Pfizer Australia

Submission in response to the Productivity Commission Draft Research Report:

Evaluation of the Pharmaceutical Industry Investment Program 2002

January 2003

Public Release

Response to the Draft Evaluation of the Pharmaceutical Industry Investment Program

Contents

Executive Summary

- Pfizer Australia is very concerned that the findings of the Productivity Commission underemphasize the extent of price suppression and its effect on activity and underestimates the value delivered by PIIP.

- In Pfizer Australia's view the Productivity Commission does not provide a complete and balanced estimation of the downward pressures on price exerted by the PBS and issues related to listing medicines on the scheme

- The Commission's reliance upon industry opinion in 1991 and 1995 about product prices in a liberalised market is unwarranted, as these opinions were expressed prior to the implementation of significant cost-containment measures such as therapeutic reference pricing.

- Pfizer Australia considers there to be good evidence that prices for medicines under the PBS are low in international terms and that the market conditions under the PBS have begun to worsen further. This justifies a positive efficiency margin in the Commission's net benefit analysis of PIIP.

- An analysis of the effectiveness of PIIP should take into account that it has maintained or incrementally developed the investments made under Factor f.

- Without Factor f and PIIP Pfizer would not have a manufacturing facility in Australia and would invest only small amounts in R&D. Instead Pfizer Australia has become one of Australia's leading investors in R&D. If this is analogous to other companies, the inducement rate in the Commission's net benefit analysis should be significantly higher.

- The spillover benefits of all of Pfizer Australia's basic and pre-clinical research and a significant proportion of its clinical research are very high. If this is analogous to other companies then the Commission should take this into account in its net benefit analysis.

- Industry exports have grown rapidly in recent years to over $1.8 billion. The additional taxation revenue from the growth in industry exports should be balanced against the marginal cost of raising funds for PIIP.

- Continued Government support for industry investment in both R&D and Production Value Added activity is justified by ongoing price suppression.

- Considering the impact on the market under which the industry operates, comment by the Commission about the PBS listing process is essential.

- The recommendation to allow generic manufacturers to export in-patent products from Australia is arguably a contravention of this nation's obligations under the WTO TRIPS Agreement.

Pfizer R&D Investment Under Factor f and the Pharmaceutical Industry Investment Program (PIIP)

As a direct result of the Factor f industry investment scheme, Pfizer's manufacturing plant in Australia was retained and became a designated regional supplier for New Zealand, South East Asia and East Asia. PIIP enabled the manufacturing plant to continue and expand this regional role.

Pfizer directly invested in an early stage research collaborations program in Australia as a result of PIIP. Expenditure on this program grew from less than $1 million in 1999-2000 to $9.6 million in 2001-2002.

Pfizer's investment in clinical research grew from $8.9 million in the first year of PIIP to $15.1 million in 2001-2002. This growth includes $2.3 million of funding for projects initiated by members of the Australian medical community.

Pfizer located its Asia/Africa Regional Biometrics Centre in Australia in 2002, resulting in a $14 million investment over 3 years. The Centre will employ over 50 highly qualified staff by 2004.

Employment in research related activity at Pfizer grew from 44 in June 2000 to 102 in June 2002. Pfizer's early stage research collaborations have employed a further 85 highly qualified scientists in universities, hospitals and other research organisations.

Introduction

Pfizer Australia appreciates the opportunity to comment on the draft report by the Productivity Commission (the Commission) into the Pharmaceutical Industry Investment Program (PIIP). The company appreciates the research undertaken by the Commission into the industry and PIIP. However Pfizer Australia has a number of concerns with aspects of the report, which are covered below.

In general terms, it is Pfizer Australia's view that the draft report underemphasizes the extent of price suppression and its effect on activity, and underestimates the value delivered by PIIP. It is also the company's view that the data on which the Commission makes its recommendations are very uncertain and this should be communicated clearly in the final report.

The following response by Pfizer Australia does not attempt to address every issue raised in the Commission's draft paper, but only those areas of notable concern on which Pfizer Australia is able to make a contribution with the information available at present. Pfizer Australia notes that many aspects of the industry and the operations of the PBS remain unresearched.

1. Price Suppression and Listing Issues

Downward pressure on price (Sections 3.2,3.3)

In the section on Reference Pricing, (page 3.7) the Commission does not appear to have fully explored the downward pressure on prices, which the Federal Government exerts through the Pharmaceutical Benefits Scheme (PBS). Reference pricing is one form of downward pressure, which applies to a significant proportion of PBS medicines. However, prices are also lowered (never raised) based on benchmarking of therapeutically related products and the application of the WAMTC (Weighted Average Monthly Treatment Costs) methodology. Examples of therapeutic groups affected by WAMTC include medicines for peptic ulcer and gastro-oesophageal reflux disease, medicines for the treatment of hypertension, serum lipid reducing agents, anti-inflammatory medicines, and anti-depressant medicines. These therapeutic groups form a significant part of PBS expenditure. In these cases, the lowest price is always taken as the benchmark and all other products within the therapeutic group must align with this. In contrast to formal reference pricing, companies are not able to charge a premium on products which are therapeutically linked by WAMTC. In the interests of balance, it is Pfizer Australia's view that this downward price pressure should be more explicitly indicated and explored in the Commission's report.

This downward price pressure is in addition to the erosion of price through inflation and currency effects. In contrast to PBS medicines, the analogous markets of over-the-counter medicines and non-PBS listed medicines have kept pace with the CPI. This should also be mentioned in the Commission's report.

The Productivity Commission notes the relatively low prices for "me-too" medicines in Australia. These prices are low because there has been

downward pressure on the price of the original innovator therapy, and the "me-too" must join in at the lower price.

This downward trend on prices significantly impacts the listing of new innovative therapies, where the comparator has experienced price erosion, particularly if the comparator was listed at a much earlier date. The benefits of a new therapy are often incremental to existing therapies. However the innovation required to develop these therapies is often costly and requires a return that justifies the investment. The requirement that a new product compete on cost-effectiveness with a product that is often over 10 years old and has experienced only downward pressure on its price since listing is unrealistic and does not reflect the nature of the pharmaceutical innovation process. This is leading to fewer products being listed with more restrictions on their use and is symptomatic of price suppression in Australia. It is Pfizer Australia's view that the Commission's report could more comprehensively articulate and explore these issues, and incorporate them into its final conclusions on price suppression.

Pfizer Australia recommends that the final report of the Commission take into account evidence that the pricing environment has changed in Australia, with the Federal Government stating that it seeks 6% annual growth in PBS expenditure, rather than the 10% of the last decade.[1] This will add further momentum to the downward price pressure which has been in existence in Australia since the early nineties. Whilst 10% or even 6% growth may appear high, the Australian Government underspends on pharmaceuticals compared to the OECD average (public expenditure only) by around $1.8 billion per annum[2]. As it has been publicly stated, the Productivity Commission should account for the lower projected expenditure on the PBS in its calculation of price suppression. A 6% "soft capped" growth in expenditure will necessarily

[1] Statements by the Assistant Secretary, Pharmaceutical Benefits Branch, Senate Hansard, 21 November 2002 CA77
[2] Calculations by Medicines Australia in A Prescription for the Future Health of Australia 2002

involve additional cost containment, rather than the application of cost-effectiveness principles alone.

Industry Estimates of Price in a Liberalised Market

In the paragraph on Page 3.11, the Commission relies upon 1991 and 1995 surveys of the industry's opinion regarding the prices that would be obtained in Australia were prices liberalised. These surveys were undertaken early into the implementation of cost-effectiveness pricing and prior to the implementation of Reference Pricing, WAMTC and therapeutic benchmarking, all of which have resulted in significant downward pressure on prices. They equally do not take into account further cost containment measures now being contemplated or exercised by the Federal Government. For this reason, Pfizer Australia considers that the 1991 and 1995 survey results would not represent current industry opinion and this should be acknowledged in the report.

Differential pricing (Page 3.4, Box 3.5, Page 3.1, Figure 3.1)

The Commission concludes that lower prices in Australia are not a major factor in reducing prices in other markets, on the basis that Australian prices are not included as part of any formal pricing criteria elsewhere. In fact Brazil, Taiwan and Korea (all substantial markets) formally use Australian prices as part of a basket to determine the price at which they will subsidise medicine. Australian prices have a weighting of 1/6 in Brazil, 1/10 in Taiwan and 1/7 in Korea. The experience of Pfizer's Global Pricing Group is that South Africa, New Zealand and Israel also informally look at Australian prices. It is Pfizer's understanding that Germany is about to implement a requirement for reference pricing to Australia. There is a concern that this may extend much further. Consumers and Governments alike negotiate a price on the basis of what they "expect to pay" rather than simply market power and this expectation can be created by low prices in other markets.

It is reasonable for the Commission to conclude (Page 3.13, figure 3.1) that markets with lower incomes are less likely to be markets that command high prices. However Figure 3.1 provided by the Commission appears to suggest that Australia's prices are lower than most other nations, even taking purchasing-power parity into account. For instance, Australia appears to have 105% of the UK's per capita income, but less than 70% of its prices. Similarly, Australia has less than 75% of the United States' per capita income and less than 40% of its prices. All other nations indicated follow this pattern of having higher prices than Australia relative to income. This is consistent with the industry's experience that prices are abnormally low in Australia, even taking factors such as costs and capacity to pay into account. Prices for most of Pfizer's products in Australia are close to the lowest in the world. On this basis, it is Pfizer Australia's view that the Commission has grounds to be less equivocal about the level of price suppression in Australia.

Effects of volume (Section 3.4)

In Section 3.4 the Commission considers the countervailing effect of volume against price suppression on the PBS. However, the section appears to only take into account the impact of price on volume. As the Commission notes in Section 3.6, many other factors constrain volume in Australia, particularly the inability for companies to advise consumers of available treatments, the need for patients to visit a doctor (and in some cases pay) to obtain a prescription and the role of doctors and regulators in acting as gatekeepers. Ultimately, the volume of prescriptions will in most cases be constrained by the epidemiology of the disease, access to medical care, and the extent of Government restrictions. It is Pfizer Australia's view that these factors should also be discussed in Section 3.4.

Furthermore, it is also relevant to discuss in this Section and in Section 3.6 the inability for companies to adjust prices upward on the PBS (by creating a

niche market) when products suffer declining volumes or are constrained to very small markets by the restrictions placed on them by the PBS (eg Pfizer's product Aricept).

2. The Effect of Price Suppression/Listing issues on Activity

When considering the effects of the Pharmaceutical Benefits Scheme on activity in Australia, the Commission considers both price suppression and other supply constraints. The following sections deal with each of these in turn as well as the question of whether the PBS listing process replicates the informed consumer.

Price Suppression (Section 3.5)

It is Pfizer Australia's view that price suppression directly impacts both production value added activity (PVA) and R&D levels. In the case of PVA perceptions of the operating environment play a dominant role, whereas in the case of R&D both profitability and perceptions play a role.

The Commission on p 3.27 acknowledges that for a small market such as Australia, more readily transferable investments such as formulation, packaging and (clinical) R&D will not be allocated by head offices, if they believe that the environment is not conducive. However, in Preliminary Finding 3.5 the Commission states that pharmaceutical Multi National Enterprises (MNEs) are basically "hardheaded" (with the implication that they are therefore not influenced by perceptions), contradicting the previous acknowledgement. It is Pfizer Australia's view that Preliminary Finding 3.5 should place greater emphasis on the role of perceptions in pharmaceutical industry decision-making.

a) The Pfizer Australia experience of price suppression

The experience of Pfizer Australia does not support the Commission's Preliminary Finding 3.5. In fact, in 1997, a planned $35 million investment by Pfizer Australia to upgrade and expand its production facilities was cancelled as a direct response to the introduction of therapeutic reference pricing. The

investment was cancelled because therapeutic reference pricing sent a message to head office that the investment environment was negative, product patents would not be respected and that the Sydney plant may not be able to maintain future volumes for the local market.

This upgrade would have allowed for future diverse activity and capacity expansion over a significant period of time, opening up major export opportunities in Asia. A scaled down plant refurbishment of around $15 million involving no new capacity was undertaken in 2001-2002.

As will be discussed in the next section, Factor f and PIIP were critical in assisting to reverse some of these perceptions and encouraging investment in Australia.

In the case of R&D, price suppression not only impacts on perceptions but also reduces the profitability of the local operations and its capacity to undertake discretionary R&D in Australia. This discretionary R&D is most likely to be of benefit to Australia, as will be explained in Chapter 3 of this submission. Pfizer Australia undertook very little R&D in Australia prior to its entry to Factor f phase two. Since Australia had capabilities in R&D at that time, this situation can be attributed mainly to the consequences of price suppression.

It is Pfizer Australia's view that Preliminary Finding 3.5 should place greater emphasis on the role of perceptions in pharmaceutical industry decision-making.

b) The relevance of gross margins

The theoretical approach adopted by the Commission in Box 3.4 into the impact of gross margins on locational decisions for manufacturing does not appear to take into account the cost of infrastructure and the opportunity cost

of capital investment. The profit-maximising model used by the Commission assumes that no additional investment is required to have a local production facility as well as a plant in the United Kingdom. In practice, companies like Pfizer rationalise their operations to ensure a maximum return on investment to shareholders and additional plants that improve short run profitability would not be attractive. For this reason gross margins are relevant to production decisions.

Non-listing, listing delays and volume controls (Page 3.31)

In some cases, pharmaceutical companies are not able to accept subsidy for their products, because the price offered through the PBS is below the world floor price. In the case of Pfizer Australia, this reduces volume and increases cost per unit and jeopardises the role of the local manufacturing plant as a regional supplier (refer Chapter 3). Similarly, non-listing, delayed listing or volume controls can reduce profitability and the discretionary funding available for local R&D. The Federal Government has increasingly sent the message to the industry that it will not list products where the uptake is "uncertain" and that total cost to the Government is playing a more significant role as against cost-effectiveness in considering whether to list a medicine. The Commission has acknowledged these concerns of industry but has not modelled a scenario of the effect on activity based on these changes. This would limit the validity of the conclusions in the Commission's final report.

Pfizer Australia's experience of non-listings or delayed listings and impact on activity

Pfizer Australia has been unable to list a number of major products on the PBS since 1993 directly because the price offered by the PBPA was below the company's world floor price. These products include: Cardura, Zithromax and Relpax. In the case of Relpax, no attempt was made to list the product in Australia in anticipation of an inadequate price being offered. The erosion of

prices for older comparators to these products through a number of downward pressures as described in Chapter 1 meant the world floor price could not be achieved under the current system.

Since 1993, the company has been unable to list one other major product, Viagra, for reasons other than price. Pfizer Australia undertook three submissions to the PBAC to subsidise the product. In Pfizer Australia's view, the PBAC rejected the first two submissions because of an unwarranted approach to usage estimates. Pfizer Australia's final submission in 2002 offered a very restricted listing which was approved by the PBAC as cost-effective. However the Federal Government did not list the product on the basis that it did not want to fund treatment of erectile dysfunction.

The product Aricept was delayed in listing by 3 years and ultimately only listed on a very restricted basis in 2001.

Most of these non-listings or delayed listings represent lost local manufacturing activity because, since 1993, Pfizer Australia generally does not import major products, but formulates and packages them locally. Aricept is a notable exception.

These products are or have been significant products worldwide – and the production lost was therefore substantial. Zithromax, for instance is the number two selling anti-biotic globally with sales of US$1.5 billion. It is difficult to be precise, but the failure to list Zithromax in Australia caused the company to forego approximately $20 million in revenue per annum in 2000 prices.

In the case of Cardura, the approximate revenue per annum foregone by not listing was $20-25 million in 1993 prices. Cardura was a substantial product in the global market during the 1990s with a global market of US$1.1 billion in 1997.

In the case of Relpax, Pfizer Australia has been named as the designated supplier for the Asian region, although production is yet to commence. The Relpax market in Australia was likely to have been only $10 million per annum in 2000 prices because of the severe restrictions imposed on this class of products under the PBS. However a more open listing would have made the market substantially larger. Relpax has a global market of US$2.23 billion in 2002.

Viagra is substantially exported from West Ryde, however production is also lower due to its omission from the PBS. A PBS listing under restricted conditions is estimated to have resulted in $20-30 million additional sales per annum in 2002 prices. Again, a more open market would have made revenue and production substantially higher.

As stated above, the delayed listing of Aricept does not represent lost manufacturing activity as the product is packaged and formulated overseas. The delay in listing Aricept cost the company approximately $75 million in total revenue (based on current sales of products in this therapeutic class), as well as not fully recognising the value Aricept provided to Alzheimer's patients. Decisions of this nature affect profitability, perceptions and the capacity for discretionary R&D.

Efficiency distortions due to policy changes (Section 3.6)

The Productivity Commission points out that there are a number of market distortions which occur in the case of the pharmaceutical industry. It also notes that new Government policies to reduce demand and supply may alter the market toward sub-optimal production, when price suppression is taken into account. As has been stated above, in Pfizer Australia's view, this is very likely to be the case, particularly considering that these measures are

accompanied by an extreme sensitivity by Government to uncertainty in cost estimates.

The cumulative effects of these policy changes, combined with the Government's intention to soft cap PBS growth at 6%, could arguably change the efficiency margin in the Commission's model to 5%.

3. The Effectiveness of PIIP and Factor f

The Effectiveness of PIIP and Lag time on Activity (Section 5)

In the Conclusion of Section 5 (5.6), the Commission states that whilst there are some differences in activity between PIIP participants and non-PIIP participants, these differences are in some cases weak. As the Commission acknowledges, the sample surveyed is too small to draw certain conclusions. For this reason Pfizer Australia believes that a stronger focus on case studies is warranted. The following is intended to provide further information on the Pfizer Australia experience that may assist the Commission to consider the impact of these programs and an appropriate inducement rate for entry into net benefit analysis, should this continue to be the Commissions basis for calculating the effectiveness of PIIP.

It is very important that the Commission fully recognises the distorting influence that Factor f may have on the results of its survey. It is Pfizer Australia's view that the ongoing effects of Factor f in PIIP are likely to be significant owing to the very long lag times in investment decision making, particularly in relation to production value added activity. However, the fact that PIIP sustains activity growth following on from Factor f does not negate its value, considering that price suppression is also ongoing.

a) Factor f/PIIP and Pfizer Australia Manufacturing

Prior to Pfizer Australia's involvement in Factor f, Pfizer Australia's manufacturing operation in Sydney was one of forty locations worldwide. At the time, Pfizer was globally rationalising its operations to 10 sites. Pfizer Australia's Sydney plant was not on the list for continuation. However, although the factory was relatively old, it had demonstrated a number of innovative practices and methods to keep costs down.

Once Pfizer Australia had the opportunity to participate in Factor f, this significantly reversed perceptions about whether the Sydney plant should continue, due to the fact that its operations could be rewarded by an additional financial return. Furthermore, Factor f allowed Pfizer Australia to list the company's leading calcium channel blocker Norvasc on the PBS, which led to significantly increased local production. As a result, Pfizer Australia's plant became one of the retained sites and a regional production facility for South East and East Asia, formulating and packaging a number of major products. The decisions during the life of PIIP to manufacture Zeldox and Relpax in Australia for export would therefore not have occurred without Factor f and the listing of Norvasc (export of Relpax is yet to commence). The economic and export benefits of Factor f are therefore still evident in 2002. In addition, Pfizer Australia's involvement in PIIP gave the Sydney plant continued competitive advantage. This assisted Pfizer Australia to secure the production of the Warner Lambert product Lipitor. Lipitor now generates approximately $80 million of PVA per annum and is likely to be a significant export earner in the next 1-2 years.

It takes approximately 3 years for registration approval in one market to source a product from a different location. Therefore, the estimated value of PIIP in maintaining and increasing exports can probably be fully calculated not earlier than three to four years into the program. If the environment in Australia were to worsen (for example through the discontinuation of PIIP and the intention to soft cap PBS growth to 6%), certain effects on PVA activity and exports will only be visible 3 years later. However, where new products coming on to the market are concerned, the cancellation of PIIP is likely to have an immediate effect on whether these products are produced locally. This would arise because of the impact on perceptions of Australia by Pfizer globally, and some loss in competitive advantage, where this advantage is small in any case.

Case Study - The impact of Factor f and PIIP on Norvasc

Factor f played an important role in delivering both economic and health benefits to Australia by allowing Pfizer Australia to achieve an acceptable price for Norvasc, Pfizer's leading calcium channel blocker. Norvasc was under consideration for listing but the price offered by the Pharmaceutical Benefits Pricing Authority (PBPA) at the time was substantially under the world floor price, to the extent that it would not have been listed in Australia. Once the opportunity emerged for Pfizer Australia to participate in the second phase of Factor f based on Pfizer Australia's R&D and production activities this provided a means through the scheme to raise the price of Norvasc to a level that was acceptable to the Pfizer Head Office. Norvasc has been a substantial product in the anti-hypertensive market since 1993, growing to around $55 million per annum in 2002. It grew at around 30% per annum after listing but price reductions after 1995 have reduced cumulative revenue on the product by around $50 –100 million. Cumulative sales since 1993 have been over $350 million.

Under the PIIP scheme, Pfizer Australia has continued to raise the price paid by the Federal Government for Norvasc through its PVA and R&D activity. Without the PIIP scheme, Norvasc in Australia would not reach the world floor price and its presence in the Australian market would certainly be in jeopardy. Norvasc is the leading medicine in the Australian market to combat high blood pressure. Its clinical and economic value is indicated by the willingness of doctors to prescribe it, and patients to purchase it, despite the fact that patients must pay a premium of either $3.25 or $5.10 for each pack, over and above the normal script price of other calcium channel blockers.

Norvasc is now exported to Taiwan, the Philippines, Singapore, Malaysia, Thailand, Hong Kong and Indonesia. The volume of exports exceeds the volume sold domestically. This is a testimony to the positive follow-on effects of Factor f and PIIP.

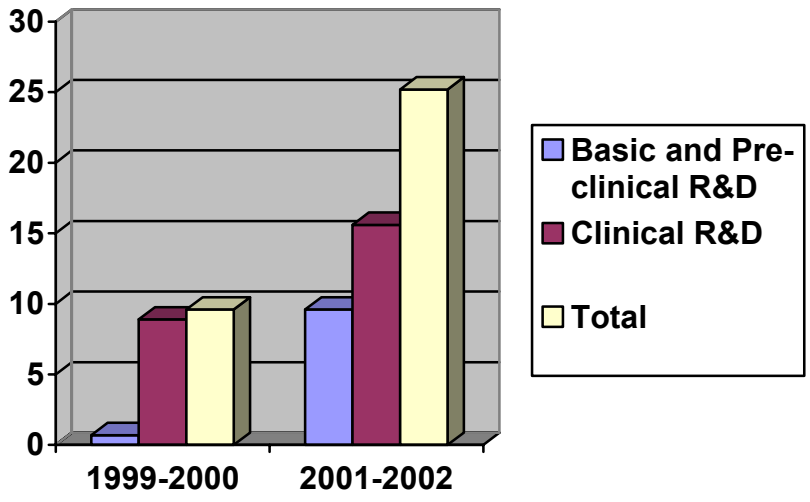
c) Impact of Factor f and PIIP on R&D activity

i. Clinical R&D

Prior to involvement in Factor f, Pfizer Australia undertook a modest amount of late Phase research and development activity in Australia. A dedicated clinical trials group (Ausclin) was established in Australia as a direct result of our participation in the Factor f scheme. It is likely that, had Pfizer Australia not qualified for the Factor f follow-on PIIP scheme, Ausclin would have been retained; however it is likely that growth in Ausclin's activity would have been zero or negative.

PIIP has been a substantial contributor to the growth in Pfizer Australia clinical trials activity from $8.9 million in the first year of PIIP to $15.1 million in 2001-2002. Total R&D related employment at Pfizer in Australia has grown from 44 in June 2000 to 102 in June 2002. A substantial proportion of this growth would not have occurred in the absence of PIIP.

Figure 1 - Pfizer Australia Annual R&D Expenditure under PIIP (in A$ millions)



In time, without any industry development program, Pfizer would be likely to reconsider its investment in Ausclin due to the increasingly competitive global environment for clinical trial activity.

ii. Biometrics Centre

The location of the Pfizer Regional Biometrics Centre in Sydney is a further example of the flow-on benefits of Factor f and PIIP. The Biometrics Centre has been created to provide statistical design and analysis services for Pfizer clinical trials in the Asia, Africa and Middle East regions. The Biometrics Centre will result in $14 million of investment in its first three years and will employ over 50 employees, many of who are highly skilled and in significant global demand, by 2004.

Without a substantial and supportive clinical research arm in Australia, the Centre would never have been located in Sydney. Similarly, without Factor f and PIIP, this clinical research arm would either never have existed, or been substantially smaller. The impact of a cut to PIIP would in all likelihood manifest itself in a reconsideration of the location of the Biometrics Centre in the medium term, by virtue of reduced clinical trial activity and the impact upon head office perceptions.

iii. Pre-clinical R&D

In the case of Pfizer Australia'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. This has enabled Pfizer Australia to bring Australian research capabilities to the attention of PGRD worldwide, resulting in a dramatic increase in research investment activities in Australia. The importance of such a program and the resultant employment of a specific Australian advocate to champion such activities is

evident in the numbers of research collaborations Pfizer has implemented in Australia since the program's inception: prior to PIIP, Pfizer had one research collaboration with an Australian biotech company. Today, Pfizer Australia 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 spent on R&D collaborations, with 18 months of PIIP still to run. Having established a collaborative research program in Australia, it is likely there would be some legacy of continued research activity in the absence of an industry investment scheme. However, without continued industry assistance, it would certainly be at a considerably reduced level to what has been achieved to date. Again, this would be due to perceptions in head office about the investment environment in Australia and the view that other scientific opportunities exist outside Australia that could equally be pursued with a reasonable expectation of a return.

d) Summary of the effectiveness of PIIP and Factor f

Therefore, both Factor f and PIIP have delivered significant and ongoing value to Australia. PIIP itself, in the case of Pfizer Australia, has a very high inducement rate whose effects may need to be calculated up to 5 years into the future. The full impact of no investment scheme, whilst having immediate ramifications, may not be realised until the next significant "decision opportunity" or global rationalisation of operations. This makes the calculation of an inducement rate for input into the Commission's cost-benefit model difficult. However on the basis of Pfizer Australia's experience, the inducement rates for activity under PIIP, particularly R&D should be higher than the values assigned by the Commission in its base case.

Spillover effects

In its cost-benefit model, the Commission uses estimates of the spillover rate for both basic and pre-clinical R&D. If Pfizer Australia's experience of its own R&D programs were indicative of the industry, there would be justification to raise these estimated spillover rates. In addition, the existence of the emerging biotechnology industry in Australia makes the spillover benefits of R&D activity by mainstream pharmaceutical companies particularly valuable. The following sections discuss these issues.

a) Advantages to the Biotechnology industry

The spillover effects of activities by the pharmaceutical industry are evident when the growth of the biotechnology industry in Australia is examined. The fledgling biotechnology industry is frequently staffed by scientists with an academic background, with skills in basic research but less understanding of medicine discovery and development requirements, including the knowledge requirements for clinical trials, data analysis, product registration, manufacturing and reimbursement. Skills developed by pharmaceutical employees can be transferred to the small Australian biotech companies that have moved beyond the start up stage and are focused on progressing their product through the testing and registration processes, providing obvious benefits.

b) Pre-clinical R&D

Table 4.1 in the Commission's report (sourced from PhRMA) does not mention the discovery of novel targets, an activity undertaken in a number of Pfizer Australia's collaborations with significant potential social and economic spillover benefits.

Much of Pfizer's collaborative R&D in Australia focuses on gaining new knowledge of disease processes and development of research tools, for example, discovery of novel targets or building assays to validate such targets or screening tests. In such cases, Pfizer usually does not seek to "own" the intellectual property that arises from this activity, but rather to allow the collaborator to publish the findings on completion of the research, or patent if they so desire. Thus, the IP is either publicly available or in the hands of the collaborating partner to be used at their discretion. This research does not tend to lead directly to compounds of use by Pfizer but rather enhances "knowledge paths" of interest to the company and the collaborator. The spillover effect of Pfizer Australia's early stage research should therefore be ranked very highly, arguably at 90%.

The nature of these early stage research projects means that the aim is often not immediate commercial opportunities, but advancing scientific knowledge to the benefit of the collaborator, Pfizer and the international research community. It is therefore too early to assess the full commercial or scientific value of this kind of research. However, there are numerous examples of where these collaborations have favourably impacted the goals and research efforts of both the collaborators and PGRD. A number of collaborators have already published and/or presented the outcomes of their work to the international community – which illustrates Pfizer's understanding of, and willingness to accommodate the needs of academia - and it is expected that many more will do so in the future. There are also clear examples of where Pfizer Australia's investment has helped build a fledgling biotech company. One example of this is highlighted in the box below:

Case study – Growth of the Institute of Drug Technology under Factor f

A good example of the ongoing benefits of the pharmaceutical industry development program is Pfizer's relationship with the Institute of Drug

Technology Australia Limited (IDT). In the mid 1990's, under the Factor f Scheme, Pfizer contracted its primary manufacture of doxycycline hyclate (for Vibramycin) to IDT. IDT invested approximately $5 million for the actives plant in Boronia, Victoria, and supplied several tonnes of material to Pfizer over several years. At the end of the Factor f period, manufacture of doxycline was concluded, and the legacy remains as the plant continues to synthesise two parenteral active compounds for a US company and one active compound for a European company. IDT's actives plant would not have been built without the industry development program and thus the significant residual benefits arising from such activity would not occur.

Under PIIP, Pfizer has retained its relationship with IDT for synthesis of other chemical material. PIIP has been an important factor in IDT being able to attract this kind of high level R&D from Pfizer's US research site, with its requirement for employment of highly qualified staff.

c) *Clinical R&D*

The spillover effects of Clinical R&D are largely toward medical and nursing staff in terms of new expertise and providing Australian employees with an understanding of, and expertise in, the process of medicine development. Clinical trials are an essential aspect of the pharmaceutical and biotechnology businesses. As employees develop these knowledge areas, they provide a human resource of value to the important and growing human use therapeutics industry in Australia. Knowledge derived through large pharmaceutical companies is likely to be cutting edge and of great value to smaller organisations.

i. Investigator Initiated Research

A proportion of Pfizer Australia's clinical research expenditure is on "investigator initiated" research. This is research initiated independently of

Pfizer Australia. Our role is in the discretionary support of the research through grants or medicine supply, where necessary.

Examples of this kind of research include investigations into the use of Viagra for Pulmonary Hypertension and Meniere's Disease, and into Zithromax for Cystic Fibrosis. These conditions are either fatal or severely debilitating, and no adequate treatment currently exists. The patient population for these conditions is usually small and development of the treatment for them is not likely to be commercially rewarding. The spillover benefit of this kind of research is therefore much higher than the 25% allocated to clinical research by the Commission.

As a specific example, Cystic Fibrosis is a genetic condition that results in death; usually by the time the patient is around 40 years of age. For much of their life the patient will suffer with significant breathing difficulties and other symptoms, affecting their quality of life. In the case of Zithromax, an investigator-initiated study found that Zithromax improved the overall health of Cystic Fibrosis patients including their capacity to breathe, and reduced the number of hospital visits required. Over the length of a Cystic Fibrosis patient's life, this represents an important health gain and reduced hospitalisation cost. Another example, that of Viagra in Pulmonary Hypertension, may provide for the use of Viagra to prevent death from this rapidly fatal condition. This study (still current) was initiated entirely in Australia through the local research arm.

All 3 studies mentioned above represent world first, groundbreaking research into the management of these conditions. If the treatments show benefit they are likely to have a significant global impact on the treatment of these diseases

The PIIP scheme provides significantly greater incentive for Pfizer Australia to support this form of scientific research into its own products, which can result

in more appropriate treatments for small patients groups in hospitals with very significant medical need. Pfizer Australia now spends over $700,000 annually on investigator-initiated research with 30 individual projects currently running. Prior to PIIP this figure was minimal with less than 10 studies receiving support in any one year.

ii. Research Grants

In addition, Pfizer Australia (and Warner Lambert prior to the merger) initiated under PIIP annual grant programs to specialist clinical researchers and general practitioners in the Cardiovascular and Neuroscience fields. The Cardiovascular Lipid Research Grants, Cardiovascular Research Grants and the Neuroscience Grants together provide $1.6 million in funding each year. The grants are independently administered and the results are made publicly available. Once again, this form of research has much higher spillover effects than the percentage allocated by the Commission to clinical R&D. An example of a positive study arising from these grants is the successful research by the Baker Medical Research Institute demonstrating that aggressive cholesterol reduction reduces blood pressure in patients with a common form of hypertension. This research may result in a significant cardiovascular risk reduction on a population basis. In 1993-4 Cardiovascular diseases in Australia cost $3.7 billion or 12% of the total health system costs, indicating that a small reduction in risk through this study could have great health and economic benefit.[3]

The funding for the research grants is at the discretion of Pfizer Australia and is underpinned by the return provided on the research through PIIP. Were PIIP to be discontinued, this kind of research would be substantially reduced, not only due to the direct loss of returns for the investment, but the reduced profitability of the overall local operation would constrain budgets so that the company would focus on core commercial activities.

[3] Australian Institute of Health and Welfare. Australia's Health 2002.

iii. Biometrics Centre

In the case of Pfizer Australia's Biometrics Centre, the spillover benefits of having a regional centre of excellence in biostatistical design and analysis is the generation and dispersal of new knowledge in this expertise. The Director of Pfizer Australia's Biometrics Centre is directly involved in the development of academic courses which will build expertise in the new specialties of health statistics. Employees in the Centre are well placed to transfer these skills to smaller biotechnology or pharmaceutical companies or alternative contexts.

Total employment effects of R&D (Section 5.4)

On page 5.15, the Commission comments that R&D employment by PIIP eligible firms did not grow commensurate with increased investment. In the case of Pfizer Australia, numbers of R&D related employees have grown from 44 in June 2000 to 102 in June 2002. However this understates the employment effects of our R&D activities, because each of Pfizer Australia's collaboration results in the new employment of on average two post-doctoral researchers at the collaborating institution. Already, Pfizer Australia's collaborations have resulted in 85 new employment positions. The employment is so closely tied to the collaboration that Pfizer Australia must in most cases pay out the contracts of the new employees if the project does not move forward.

4. Economic Efficiency of PIIP (Section 6)

Effect on Employment efficiency (Section 6.1)

The Commission comments (Page 6.2) that marketing staff and scientists would be productive elsewhere in the Australian economy if not for the activity of the industry. This is not always true for the highly specialised staff required in some areas of the pharmaceutical industry. In the case of Pfizer's new Biometrics Centre, Pfizer Australia has needed to employ 14 additional staff in the first year of its operation. The unique combination of scientific training and industry experience required has meant that 8 of the 14 had to be brought from overseas. Were the Biometrics Centre to be discontinued, most of these staff would leave Australia, as few similar appropriate opportunities exist for them locally.

Displacement of medical and scientific resources

It should be noted that Pfizer Australia's experience with Australian R&D collaborative partners does not suggest that other companies would simply fill the void created by Pfizer's absence from research in Australia. In discussions with around 250 potential collaborators, only once has the other party been unable to work with Pfizer Australia due to collaborations with other commercial partners. This reflects the diversity of research interests within the pharmaceutical industry and the need to match interests with research conducted locally. That is, Pfizer Australia searches for partners that provide a strategic fit with its research objectives. Other companies are likely to have similar but sufficiently different research objectives that may not translate into these companies "filling the void" were Pfizer Australia to conclude such activities. Furthermore, there are very few pharmaceutical companies that have dedicated efforts searching for research opportunities within Australia, and thus the potential pool of partners is limited.

Marginal Cost of Raising Funds (Page 6.9)

The report by the Commission does not make clear the reason that it assigns a cost to raising public funds for PIIP, but does not calculate the full value of the additional income tax and other taxes generated by greater employment, manufacturing and exports under the program. On the basis of the assumptions used by the Commission, it would appear that any industry investment scheme would have great difficulty in demonstrating its value and activities involving taxation would rarely be justifiable.

In considering the cost to public funds of pharmaceutical industry investment schemes, Pfizer Australia suggests that the significant growth in pharmaceutical exports from Australia since 1990 should be taken into account. Using more recent figures available, exports by the industry have grown from $1.12 billion in 1996-97 to $2.02 billion in 2000-01.[4] Assuming a 15% profit margin and a 30% tax rate, this represents additional revenue to the Federal Government of $30 million per annum in 2000-01. The attached table (Table 1) provides a model of the taxation revenue growth to Government through export growth based on the above assumptions.

This figure would be much higher if the base was the level of exports at the commencement of Factor f. Even assuming a moderate inducement rate for export growth through PIIP, taxation revenue to Government through the scheme would be significant. The Commission does not appear to have taken revenue from export-related activity into account in its net benefit methodology. It should also be noted that this growth in exports (16%) represents greater growth than would be achieved in most other industries, indicating that pharmaceutical industry investment schemes are of particularly high value.

[4] Department of Industry information from www.industry.gov.au based on ANZSIC 2543

Table 1 - Pharmaceutical Industry Export Growth and Government Revenue – Modeled Scenario

Figures are in A$millions

Year	Exports	Base	Additional Exports	Profit Margin	Taxes
	Actual	5%		15%	30%
1996-1997	1120	1120			
1997-1998	1229	1176	53	8.0	2.4
1998-1999	1468	1235	233	35.0	10.5
1999-2000	1773	1297	476	71.4	21.4
2000-2001	2025	1361	664	99.6	29.9
Total	7615	6189	1426	214	64.2

Calculation of Net Cost/Benefit of PIIP to Australia (Section 6.3)

Based on the information provided in the sections above, Pfizer Australia's view is that the calculation of the net cost/benefit of PIIP should have a more positive outcome, assuming the activities of other companies are broadly analogous with our own.

Current price suppression and a more restrictive operating environment now faced by the industry justify a marginal efficiency that is greater than zero. An assumption of 5% is a reasonable conservative estimate. Similarly the inducement rates suggested by the Commission should arguably be higher. Taking into account the longer-term impacts of PIIP, an inducement rate of above 70% is warranted. On the basis of Pfizer Australia's experience, spillover effects of both pre-clinical and clinical R&D are underestimated in the Commission's base case. Spillover effects of pre-clinical R&D should be 90% with spillover effects of clinical research at 50%.

In addition, the value of additional exports by virtue of PIIP (both immediately and in the longer term) would significantly reduce the cost of raising public funds.

It is Pfizer Australia's view that the Commission should revisit the assumptions behind the final calculation of the net benefit of PIIP. Attachment 1 is a chart documenting suggested modified assumptions by Pfizer Australia.

5. Dealing with PIIP deficiencies

Recommendations of the Action Agenda

Pfizer Australia supports the recommendations of the Pharmaceutical Industry Action Agenda regarding a future industry investment scheme. The most important points to derive from these recommendations regarding a new scheme are:

- It should be flexible and accessible by a wider range of companies
- The scheme should support current activity as well as additional activity
- A ten year commitment by Government (analogous to that recently provided to the motor industry) is optimal for creating investment certainty
- Additional funding would deliver broader benefits

Production Value Added Activity (Section 7.2, page 7.6)

Although major decisions about investment in manufacturing capacity occur relatively infrequently, it is not Pfizer Australia's experience that industry investment schemes and pricing have little impact on major production investment in Australia (Page 7.6). As has been cited above, the Pfizer Australia manufacturing plant in West Ryde would not exist without Factor f and the plant would have been substantially expanded (along with exports) had Therapeutic Reference Pricing not been introduced in 1997. For this reason, Pfizer Australia is strongly of the view that PIIP should continue to cover PVA activity.

The comment by the Commission that an industry investment scheme to support replacement activity (and by implication support the industry gains of the last decade) raises questions about the long-term sustainability of the

industry appears to discount the central reason for any such scheme – that of price suppression. Ongoing price suppression would justify ongoing targeted assistance.

Clause (f) (Section 7.3, Page 7.18)

The Commission is of the view that Clause (f) should be removed from pricing criteria. It was originally inserted as an acknowledgement that the Federal Government, as the purchaser of the overwhelming share of pharmaceuticals in Australia, should account for the growth of the industry in setting prices.

As the example of Norvasc has shown, the link between industry investment schemes and the price of nominated products is important, particularly from the point of view of Pfizer's head office, which is looking to see the world floor price maintained in Australia. Without the capacity to make such a link, Norvasc would not have been listed locally. It may be preferable to reframe Clause (f) to refer to prices being raised according to local activity under an industry investment scheme for which the participating company is eligible.

6. Other Measures (Section 8)

Access to the R&D Tax Concession (Section 8.2)

Pfizer Australia strongly supports broader access to the R&D tax concession for pharmaceutical MNEs. A copy of Pfizer Australia's submission to a Senate Committee Inquiry on this issue is attached (Attachment 2).

It is Pfizer Australia's view however that to prefer the R&D tax concession over an industry investment scheme would not be in Australia's interests, as some companies may have particularly significant contributions either in manufacturing or (if this is not eligible for the concession) in clinical trials. These investments would then be without support to counter the poor operating environment. In addition, tax concessions are subject to policy change and are less likely to create industry certainty.

Patent Extension and "Springboarding" (Section 8.3)

It is Pfizer Australia's view that the Commission's recommendation in regard to the capacity of generic manufacturers to export in-patent products to countries where the patent has expired is clearly outside the scope of its terms of reference for this report. This proposal arguably contradicts Australia's obligations under the WTO TRIPS Agreement, which is designed to encourage innovation by providing appropriate global patent protection.

Conclusion

The Factor f scheme was first initiated by the Federal Government in response to the declining levels of local activity by the Australian pharmaceutical industry in a poor operating environment. It was the view of the Federal Government at the time that it was in Australia's interest to build high technology industries, which deliver high growth, high wages and export growth to the Australian economy, as Australia could not economically afford to continue as a net importer of innovation. It is Pfizer Australia's position that this perspective is still valid in 2003.

Pricing regulation in Australia continues to be an impediment to further growth of the locally based pharmaceutical industry. This is the experience of most pharmaceutical industry leaders in Australia and certainly that of Pfizer Australia. The absence of an industry investment scheme will in the medium term most likely see the industry return to its pre-Factor f state of low R&D and manufacturing activity, unless price suppression is removed.

Many of the conclusions ultimately adopted by the Commission contradict the experience of the local industry and are in Pfizer Australia's view premised on a number of basic uncertainties that make the strength of its final conclusion on the future of PIIP untenable.

On the contrary, it is Pfizer Australia's position that there are reasonable grounds for concluding that:

- The pharmaceutical industry delivers great benefit to Australia
- The business environment created by the PBS is generally negative
- Pharmaceutical industry investment schemes have value in promoting efficient and beneficial levels of activity by this valuable industry.