

It is estimated to cost approximately $US 802 million to bring a new drug to market. Much of the cost is in the "D" phase and involves large scale, worldwide clinical trials.

The Australian capital market is not large enough to support an Australian biotech company in bringing a product to market. Some academic work done by the Centre for Strategic Economic Studies has found that most Australian biotech companies only raised amounts of up to $AU15 million, over the 4 years from 1998 to 2002. The top amount raised was a mere $AU55 million. This starkly contrasts with the $US802 million needed to commercialise a single drug.

Global companies have the ability to fund such projects through to completion.

Successful Australian innovation in the pharmaceutical and biotech sector will require partnerships and alliances between Australian companies and global companies who can bring commercialisation skills, which has been identified as a major hurdle.

Developing Australian biotech companies frequently lack the expertise necessary to successfully commercialise a product. Namely, in the critical areas of:

(a) Regulatory and marketing issues;

(b) Manufacturing expertise; and

(c) Development of human capital with experience in industrial research and business management skills.

Global research based pharmaceutical companies have excellent skills and experience in these precise areas. The industry is a part of the infrastructure that the Government is seeking to build.

It can be argued that the credibility gained on financial markets from successful global commercialisation of even one locally developed pharmaceutical agent would disproportionately accelerate the maturing of our biotechnology sector, and its investment attractiveness, and the development of an indigenous Australian biotechnology industry.

These benefits from investment by MNEs in Australia supported by the PIIP were undervalued in the spillover analysis contained in the Draft Report.

Preliminary Finding 4.1 should be amended to:

- Take greater account of the reliance of Australia's medical research and emerging biotech sector upon a strong Australian pharmaceutical industry as an enabler for commercialisation of research, skills transfer and financial support; and

- Remove the second sentence which is not supported by any evidence contained in the Draft Report.

SECTION 4

Economic Modeling issues

Medicines Australia commissioned Access Economics to undertake an analysis of the Productivity Commission's Draft Report. (A copy of the report is attached, see Appendix 1).

Access Economics has specifically commented on the Productivity Commission's analysis of the effectiveness and efficiency of the PIIP.

This report concludes that the Productivity Commission's strong statements of findings regarding the PIIP are unwarranted given the Productivity Commission's reliance on a regression analysis on a very limited data set (signifying very large confidence intervals).

Access Economics goes into a far more detailed analysis of the economic modeling undertaken by the Productivity Commission. The fact that the Productivity Commission has relied on an analysis of PIIP versus non-PIIP companies to determine incremental benefit from the program leads to uncertainty about the results generated. As such, it also cast doubt on the conclusions reached and the recommendations made.

Access Economics Findings

The Access Economics finding are as follows with regard to the effectiveness of the PIIP:

> The regression anaylsis is based on a very limited dataset. Despite this, the commission is able to make strong positive findings about the program.
>
> Given the risks attaching to making a regression analysis, we would have expected the commission to have had made more use of case studies of the behaviour of participants and non- participants.
>
> We therefore conclude that the commission has not fully evaluated the PIIP's effectiveness in achieving all its underlying objectives – notably those with possible long-run strategic significance.

And with regard to the efficiency of the PIIP:

> It is entirely appropriate for the commission to seek to measure the net economic benefit to Australia resulting from the PIIP. However, (as the commission is aware) this is an extremely difficult undertaking.
>
> The commission claims to have used "a standard social benefit-cost framework to assess the efficiency (or net social benefits) of the program" (overview p xxi). However, it nowhere reviews carefully the theoretical basis of its equation for net social benefit (Box 6.2).

We suggest that this leaves it open to criticism that it has ignored potentially significant short run and economy-wide impacts.

The detailed application (Chapter 6.2) also appears somewhat deficient, even with its own terms.

In short, we do not believe the commission has yet satisfactorily demonstrated that "it is likely that the program generates net costs for Australians".

In assessing the Net Benefit Methodology Access Economics concludes:

A simple spreadsheet calculation suggests that these adjustments[5] might improve the overall net social benefit of the program by around $50 million over the three year period. This would more than offset the estimate of negative total net benefit (-$42.8 million) in the commission's base case.

This one correction illustrates the possible pitfalls of drawing strong conclusions from the commission's present analysis.

Medicines Australia believes the economic analysis of the Productivity Commission and its conclusion regarding the PIIP and its net social benefit are open to question. Given the limited data available to the Commission, greater weight should have been accorded to case studies in analysing the effectiveness of the PIIP.

[5] 'A careful reworking to reclassify a portion (30%) of induced value added to producer surplus that would not be earned in the absence of PIIP. The whole of that accruing to Australian companies would then be included as net benefit in the calculation as well as the company tax paid on the portion accruing to foreign companies.' See Access Economics Report page 8.

SECTION 5

A future industry investment program (Preliminary Recommendation 7.2)

Medicines Australia supports the recommendation for a new PIIP, but believes the design suggested by the Productivity Commission is not the appropriate starting point.

The Pharmaceuticals Industry Action Agenda should be the starting point for any discussion of a new program, as this was the result of extensive stakeholder consultation and input.

The Action Agenda spells out the principles that should guide the development of any new industry development program. The principles are as follows (p.55 Action Agenda):

- establishing a firm commitment by Government and Industry to the first five years of the program beginning 1 July 2004, with an in principle commitment for a full ten-year program;
- being accessible for all parts of the value chain;
- building partnerships and collaborations among major companies, small firms and Australian research institutions;
- improving and increasing commercialisation of the outcomes of Australian research;
- addressing gaps in infrastructure;
- strengthening the investment by multinationals in Australia by encouraging the establishment of global hubs in R&D, manufacturing and services;
- encouraging high quality activities most likely to enhance the sustainability of the Australian industry and with most spin-off benefits for the Australian economy;
- having flexibility to support substantially more companies than have been supported under either the Factor (f) Scheme or the PIIP; and
- complying with WTO requirements.

Industry has also outlined a set of criteria that it believes should form the basis of any new industry development program (Appendix C of the Pharmaceuticals Industry Action Agenda).

The Productivity Commission's suggestion of a program with duration of 5-6 years is at odds with the principles laid out in the Action Agenda.

Industry has sought an "in principle" commitment to a 10-year industry development program (with 5 years of firm funding) to provide certainty and stability and to make us internationally competitive.

The rationale for this is best explained at p. 23 of the Action Agenda document.

"The pharmaceuticals industry operates on long development times and product cycle times, in contrast to the IT industry, where a product can be obsolete within a year of launch. The discovery, development and manufacture of therapies for human use is a high-risk, high-cost activity taking from 10-15 years to complete. The three to five year life of most government programs does not fit comfortably with the industry's investment decision cycles that require greater medium to long-term stability. Australia is often unfavourably compared with Singapore in this regard, as Singapore structures its assistance packages around at least 10-year timeframes."

In addition, the Pharmaceutical Industry Action Agenda outlines the limitations of PIIP in addressing wider industry problems because of its application to a small number of companies and that 'the size of PIIP (at $300m over 4 years) is not the compelling incentive required to maintain and grow the industry over the next decade – it may only slow down the level of investment.

Medicines Australia considers that any new industry development program should build on past programs whilst addressing the findings of the Action Agenda to better meet the needs of the Industry and deliver greater benefit to Australia.

Medicines Australia considers that Preliminary Recommendation 7.2 should be replaced with a recommendation that a new PIIP be developed using the principles detailed in the Pharmaceutical Industry Action Agenda.

SECTION 6

Other issues

- **Preliminary Recommendation 7.3 – Clause (f)**

Medicines Australia does not support this preliminary recommendation. The Commission argues that the clause is redundant with the PIIP in place whilst recommending the removal of PIIP.

The Commission should not make recommendations with regards to isolated parts of the PBS process without regard to the general listing environment.

Removal will add to negative head office perceptions about the environment.

Medicines Australia considers that Preliminary Recommendation 7.3 should be removed from the final Productivity Commission Report.

- **Preliminary Recommendation 8.1 – access to the R&D tax concession**

Medicines Australia supports this preliminary recommendation as it is consistent with concerns raised through the Action Agenda (see p.42 of the Action Agenda).

There were a range of taxation issues raised throughout the Action Agenda process. The Operational Note at p.76 of the Action Agenda document proposes that industry establish a joint working party to report to the Action Agenda Implementation Group and the Pharmaceutical Industry Working Group on those parts of the tax system that are impeding industry growth.

Medicines Australia supports Preliminary Recommendation 8.1 whilst noting that significant fundamental changes would need to occur to this program to enable industry access.

- **Preliminary Recommendation 8.2 – generic drug exports within patent period.**

Medicines Australia argues that this recommendation should be removed:

(a) The recommendation is drawn without any analysis or background supporting data being provided.

(b) It is questionable whether this recommendation falls within the Terms of Reference.

(c) Given the Commission's reluctance to take up other issues, such as the PBS processes, that have a much greater impact upon the operating environment within Australia, it is inappropriate to comment on issues outside the terms of reference without supporting data and extensive consultation with the industry on this matter.

(d) The Government has seen this as an issue important enough to set up a separate IDC and stakeholder consultation to review and assess. As such, an unsupported recommendation by the Productivity Commission, outside of this IDC process, is inappropriate.

(e) The Commission's recommendation goes beyond that proposed by the Generic Manufacturers' Industry for Government consideration. That is, to allow for springboarding within the patent extension period only.

(f) In addition, Medicines Australia has serious concerns about the genuineness of the supposed export opportunities that the proposals may offer. Medicines Australia members include a number whom also manufacture generic pharmaceuticals. These members have cast serious doubt whether they, or any other Australian generic manufacturer, have the capacity to make significant additional export gains through this measure. These manufacturers suggest that changes in taxation arrangements, rather than changes in patent laws, are more likely to bring additional investment to Australia.

Medicines Australia considers the Productivity Commission has made Preliminary Recommendation 8.2 without the consultation and expertise to be able to make an informed recommendation. As such, this recommendation should be removed from the final report.

APPENDIX 1

Productivity Commission Draft Research Report
Evaluation of the Pharmaceutical Industry Investment Program

Prepared for

Medicines Australia

by

Canberra
January 2003

CONTENTS

While every effort has been made to ensure the accuracy of this document, the uncertain nature of economic data, forecasting and analysis means that Access Economics Pty Ltd is unable to make any warranties in relation to the information contained herein. Access Economics Pty Ltd, its employees and agents disclaim liability for any loss or damage which may arise as a consequence of any person relying on the information contained in this document.

1. INTRODUCTION

In this report we provide comments on aspects of the analysis in the Productivity Commission's Draft Research Report Evaluation of the Pharmaceutical Industry Investment Program. Specifically, we comment on the commission's analysis of the effectiveness and efficiency of the program in chapters 5 and 6 of the draft report.

We do not review here the commission's broader arguments that:

- question the traditional rationale for assistance to the pharmaceutical industry to compensate for the loss of economic efficiency caused by "price suppression"; and that
- generic programs such as those administered by Invest Australia should be adequate to foster industry development.

As the commission comments,

> *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 substantial R&D intensity by Australian manufacturing standards. It has strong global orientation through ownership links to multinational enterprises (MNEs) and through increasing exports, especially to the Australia-Pacific region. (Overview p xv)*

Support for the industry's development might therefore be seen as likely to be in Australia's long-term strategic interest.

Hence, irrespective of the precise rationale for the program, it is of concern that the commission finds that:

A. the PIIP has been moderately effective in stimulating R&D and value added; but that;

B. despite its modest budgetary cost, the program has generated net social costs in its first three years of operation.

It is therefore important to establish the robustness (or otherwise) of the commission's methodology and findings as they relate to the program's effectiveness and efficiency.

2. CHAPTER 5: EFFECTIVENESS OF THE PIIP

Chapter 5 reports the commission's preliminary results of empirical testing of the effectiveness of the PIIP in achieving its objectives.

The commission focuses on the impact on major economic aggregates (value added, exports, employment, R&D expenditure, investment etc.). It uses regression analysis to examine differences in behaviour of PIIP participants, unsuccessful applicants for PIIP and other firms in the industry. It tests a variety of hypotheses on different configurations of the data.

> The regression analysis is based on a very limited dataset. Despite this, the commission is able to make strong positive findings about the program's effectiveness.

The main concern with the commission's approach is the small number of observations in the dataset. There are only 9 PIIP participants and 10 surviving unsuccessful applicants. The commission had survey responses from only 9 non-participants (since risen to 10). These are very small numbers on which to base a statistical analysis.

There is a serious risk, moreover, that the underlying assumption – that the observation errors are independent random drawings from the same underlying normal distribution – does not hold. The number of observations is probably too small to allow confident testing of this. If the assumptions about the distribution of random errors do not hold exactly, many of the statistical tests might still have asymptotic validity. However, this highlights again the problem of the small data sample at the commission's disposal.

The commission acknowledges that the less than complete survey response, "combined with the inevitable inaccuracies that affect all surveys, the small number of firms in the program, and the impacts of mergers and selection biases, make empirical analysis of the PIIP especially vulnerable to error." (Draft report p 5.9)

We strongly agree with this sentiment.

It is notable then that, despite the inadequacy of the data, the commission is still able to make quite strong findings about the effectiveness of the program in inducing additional value added and R&D.

> Give the risks attaching to use of regression analysis, we would have expected the commission to have made more use of case studies of the behaviour of participants and non-participants.

The commission's quest for quantitative assessments of parameters leads it to downplay the role of case study analysis of the behaviour of participants and non-participants. The commission has not

sought to understand the nature of the changes underlying the headline reports of activity and R&D, nor the reasons for variations in performance relative to expectations.

Case studies could also have been used to explore issues of resource use, opportunity costs and spillovers that are central to the subsequent analysis of net economic benefit.

The program's underlying principles refer to objectives of:

- encouraging high value adding per unit activity over lower value adding per unit activity;
- undertaking additional activity that is different in scope from existing activity, or is new to the company and of 'significance' to its operations and/or its position in the global environment.

The analysis in Chapter 5 throws little light on these issues.

Since it is limited to hard data, the commission can also form no reliable view about possible longer term impacts of the program beyond its initial three years. It places weight on the PIIP's (variable and apparently often small) impact on fixed investment levels. But it does not go beyond this to investigate to what extent the PIIP has achieved its Principle 4, namely:

- to encourage a sustainable pharmaceutical industry in Australia, undertaking activity which is internationally competitive and of benefit to Australia.

We therefore conclude that the commission has not fully evaluated the PIIP's effectiveness in achieving all its underlying objectives. – notably those with possible long-run strategic significance.

3. CHAPTER 6: ECONOMIC EFFICIENCY OF THE PIIP

It is entirely appropriate for the commission to seek to measure the net economic benefit to Australia resulting from the PIIP. However,(as the commission is aware) this is an extremely difficult undertaking.

The commission claims to have used "a standard social benefit-cost framework to assess the efficiency (or net social benefit) of the program" (Overview p xxi). However, it nowhere reviews carefully the theoretical basis of its equation for net social benefit (Box 6.2).

We suggest that this leaves it open to criticism that it has ignored potentially significant short run and economy-wide impacts.

The detailed application (Chapter 6.2) also appears somewhat deficient, even within its own terms.

In short, we do not believe the commission has yet satisfactorily demonstrated that "it is likely that the program generates net costs for Australians".

3.1 SECTION 6.1: THE MEANING OF EFFICIENCY AND NET SOCIAL BBNEFIT

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.

The impact on economic welfare is normally defined as the net impact on the wellbeing of Australian households[1]. As the commission argues, the resources used in the industry (especially the labour) would most likely be employed in some other industry, if they were not used to make pharmaceuticals. Hence it is only the net increase in real incomes that is relevant to the assessment of net benefit.

In the Appendix we summarise the standard economic approach to measurement of economic welfare and its relationship to cost benefit analysis.

The general equilibrium approach to assessing economic welfare

The rigorous approach to the measurement of economic welfare involves comparing the overall welfare of Australian households under two different states of the world – with and without the PIIP. The most comprehensive way to compare economic welfare in two scenarios involves using a general equilibrium model of the economy[2]. However to make such a model operational, the constraints that

[1] See any good advanced microeconomic text, for example: G.D. Myles Public economics, Cambridge University Press, 1995

[2] The comparison focuses on the amount of money households collectively require to make them indifferent to the choice of scenario. Technically this is known as the compensating or equivalent variation.

need to be imposed (on assumptions about household utility and on markets and production[3]) are so strong that they are unlikely to be satisfied in the real world. Moreover, the real world is in a state of dynamic evolution, not equilibrium. There is for example no role for R&D in a general equilibrium model, since all technologies are already known.

The commission itself exploits these limitations in arguing that the traditional justification for pharmaceutical industry assistance based on economic inefficiencies resulting from price suppression has no sound theoretical basis. It argues that we cannot demonstrate that economic welfare would increase if activity levels were "restored" to those that might apply if there were no PBS.

The general equilibrium model is generally seen as applying only in the long run. However, the real world is composed of a succession of short runs that may not converge to a particular long run. In the short run (such as the three year horizon considered by the commission), idle resources can be brought into play; use of capacity can increase; and there are limited opportunities to retrain staff. It is inappropriate to assume that resources in the short run are fully employed in alternative activities. Hence increases in activity in a particular industry may well result in net increases in economic wellbeing.

The commission does not use a general equilibrium approach to assessing the net economic benefit of the PIIP. This is not because it believes that the short run (three-year) focus of its quantitative analysis makes a long run equilibrium approach inappropriate. Rather, it argues that market failures in pharmaceuticals make it especially difficult to establish that the general equilibrium conditions are satisfied in the industry[4].

While this is a reason why it is difficult to define the socially optimal level of activity in the pharmaceutical industry itself, it is not a reason for abandoning the general equilibrium approach to assessing the economy-wide net impacts of given configurations of activity in the pharmaceutical industry.

For example, if the PIIP results in additional substantial import substitution by the pharmaceutical industry, then this will raise the real exchange rate. This in turn will tend to crowd out other exports, but will also increase imports and real consumption by households[5]. The (likely positive) net impact on welfare of these economy-wide adjustments can only be assessed using a general equilibrium model. Their impact on economic welfare then needs to be set against the impacts generated by the initial adjustments in the pharmaceutical industry and factor markets, and the government's need to fund the intervention.

---

[3] Producers are price takers, face diminishing returns to scale, and have perfect knowledge of technology and market opportunities. There are no market failures (e.g. distortionary taxes and subsidies; non-existent markets; nor externalities not reflected in market prices).

[4] The commission's net social benefit equation (Box 6.2) includes a MARGIN term that is described variously as "the difference, if any, between the private post PIIP rate of return on induced activity compared with alternative uses of those resources" (Box 6.2) and as "the difference between the social rate of return on additional resources used in producing induced value added and R&D, and their alternate use outside the industry" (p. 6.5) (emphasis added) The Box 6.2 definition indicates a cost-benefit provenance. The text definition hints at a wider purpose (maybe based on some sort of general equilibrium reduced form). The obscurity of the MARGIN term is an additional factor making it hard to the adequacy of the commission's analysis.

[5] Note also that an increase in the real exchange rate reduces the real burden of foreign debt owed by Australians. This also is a source of improved economic wellbeing.

Cost benefit analysis

The alternative to an economy-wide general equilibrium approach is a sectorally focussed cost benefit analysis. The commission's net benefit equation would appear to be broadly based on cost benefit principles.

Cost benefit analysis also compares two scenarios – again scenarios with and without PIIP. The focus of cost benefit analysis is on the direct consequences of the program for the pharmaceutical sector. However, it should also include flow-ons to other markets, where these are likely to be substantial.

Cost benefit analysis involves expressing costs and benefits of the program's impacts in money terms, so that they are comparable with one another. By summing the money values of costs and benefits a single estimate of a program's net benefit results. We conventionally consider only those impacts that can be quantified with reasonable accuracy. Other impacts are excluded from the formal analysis, but may be included in the overall judgmental assessment of the program.

The analysis involves estimating the net present value of the overall social return to a project. The general presumption would be that the social cost of additional inputs to the pharmaceutical sector, and the social value of the additional outputs, can both be valued at market prices. If this is everywhere the case, then the commercial return to the industry is the same as the social return, and there is no case for governments seeking to modify commercial decision making through a program such as PIIP.

However, the social return may differ from the commercial return, where:

- market prices do not accurately reflect the opportunity cost of an input. (For example a project may draw on underutilised labour. In this case the opportunity cost of the labour input may be less than the wages paid); or
- some consumers value an output at more than the amount they must pay for it. (This is the concept of consumer surplus); or
- some producers make profits above the cost of the resources valued at market prices ("producer surplus"), or
- there are costs or benefits to households (externalities) that do not reflect directly in the prices of project inputs or outputs. Environmental or health impacts often fall into this category.; or
- there are higher or lower net transfers from overseas to Australian residents, or governments, or changed local availability of public goods, as a result of the program.

Each of these differences between private and social cost or benefit needs to be quantified and summed to give the net excess (or deficit) of social, compared with private, return. For further details of the cost benefit approach see the Appendix.

Cost benefit analysis involves the concepts of consumer and producer surplus. However, earlier, we indicated that the more comprehensive general equilibrium approach measures the wellbeing of households in terms of utility and derived money measures (compensating and equivalent variation). The question arises: what is the relationship of consumer and producer surplus to the more comprehensive measures?

The short answer is that they are nearly the same, if we make enough simplifying assumptions. It turns out, moreover, that the key simplification is that, by confining attention to a single (or small

number of) market(s), there is an assumption that changes in prices in other markets are negligible. This is precisely the simplification that the commission makes in its assessment of net benefit of PIIP.

3.2 SECTION 6.2: NET BENEFIT METHODOLOGY

In reviewing the commission's use of cost benefit methodology, the questions we need to ask are:

A. are the simplifying assumptions necessary to justify the commission's use of a partial cost benefit approach rather than an economy wide general equilibrium approach sufficiently satisfied? and

B. is the commission's analysis a sound application of the cost benefit methodology?

Our response to (A) is "No!" The PIIP has a sufficiently large impact on net exports of pharmaceuticals (and hence on the real exchange rate) that it is unwise to ignore the possibility of substantial economy-wide general equilibrium effects.

On (B), viewed through a cost benefit lens, each of the terms in the commission's net benefit equation (Box 6.2) seeks to measure an appropriate concept.

However, there appears to be some looseness in commission's detailed application, perhaps reflecting the fact that the approach has been carried over largely unchanged from earlier similar analyses by the commission and its antecedents. In particular, the commission has not fully grappled with the consequences of having only a short run of data on the program's impacts.

We highlight this in relation to the commission's radical assumption that induced production value added has brought no net economic benefit.

Production value added

The main point at which the additional production value added enters the assessment of net benefit is through the MARGIN term. This is defined as the difference between the social rate of return on additional resources used in producing induced value added (and R&D) and their alternative use outside the industry.

This is shorthand for many complex effects that impact on economic welfare – including the general equilibrium effects that the commission omits from the analysis. There is also a considerable tension between the short run focus of the commission's empirical analysis and the long run equilibrium concept underlying the concept of differential social rates of return.

It is illuminating to apply the cost benefit methodology more strictly.

The starting point of the analysis is the private return to net additional production in the pharmaceutical sector. This is given by:

ADDITIONAL PRODUCTION VALUE ADDED

plus

PIIP SUBSIDY

less

ADDITIONAL PAYMENTS TO LABOUR
USER COST OF ADDITIONAL CAPITAL DEPLOYED IN PHARMACEUTICALS
ADDITIONAL COMPANY TAX

From a cost benefit standpoint, the commission assumes that (apart from the PIIP subsidy on non-induced activity that leaks to foreigners) this private return exactly matches the equivalent social return to the same resources deployed elsewhere in the economy.

Given the complexities, we have some sympathy for this. However, we believe it is too simple a view:

1. the commission comments that the PIIP has not led to an expansion in pharmaceutical production capacity. Rather the increased production has led to an increase in utilisation of existing facilities. This suggests that little extra capital has had to be deployed in the pharmaceutical sector – implying that the additional user cost is correspondingly low;
2. likewise, the commission finds that PIIP has had little net impact on industry employment. This suggests that that utilisation of existing labour has increased, rather than labour being drawn from other parts of the economy;
3. according to industry data reported in the Action Agenda, wages account for only about 40 percent of industry gross product[6]. It is likely that the remaining 60 percent includes a substantial return to firms' knowhow, as well as the required return on physical capital. While we do not know the proportion of the PIIP's production value added that is gross operating surplus, we conjecture that it is likely to be substantial. For the purposes of the cost benefit analysis, the return on firms' knowhow is equivalent to producer surplus. It does not represent a resource cost that must be drawn from the rest of the economy. Nor could an equivalent return be earned if it were redeployed to some other sector of the economy.

A careful reworking would, we suggest, classify a substantial part (say 30 percent) of the induced value added as producer surplus that would not be earned in the absence of the program. The whole of that accruing to Australian companies would then be included as a net benefit in the calculation, as would the company tax paid on the portion accruing to foreign companies. The whole of the additional company tax paid on producer surplus would go to offset the net funding requirement in the FINANCING term of the cost benefit equation.

A simple spreadsheet calculation suggests that these adjustments might improve the overall net social benefit of the program by around $50 million over the three year period. This would more than offset the estimate of negative total net benefit (-$42.8 million) in the commission's base case.

This one correction illustrates the possible pitfalls of drawing strong conclusions from the commission's present analysis.

Although it is pressing our rough calculation to its limits, we note, moreover, that about half of the adjustment reflects the induced producer value added of the Australian PIIP participants. This would

[6] ABS data on the human-use pharmaceutical manufacturing industry at Table 1.1 of the commission's draft report tell the same story.

appear sufficient to make their net social benefit from the program positive. The net social benefit of the payment to foreign firms would remain negative, but less so than at present.

If we follow the commission in assuming that the additional production does not result in any change to prices (and hence to consumption) of pharmaceuticals in Australia, there is no change in consumer surplus under the PIIP. However, we note that this ignores possible general equilibrium effects on consumers' real incomes and on relative prices elsewhere in the economy.

Rather, the additional production displaces imports or increases pharmaceutical exports from Australia. This means that the changes in producer surplus identified above have a direct counterpart in foreign exchange flows. This would we suggest reinforce the argument in favour of treating them as a specific addition to economic welfare, along the lines suggested above.

Other issues

This end piece contains brief notes on other issues that may be relevant to the assessment of effectiveness and efficiency.

1. The commission makes no allowance for any net benefits from production value added beyond the three year horizon. This is clearly a rather conservative assumption. The source of benefit identified in the previous section would continue for the life of the program. Case studies of the circumstances of individual PIIP participants would allow the commission to judge to what extent benefits might continue beyond the program's expiry.
2. A potential source of social benefit not considered by the commission is any improvement in the health of Australians that results from the R&D induced by the PIIP. Benefits of this kind would seem more likely to arise from R&D funded by the pharmaceutical sector than from R&D funded by other industries. The commission only considers the commercial spillovers from R&D to other producers of goods and services.

Access Economics

January 2003

4. APPENDIX: MEASUREMENT OF NET ECONOMIC BENEFIT

4.1 DEFINITION OF NET ECONOMIC BENEFIT – THE ECONOMISTS' APPROACH

An economist naturally equates "net economic benefit" with economic welfare. This we identify in terms of the economic welfare of Australian households.

4.1.1 The general equilibrium approach to assessing economic welfare

In standard economic theory[7], households gauge their welfare by setting a value ("utility") on each bundle of effort, leisure, and the consumption of goods and services. They then choose bundles of consumption, effort and leisure that maximise their utility – given the prices and wage rates that they experience, and their initial endowments of human and non-human wealth.

If we add some rather simple assumptions about production and markets[8], the economy generates a "general equilibrium" that is also a "Pareto optimum" in welfare terms. This means that we cannot reallocate goods to make one household better off, without also making some other household worse off.

Making the theory operational requires further simplifying assumptions. For example, we can assume that a household's utility function is the same at each point in time, and that the household has a constant rate of time preference (i.e. a discount rate). This allows us to express a household's utility as the net present value of the utility of current and future consumption.

We need to impose severe restrictions on the individual utility functions if we want to make clear statements whether society as a whole is better, or worse, off as a result of some change. It turns out that, to do this, we need to be able to sum utilities across households[9], thereby creating an index of "social welfare". It does not mean that all households need have exactly the same utility function – though this assumption is also often made in the interests of making the theory more workable.

In principle, if we had a quantitative economic general equilibrium model containing an explicit measure of social welfare, then we could use it to compare the net present values of social welfare in scenarios with and without the PIIP. We could also obtain a money value of the difference in welfare between the two scenarios by estimating the maximum amount of money (which might be negative) that Australian households should be prepared to pay in order to see the program in place[10].

---

[7] See any reasonably advanced microeconomic economic textbook, for example G.D. Myles Public Economics Cambridge University Press, 1995

[8] Producers are price takers, face diminishing returns to scale, and have perfect knowledge of technology and market opportunities. There are no market failures (e.g. distortionary taxes and subsidies; non-existent markets; information failures, nor externalities not reflected in market prices)

[9] It would be possible for government to decide what weights to give the utilities of households according to their socioeconomic status, thereby giving expression to priorities with respect to income distribution, for example.

[10] This money measure of welfare change (the Equivalent Variation) is an estimate of the amount of money households could pay, once the project goes ahead, and still be as well off as they were in the world without the project. For a discussion of this measure (and the closely related Compensating Variation), see text books such as R W Boadway and D E Wildasin Public Sector Economics Second Edition, Little Brown & Co, Boston, 1984

4.1.2 An alternative partial equilibrium approach

The traditional approach to measurement of changes in economic welfare involves estimation of changes in consumer and/or producer surplus, resulting from a shock to price or quantity in a particular market.

Consumer surplus (see Figure 1) is defined as the difference between the amount consumers would be willing to pay for a good and the mount that they actually have to pay for it[11].

FIGURE 1. CONSUMER SURPLUS

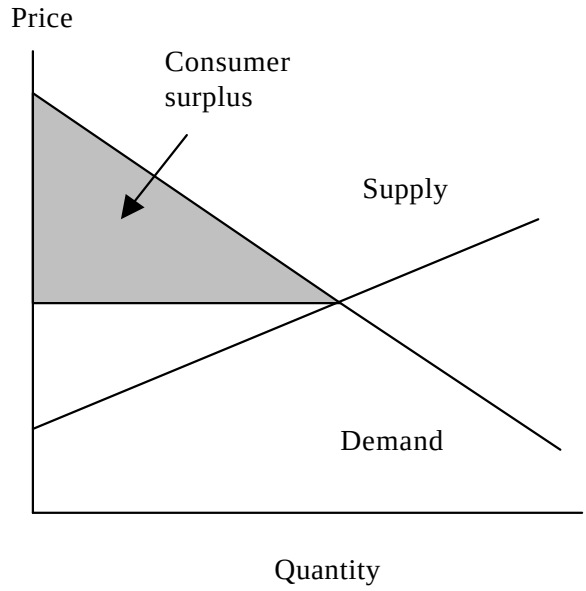
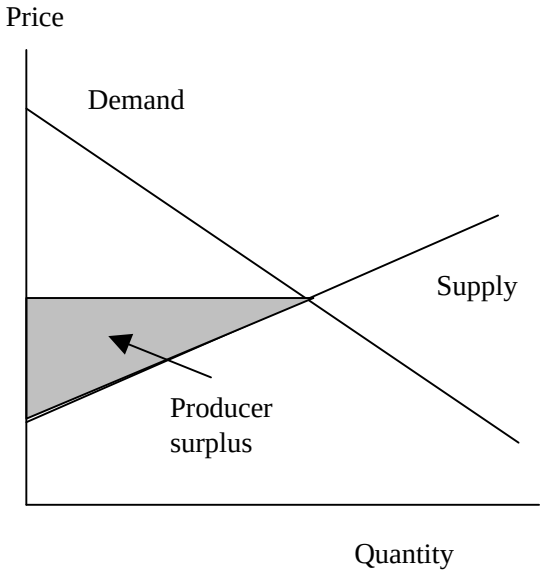


FIGURE 2. PRODUCER SURPLUS



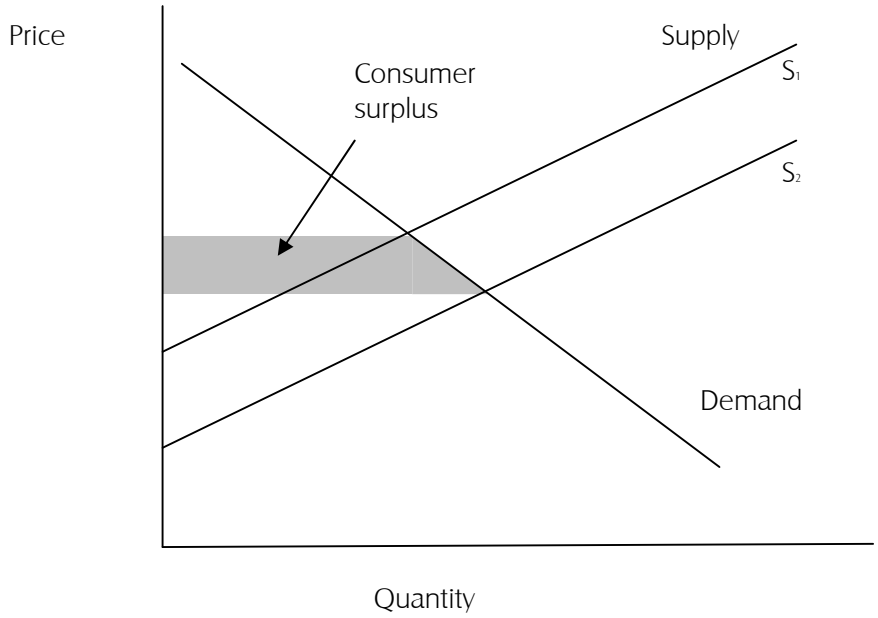
The quantity purchased is determined by the intersection of the demand and supply curves in Figure 1. Consumer surplus is accruing to all those consumers that would have purchased some of the good at prices higher than that currently prevailing.

Likewise, producer surplus is defined as the difference between the amount producers actually receive and the minimum amount at which they would have been prepared to supply the quantity sold. (See Figure 2).

If there is a change in supply conditions – represented by a shift in the supply curve in Figure 3 from S_1 to S_2 – then the resulting change in consumer surplus can be estimated from the figure. In this case there would also be a change (not shown) in producer surplus.

[11] For a discussion of consumer and producer surplus see any comprehensive microeconomic textbook, or treatise on cost benefit analysis.

FIGURE 3. CHANGE IN CONSUMER SURPLUS



4.1.3 Relationship of the two approaches

What is the relationship of changes in consumer and producer surplus to the welfare measures based on hypothetical compensation payments in the comprehensive economic model, discussed in Section 4.1.1?

The short answer is that they are nearly the same, if we make enough simplifying assumptions. It turns out, moreover, that the key simplification is that, by confining attention to a single (or small number of) market(s), there is an assumption that changes in prices in other markets are negligible[12]. If this assumption holds, then the comprehensive measure of welfare change (based on equivalent variation) and the partial measure (based on consumer surplus) will give similar answers.

Other simplifying assumptions in the partial approach include

it ignores the impact on consumption of changes in real income caused by the change in the market price of the good in question (the "income effect");

it assumes that all consumers of the good have the same marginal utility of income – that is, we can add dollars of consumer surplus, no matter to whom they accrue; and

there is no feed-back from any associated changes in producer surplus to household incomes, and hence to the level of consumption demand.

For a fuller treatment see R D Willig, "Consumer's surplus without apology", American Economic Review 66 (4) 589-597, September 1976.

Thus, key issues in applying the consumer surplus approach include: determining what markets to examine in applying the analysis; and deciding what flow-ons to the wider economy to include in the analysis.

4.2 APPLYING THE APPROACHES IN PRACTICE – COST BENEFIT ANALYSIS

Cost benefit analysis compares two scenarios – in this case, scenarios with and without PIIP. The focus of cost benefit analysis is on the direct consequences for the pharmaceuticals sector. However, we should include flow-ons through the wider economy and community, where these are likely to be substantial.

Cost benefit analysis[13] involves expressing costs and benefits in money terms, so that they are comparable with one another. By summing the money values of costs and benefits a single estimate of a project's net benefit results.

Consideration is confined to those impacts that can be quantified with reasonable accuracy. Other impacts are excluded from the formal analysis, but may be included in the overall judgmental assessment of the project.

The analysis involves estimating the net present value of the overall social return to the program. The general presumption is that the social cost of inputs to the sector, and the social value of outputs from the sector, can both be valued at market prices. If this is everywhere the case, then the commercial return is the same as the social return, and there is no case for governments seeking to modify commercial decision making.

However, the social return may differ from the commercial return, where:

- market prices do not accurately reflect the opportunity cost of an input. (For example a project may provide jobs in an area with persistent high unemployment. In this case the opportunity cost of the labour input may be less than the wages paid); or
- some consumers value an output at more than the amount they must pay for it. (This is the concept of consumer surplus); or
- some producers make profits above the cost of the resources valued at market prices ("producer surplus"), or
- there are costs or benefits to households (externalities) that do not reflect directly in the prices of project inputs or outputs. Environmental or health impacts often fall into this category.; or
- there are higher or lower net transfers to Australian residents, or governments, or changed local availability of public goods, as a result of the program.

Each of these differences between private and social cost or benefit needs to be quantified and summed to give the net excess (or deficit) of social, compared with private, return.

Access Economics
January 2003

[13] There are numerous texts on cost benefit analysis. See for example Department of Finance Handbook of cost benefit analysis, AGPS Canberra, 1991, or F Perkins Practical cost benefit analysis, MacMillan Education Australia, Melbourne, 1994.