

**THE PRODUCTIVITY COMMISSION  
EVALUATION OF THE PHARMACEUTICALS  
INDUSTRY INVESTMENT PROGRAM**

**THE VICTORIAN GOVERNMENT POLICY  
CONTRIBUTION**

**OCTOBER 2002**

## CONTENTS

Executive summary	3
PIIP replacement	3
International investment incentives	4
Local policy initiatives	4
Introduction	5
The pharmaceuticals industry in Victoria – its components and size	5
Performance of the pharmaceuticals industry	8
The PIIP in practice	8
Strategic economic and health significance of the pharmaceuticals industry	10
Changing shape of the pharmaceuticals industry	13
The international outlook and sustaining competitive performance	16
Other policy and program measures	20
Increase inter-government co-operation and co-ordination	20
Enhance Australia’s preclinical capability	21
Enhance Australian company access to clinical trials	21
Address PBS listing difficulties where appropriate	22
Remove trade barriers (including regulatory barriers) to overseas markets	23
Improve generic export opportunities	24
Australia’s taxation regime	24
Conclusion	25

## Executive summary

The Victorian Government considers that a replacement Pharmaceuticals Industry Investment Program (PIIP) should be introduced. However, it alone will not be sufficient to build the Australian pharmaceuticals industry. Competitive international investment incentives will be required to attract major strategic investments in the sector. In addition, a suite of measures is needed to build a sustainable biotechnology and pharmaceutical sector in Australia, adding value to the excellent basic research and development capabilities of our nation.

### *PIIP replacement*

The Victorian Government recommends that the Productivity Commission include the following in its recommendations in regard to its evaluation of the PIIP:

1. ***Continue a modified PIIP:*** That the PIIP, which is intended to provide partial compensation for low pharmaceutical prices as a result of the operation of the Pharmaceutical Benefits Scheme (PBS), be extended in a modified form, or a similar modified scheme be introduced, to at least the year 2014, with a review mechanism after five years.
2. ***Ensure certainty:*** That the form and timing of future assistance be announced as early as possible to enable forward planning by the pharmaceuticals industry, and be simple and flexible in terms of access, compliance and administration.
3. ***Ensure long term stability:*** That the federal government adopt a long term strategic approach to pharmaceutical industry policy.
4. ***Adopt a whole-of-government approach to this complex issue:*** That the federal government recognise that pharmaceuticals industry development policies impact on other areas of policy development and that it adopt a whole-of-government approach to pharmaceutical policy issues, requiring consideration of health, fiscal and industry development questions.
5. ***Consult widely:*** That the federal government consult closely with industry and State Governments in relation to the design of any future assistance to the pharmaceuticals industry.
6. ***Widen access to more pharmaceutical companies:*** That the new PIIP scheme be available to more pharmaceutical companies, recognising that PBS price factors impact across pharmaceutical companies.
7. ***Provide multiple entry points:*** That the design and administration of a modified PIIP permit new companies to enter the scheme and participating companies to extend their activity after the initial allocation, with multiple entry points over a ten year period.
8. ***Widen access across the pharmaceuticals sector:*** That the new PIIP scheme design be sufficiently flexible to reward small Australian biotechnology companies and research institutes, where they contribute to the pharmaceuticals development process through increased production value add and research and development.
9. ***Recognise scientific developments:*** That the new PIIP scheme design be sufficiently flexible to take into account the development of personalised medicine.
10. ***Build manufacturing capability:*** That the new PIIP scheme contribute to Australia capturing new opportunities in manufacturing, including biologicals and recombinant proteins.

11. **Ensure WTO compliance:** That the federal government ensure that the new PIIP scheme is compliant with WTO obligations
12. **Build skills:** That the federal government consider including skills targets under any new PIIP scheme.

#### ***International investment incentives***

13. **Provide internationally competitive investment incentives:** That, in addition to support provided through any PIIP-like scheme, the federal government agree to offer investment incentives to attract appropriate investment from international pharmaceutical companies at all stages of the industry value chain (discovery R&D, preclinical development, clinical trials and manufacturing).

#### ***Local policy initiatives***

14. **Increase inter-government co-operation and co-ordination:** That the federal government align its biotechnology and pharmaceutical industry development policies and programs with those of the various State and Territory Governments, and show leadership in relation to biotechnology investment attraction activities.
15. **Enhance Australia's preclinical capability:** That the federal government work with industry and the State Governments to identify interventions in the preclinical arena that would result in additional investment, production and research and development, and uses the findings of the "Maximising Australia's Preclinical Capacity" forum as a starting point.
16. **Enhance Australian company access to clinical trials:** That the federal government work to encourage Australian biotechnology companies to take potential pharmaceutical products through at least the early phase clinical trials.
17. **Address PBS listing difficulties where appropriate:** That changes should be contemplated where appropriate to the pharmaceutical listing process to overcome difficulties being experienced, while retaining the integrity of the Pharmaceutical Benefits Scheme.
18. **Remove trade barriers (including regulatory barriers) to overseas markets:** That the federal government increase its efforts to ensure trade barriers (including regulatory barriers) are removed from overseas markets.
19. **Improve generic export opportunities:** That the federal government examine interventions relating to patent protection to encourage the growth of generic manufacturing in Australia for export.
20. **Consider taxation measures:** That the federal government examine options for introducing taxation measures assessed by the Productivity Commission as possible alternative mechanisms under the terms of reference for this evaluation.

## Introduction

The Victorian Government is strongly committed to the development of Victorian biotechnology, for the economic and health outcomes it brings to the State. A strong and sustainable pharmaceuticals industry is vital for the future development of the biotechnology sector in Victoria and across Australia. It is also important for the future of the manufacturing sector in the State. The Government welcomes this opportunity to contribute to the Productivity Commission's evaluation in these important areas.

The terms of reference define "pharmaceuticals industry" as "all those who contribute to the discovery, development, manufacture and supply of pharmaceutical products and services in Australia, thus including the bio-medical sector". This contribution will use the term "pharmaceuticals industry" as defined in the terms of reference, unless otherwise indicated. However, it is important to recognise that while pharmaceutical companies and many biotechnology companies, fundamental biomedical researchers, manufacturers and service providers, are all engaged in that industry as defined, there are some economic drivers relevant only to some parts of the industry. These need to be addressed as well as broader issues relevant to the business and investment environment applicable to all parts of the industry.

As well, it is not clear whether the evaluation will encompass issues relating to over-the-counter drugs and complementary medicines. It is important to recognise that over-the-counter drugs and complementary medicines are very important components of the pharmaceuticals industry and are becoming increasingly relevant in modern healthcare delivery.

This contribution acknowledges the strategic position the pharmaceuticals industry currently occupies in the Victorian and national economies and the future potential of the industry in an Innovation Economy. However, it notes that the industry's future performance and long term sustainability are not guaranteed. As the PIIP in its current form is due to end in 2004, the Victorian Government welcomes the opportunity to participate in the policy debate over what future federal government intervention, if any, would be appropriate to ensure the long term sustainability of the pharmaceuticals industry in Australia.

## The pharmaceuticals industry in Victoria – its components and size

The pharmaceuticals industry is comprised of several important parts. While these overlap in critical ways (and some companies are involved in or associated with more than one part), this section seeks to identify the defining characteristics of each part of the industry.

**Biotechnology companies:** As at June 2002, there were 86 dedicated biotechnology companies in Victoria, accounting for over one third of the 252 in Australia. An additional 108 companies are operating in Victoria with significant life science involvement in their spectrum of activity, or in related bioscience areas.<sup>1</sup>

Human health is a particular strength among Victoria's dedicated biotechnology companies, with 52 of the 86 enterprises (60%) having a significant focus on health.<sup>2</sup> Clearly, not all biotechnology companies will be directly involved in the pharmaceuticals industry as defined in the terms of reference. The ones most obviously involved will be those with activity in pharmaceutical development. Victoria has at least 31 such dedicated companies, and a further 21 related

---

<sup>1</sup> *Victorian Biotechnology and Bioscience Based Industry*, a report prepared for the State Government of Victoria by David Fayle, BioAccent Pty Ltd, June 2002, pp 2, 9. It should be noted that data relating to the biotechnology sector is difficult to obtain and compare, due to differing or emerging definitions of "biotechnology" across jurisdictions.

<sup>2</sup> *Ibid*, p 5.

bioscience companies.<sup>3</sup> However, there are other areas of biotechnology and bioscience activity with direct or indirect application to the pharmaceuticals industry, including drug delivery, cell and tissue engineering, biologicals, genomics, phenomics and chemicals, in which Victorian companies are active.<sup>4</sup>

Employment estimates in the biotechnology sector are difficult to obtain, due to varying definitions. In 2001, it was estimated that Australia's biotechnology industry employed over 5,700 staff (representing a growth of 46% since 1999).<sup>5</sup> However, a report in 2000 found that 27,531 Australian employees were engaged in "bioindustries", with Victoria having 8,352 (30.5%) of the Australian workforce.<sup>6</sup>

There is a significant overlap between the biotechnology sector and the pharmaceutical sector. Many pharmaceutical companies are engaged in biotechnology-related activities, but their manufacturing and marketing activities tend to distinguish their activities from biotechnology companies in the main. The boundaries between the sectors are blurring further as the sectors develop in an increasingly convergent manner.

***Pharmaceutical companies:*** These are companies engaged in pharmaceutical manufacturing, sales and marketing, regulatory affairs, clinical research and discovery research and development. There are around 30 firms in Victoria, employing approximately 5,000 people. These include both multinational firms and domestic companies, who supply product for export sale and local markets. Victoria's general manufacturing skill base and low cost base have been an important factor in the growth of this part of the industry and its international competitiveness.

Pharmaceutical manufacturers are an essential part of Victoria's overall manufacturing capability. The manufacturing sector as a whole is crucial to Victoria's economy. It employs 340,000 people, providing 15 per cent of all Victorian jobs and more full time jobs than any other industry. It is Victoria's largest exporter, providing 60 per cent of total exports, including associated services. It generates 16 per cent of Victoria's economic activity, and accounts for 50 per cent of business spending on research and development.<sup>7</sup>

A recent report estimated that medicinal and pharmaceutical product manufacturers in Australia enjoyed a turnover of almost \$6 billion in 2000-01, employing over 13,000 people in nearly 140 enterprises.<sup>8</sup> Manufacturers include Bristol-Myers Squibb, CSL, Ego Pharmaceuticals, GlaxoSmithKline, Institute of Drug Technology, Mayne Pharma, Sigma Pharmaceuticals, and RP Scherer, all companies with manufacturing facilities in Victoria.

The cost of developing pharmaceuticals, then marketing and distributing them, is high.

Marketing and distribution costs make up the largest proportion of industry expenditure and have been growing rapidly at the global level. An estimated up to \$1 billion is spent on pharmaceutical marketing in Australia each year.<sup>9</sup> The Victorian Government urges the Productivity Commission

---

<sup>3</sup> *Ibid*, pp 5,10. Note that the related companies include many pharmaceutical companies.

<sup>4</sup> *Ibid*, pp 12-13. Note that some Victorian companies are engaged in more than one of the activities cited.

<sup>5</sup> *Australian Biotechnology Report 2001*, Ernst & Young, Freehills and the Federal Government Department of Industry, Science and Resources, pp 16-17.

<sup>6</sup> *Biobusiness: Queensland's Competitive Strengths and Challenges in the Life (Bio) Industries – 2000*, Brisbane Institute, 2000, p 25.

<sup>7</sup> *Agenda for New Manufacturing*, Victorian Government, June 2002, p 3.

<sup>8</sup> C2543 - *Medicinal and Pharmaceutical Product Manufacturing in Australia*, August 2002, IBISWorld. Note that the main products supplied by these enterprises included items other than pharmaceuticals.

<sup>9</sup> *Pharmaceuticals Industry Action Agenda Discussion Paper*, Federal Government Department of Industry, Science and Resources, September 2001, p 24.

in its evaluation to examine whether there are any ways of achieving cost savings in these areas of expenditure that would encourage R&D and manufacturing expenditure in Australia.

There are varying estimates of development costs on a global basis, but they are likely to be in the hundreds of millions of dollars, even after taking into account any tax concessions that may be available. While it is difficult to obtain an exact figure for the costs of development done in Australia (given all the variables), AusBiotech estimates that it could cost up to around A\$460 million to take a biological therapeutic through to TGA registration in Australia, with all work, from discovery on, including preclinical and clinical trial work done domestically. There is a need to better understand the actual costs of drug development in Australia, to assist in any debate over pricing issues.

**Fundamental biomedical research:** Victoria's biomedical research base is extensive. It has 9 research-based universities, over 20 not-for-profit medical research institutes and 7 major teaching hospitals. It offers world class research in a range of areas, including neurosciences, immunology, cancer, diabetes, cardiovascular research and stem cells, as well as an excellent clinical trials environment and a growing nanotechnology capacity. Victoria was the recipient of 41 per cent of Australia's NHMRC medical research funding in 2002. This NHMRC funding level, to a State with only 25 per cent of the nation's population, is indicative of the strength of Victoria's biomedical research base.

Victorian biomedical research, and biotechnology research in general, has developed largely around a series of geographically-based research clusters. The biomedical clusters are located as follows:

Location	Biomedical Cluster
Clayton	Monash Health Research Precinct and International Centre of Science Technology and Emerging Industries
Heidelberg	Austin Biomedical Alliance
Parkville	Bio21
Prahran	Alfred Medical Research and Education Precinct

Many biotechnology companies are located or will soon locate at a number of these clusters. This reflects the move to collaboration and critical mass-building that is occurring in the Victorian biotechnology sector and is characteristic of national and international trends with regard to clusters of like-minded companies.

The establishment of the Australian national synchrotron at Monash University will provide further support for the development of new pharmaceuticals in Australia. Synchrotron radiation is used in over 70% of all structure determinations of macromolecules,<sup>10</sup> and will be crucial for the design of many new drugs.

**Service providers:** There is a range of service providers directly associated with the pharmaceuticals industry, offering services ranging from toxicology and pharmacology, to clinical trial management and laboratory supply. These services are sometimes provided by biotechnology companies themselves. In addition to these service providers, professional advisers in law, accounting, recruitment, finance, intellectual property management and commercialisation, construction and manufacturing are integrally linked to the development of the pharmaceuticals industry in Australia.

---

<sup>10</sup> Website for the new UK synchrotron, [www.diamond.ac.uk/Activity](http://www.diamond.ac.uk/Activity).

## Performance of the pharmaceuticals industry

The recent Wills Report highlighted Australia's excellence in basic research. For example, Australia, with 0.3 percent of the world's population, produces 2.5 percent of the world's research, with 1.3 percent of Australian publications in the world's top 1 percent cited.<sup>11</sup> Victoria has particular, and historic, strengths in biomedical research.

The biotechnology corporate sector in Victoria is comprised largely of young companies – more than 75% of the State's dedicated biotechnology companies commenced their biotechnology activities between 1993-2002, and half since the beginning of 1999.<sup>12</sup> Australian revenue growth, where data exists, has not been insubstantial. In 2001, a study found that revenue growth in listed Australian core biotechnology companies rose 23% over the previous year, with total revenues of the then 35 listed core biotechnology companies of A\$897 million.<sup>13</sup>

However, this revenue has not necessarily translated into profitability for Australia's core biotechnology companies. In 2001, the same study found that the majority of Australia's core biotechnology companies were investing significant proportions of their revenues in product development and were consequently not yet profitable. The study, looking at some biotechnology companies in the human health sector, concluded that around twice as many products were under development or being trialed as were on the market.<sup>14</sup>

Characteristically for the global biotechnology sector, much of the biotechnology companies' contribution to the Australian economy is in the future, as the products under development or on trial move through to the market. This future benefit could potentially be enormous. In addition, there are already profitable biotechnology companies in Victoria. The most notable is CSL Ltd, which at the beginning of May 2002 comprised 75% of the combined market capitalisation of ASX-listed core biotechnology companies.<sup>15</sup> In addition, biotechnology companies across the sector are already generating employment, direct and indirect revenues, research and development spending, and tax revenues.<sup>16</sup>

The Australian market is estimated to consume around 1 percent of global pharmaceutical sales. In 2000, Australia was the 18<sup>th</sup> largest pharmaceuticals market by sales, while being 50<sup>th</sup> out of 187 countries ranked on population.<sup>17</sup> In Australia, pharmaceuticals are the third largest class of elaborately transformed manufactured goods, ahead of other chemicals, wood and paper products, TCF and ICT. In Victoria, they are the fourth largest, behind automotive, equipment, and other chemicals.<sup>18</sup>

## The PIIP in practice

Under the PBS, the federal government exercises a monopsony purchasing power when purchasing listed pharmaceuticals in Australia. The pharmaceuticals industry argues that the PBS

---

<sup>11</sup> The Wills Report, 1999, Chapter 2, cited in *Op cit. n. 9*, p 20.

<sup>12</sup> *Op cit. n. 1*, p 6.

<sup>13</sup> *Op cit. n. 5*, p 20.

<sup>14</sup> *Ibid*, pp 14, 20.

<sup>15</sup> *Op cit. n. 1*, p 4.

<sup>16</sup> An American study found that in 1999 the US biotechnology industry generated 437,400 jobs and US\$47b in additional revenues (directly and indirectly), US\$11b in R&D spending, and US\$10b in tax revenues (*The Economic Contributions of the Biotechnology Industry to the US Economy*, Prepared for the Biotechnology Industry Association by Ernst & Young Consulting and Quantitative Analysis, May 2000, p 1). It would be useful to obtain a study directly referable to the Australian biomedical context.

<sup>17</sup> Department of Industry, Tourism and Resources website.

<sup>18</sup> Standard International Trade Classification export statistics for 2001-02, by value. DFAT customised trade data.



effect on prices (examined later in this contribution) makes it difficult to run sustainable businesses in Australia.

The federal government has long recognised the need to compensate companies for this effect of the PBS on pharmaceutical prices in Australia. The Factor (f) program was introduced in 1988, and continued to 30 June 1999, providing payments by way of higher prices to pharmaceutical companies. These payments were related to the increase in their value added and R&D activities. Agreements were negotiated with each company. Over the two phases of the program, the federal government paid over \$900m to pharmaceutical companies (20 in the first phase and ten in the second).<sup>19</sup>

Following the conclusion of Factor (f), the PIIP was introduced. The PIIP commenced on 1 July 1999 and is anticipated to continue until 30 June 2004, with \$300 million allocated over the five years. The PIIP aims to increase the total level of pharmaceutical industry activity undertaken in Australia. While it is similar to Factor (f), it is smaller in magnitude - capped at \$300 million over the five-year period – with funding available on a competitive basis. Participating companies are entitled to partial compensation for the effects of price and volume constraints under the PBS by increasing either or both their production value added and R&D activities.<sup>20</sup> This compensation is done by paying higher prices on nominated products supplied by participating companies in return for those companies meeting their commitments.

The PIIP and its predecessor, Factor (f), have assisted in building Australia's pharmaceuticals capacity. Over the life of the \$300m PIIP program, the 9 PIIP participants are expected to undertake production value added activities worth over \$6b and \$1b of R&D.

As the Productivity Commission would be aware, there have been a number of previous studies assessing the effectiveness of the Factor (f) scheme. These have looked, in particular, at the extent to which the additional expenditure would not have occurred without the Factor (f) program, and the broader economic and social benefits derived from these outcomes. While these outcomes are difficult to measure, most industry observers conclude that the Factor (f) program was a very successful policy in social cost benefit terms.<sup>21</sup> The Victorian Government looks forward with interest to the Productivity Commission's analysis of the PIIP, looking at similar factors.

In practice, the PIIP has the following participants, with manufacturing operations as shown:

**Victoria**

AMRAD

Bristol-Myers Squibb

CSL

Faulding (Mayne) (also with operations in SA)

GlaxoSmithKline (also with operations in NSW)

**Remainder of Australia**

Eli Lilly

Janssen-Cilag

Pfizer

Pharmacia

It is likely that the production value add spending under the PIIP occurs at the locations above. R&D expenditure, once joint and collaborative partnerships are considered, may be more diffuse and less dependent on company location. However, with those limitations in mind, the Victorian Government broadly estimates that in the first two years of the PIIP's operation, Victoria has

---

<sup>19</sup> *Op cit. n. 9*, pp 63-64.

<sup>20</sup> *Pharmaceutical Benefits Pricing Authority Annual Report For the year ended 30 June 2001*, Federal Government Department of Health and Ageing, 2001, p 25.

<sup>21</sup> *Pharmaceuticals in Australia: Equity, Cost Containment and Industry Development*, Centre for Strategic Economic Studies, Victoria University, Melbourne, October 1999, pp 39-42.

secured benefits of around \$230 million in increased production value added and \$21 million in increased R&D.<sup>22</sup>

The pharmaceuticals industry has built substantial additional capability in Victoria, during the life of both the PIIP and Factor (f) programs. Examples include CSL's major blood product expansion and research into vaccines and biosynthetic hormones, Bristol-Myers Squibb's major expansion and upgrade of production facilities in Melbourne, and GlaxoSmithKline's major expansion at Boronia in Melbourne and production facility at Port Fairy in regional Victoria.

Note, however, that the PIIP does not appear to have addressed the impact of low prices fully. Merck Sharp & Dohme states that the major impediment which constrains it from increasing investment in R&D is the pricing and reimbursement environment.<sup>23</sup> GlaxoSmithKline argues that issues like pricing and reimbursement processes undermine the competitiveness of the Australian operating environment. While a range of factors are likely to have contributed to the company's decision, it states that this year it postponed the construction of a new \$25 million administration building and restructured its pharmaceutical commercial operation with the loss of 77 staff due to the flow on effect of these issues to the company.<sup>24</sup>

### **Strategic economic and health significance of the pharmaceuticals industry**

It is increasingly recognised that scientific advances, technological change and innovation are key drivers of economic performance.<sup>25</sup> At a macroeconomic level, innovation is recognised as contributing to the three factors of output growth – capital, labour and multifactor productivity. The ability to harness the potential from scientific knowledge and diffuse it widely has become a significant source of competitive advantage, wealth creation and improvements in the quality of life.<sup>26</sup> The pharmaceuticals industry in Australia possesses all the drivers – scientific advances, technological change and innovation. It has a high R&D intensity, and the networks across and beyond the industry are strong.

These direct economic benefits are, of course, in addition to the role the pharmaceuticals sector plays in delivering better health outcomes for Australians, as well as hospital and health care savings through better treatments.

These savings are welcomed, as health expenditure in Australia is a significant component of government budgets, at both the State and Federal levels, and has nearly doubled over the last decade.<sup>27</sup> State and Territory governments are the major providers of publicly provided health goods and services in Australia. As such, they must be closely involved in and consulted about any significant policy initiatives that may affect this expenditure.

---

<sup>22</sup> *Pharmaceutical Benefits Pricing Authority Supplementary Annual Report For the year ended 30 June 2001*, Federal Government Department of Industry, Tourism and Resources, 2002, p 5, and *Pharmaceutical Benefits Pricing Authority Supplementary Annual Report For the year ended 30 June 2000*, Federal Government Department of Industry, Science and Resources, 2001, p 5. Estimates were calculated using the full PVA and R&D figures for each company with operations based in Victoria, except that the figures for Faulding and GlaxoSmithKline were halved in an attempt to account for their manufacturing operations in SA & NSW respectively.

<sup>23</sup> *Submission from Merck Sharp & Dohme (Australia) Pty Ltd (MSD) to the Standing Committee on Science and Innovation's inquiry into Business Commitment to Research and Development in Australia*, MSD, 2002, p 3.

<sup>24</sup> *GlaxoSmithKline Submission to the House of Representatives' Standing Commission on Science and Innovation "Inquiry into Business Commitment to Research and Development in Australia"*, GlaxoSmithKline, August 2002, p 6.

<sup>25</sup> *Science, Technology and Industry Outlook. Drivers of Growth – Information Technology, Innovation and Entrepreneurship*, OECD, 2001, p 51. See also *Benchmarking Industry-Science Relationships*, OECD, 2002, p 15.

<sup>26</sup> *Science, Technology and Industry Outlook. Drivers of Growth – Information Technology, Innovation and Entrepreneurship*, OECD, 2001, pp 51-52.

<sup>27</sup> *Health Expenditure Australia 2000-01*, Australian Institute of Health and Welfare, September 2002, p 8.

While pharmaceutical use often delivers savings through better treatments, some new treatments have very high upfront costs. The PBS is intended to defray some of these costs to the Australian consumer and ensure universal and equitable access to medicines. Between 1992-93 and 1999-2000, government spending on pharmaceuticals rose from under 12 per cent of public expenditure on health to over 15 per cent. In 2000-01, the cost to the Commonwealth Government of the PBS was over \$4 billion.<sup>28</sup> Although these PBS costs appear to be growing rapidly, the Victorian Government considers that the health benefits delivered by universal and equitable access to medicines justify a continued system of subsidised medicine prices in Australia.

Some pharmaceutical company advocates argue that Australian consumers are starting to miss out on the best and latest medicines, for a range of reasons linked to the PBS. These include that the policy framework and process of the PBS, because of a cost-containment imperative, have resulted in fewer Australian patients being able to access the same therapies as counterparts in other developed countries. In addition, they argue that support for a viable industry is being undermined because the prices paid for medicines in Australia are the lowest among OECD countries and price erosion continues after initial listings.<sup>29</sup>

It is useful to examine the relative level of Australian prices internationally. The Productivity Commission recently found, significantly, that there was evidence to support the view that Australia's cost containment arrangements, particularly reference pricing, may have contributed to keeping prices relatively low.<sup>30</sup>

Lower prices reduce the returns for pharmaceutical R&D spending and hence the incentive to conduct further R&D. However, the PBS underwrites a broad access to drugs for which demand would otherwise be limited. The Commonwealth's PBS expenditure can therefore be seen as a largely guaranteed market for the pharmaceutical industry. Even with lower prices, pharmaceutical consumption in Australia is only just below the OECD average.<sup>31</sup>

Nevertheless, even if consumption overall is near the OECD average by value, the price per drug is relatively low. This may be a consequence, at least in part, of the PBS pricing system, particularly reference pricing.<sup>32</sup>

The Victorian Government considers that in order to stimulate investment in pharmaceutical activity in Australia there is a continuing justification for a compensatory mechanism for companies to counterbalance these low prices.

As the OECD has found, innovation is a key driver of economic growth. For pharmaceutical companies, achieving reasonable prices on market entry provides a return on companies' investment in innovation, which in turn encourages further investment in innovation. In addition, paying a reasonable return to the innovator may assist in international recognition that Australia is willing to pay its fair share of the overall R&D costs and thus attract further investment in R&D.<sup>33</sup> The PIIP provides an offsetting mechanism to allow that return to be delivered indirectly to companies. The Victorian Government will address issues relating to direct returns, as well as returns to other players in the pharmaceuticals industry, later in this policy contribution.

---

<sup>28</sup> Research Report - *International Pharmaceutical Price Differences*, Productivity Commission, 2001, p xvi.

<sup>29</sup> *A prescription for the future health of Australia*, Medicines Australia Inc, 2002, pp ii-iii.

<sup>30</sup> *Op cit. n. 28*. The Commission found that the price differences appear to vary across different categories of pharmaceuticals, with prices for new innovative pharmaceuticals much closer to those in the other countries.

<sup>31</sup> *Op cit. n. 9*, pp 58-59.

<sup>32</sup> *Op cit. n. 28*.

<sup>33</sup> *Op cit. n. 29*, p 22.

The Victorian Government considers that the PIIP in a modified form should be extended, or a similar scheme should be put in place, once the PIIP concludes in 2004. The federal government should announce as soon as possible what the replacement or extended scheme would look like, to allow the industry time to plan. The industry also needs to have significant input into the structure of the new program as appropriate. The pharmaceutical industry operates on extremely long developmental and planning time lines. It needs certainty of government policy in this planning process. Changes to the eligibility for the R&D tax concession, and the stopping of the R&D START program are most unfortunate examples of the lack of policy certainty in the current settings.

The Victorian Government considers that there remains a strong economic justification for intervention in the pharmaceuticals industry, and considers that it is appropriate to retain an industry development program intended to counteract price outcomes under the PBS. The Victorian Government is strongly supportive of the development of a new industry development program.

It is important to recognise that Australia's budget is limited, and there are many competing pressures both from a health and industry perspective. An uncapped program with applicants meeting eligibility criteria, or a program capped at a higher level than the current PIIP with competitive assessment, would have a cost to the federal budget higher than the current PIIP. However, the PIIP itself represented a significant decrease in expenditure from the Factor (f) program, despite the returns generated from that earlier program. Those early returns suggest that an increased expenditure on a new PIIP would generate significant returns, particularly if the new PIIP was surrounded by a range of related measures, as recommended later in this contribution.

#### **Recommendation 1**

That the PIIP, which is intended to provide partial compensation for low pharmaceutical prices as a result of the operation of the PBS, be extended in a modified form, or a similar modified scheme be introduced, to at least the year 2014, with a review mechanism after five years.

The Victorian Government does not propose to recommend a specific model for a future PIIP in this policy contribution. The Victorian Government suggests that the Productivity Commission consider several models in its draft report for discussion by interested parties. These could include one or more of the following:

- the industry development program proposal outlined in Appendix C of the draft Pharmaceuticals Industry Action Agenda;
- an uncapped program where companies meeting certain criteria are eligible for payment or a program with a cap higher than the current PIIP;
- greater reward for truly innovative R&D over incremental R&D;
- greater reward for companies that do both R&D and manufacturing;
- greater reward for R&D collaboration; or
- A separate scheme for small biotechnology companies engaged with PIIP recipients.

There are benefits and disadvantages to all of these models. For example if extra payments are achievable for R&D done in collaboration with small Australian biotechnology companies, that may encourage pharmaceutical companies to close down local internal R&D operations. This may in turn reduce the linkages that those pharmaceutical companies have with Australia and therefore reduce the possibility of further R&D and investment in manufacturing facilities. This is particularly crucial at a time when R&D skills are becoming increasingly linked to manufacturing, for specialised biologicals. It is, however, important to recognise that many pharmaceutical companies are already moving to an increasingly outsourced model for R&D. Providing

incentives for such outsourcing to occur with Australian biotechnology companies may capture benefits for Australia that may otherwise go elsewhere.

Flexibility will be required in the administration of any new scheme.

#### **Recommendation 2**

That the form and timing of future assistance be announced as early as possible to enable forward planning by the pharmaceuticals industry, and be simple and flexible in terms of access and compliance for applicants and also administratively.

In determining policy settings for the pharmaceuticals industry, it is important to recognise that the sector operates in long time frames, up to 20-30 years.

#### **Recommendation 3**

That the federal government adopt a long term strategic approach to pharmaceutical industry policy.

The Victorian Government notes that the federal government has requested a review of the PBS system, due to report this year. The Victorian Government urges the federal government, in its response to that review, this Productivity Commission evaluation, and any other pharmaceutical policy issues, to take into account health, fiscal and industry development issues.

#### **Recommendation 4**

That the federal government recognise that pharmaceuticals industry development policies impact on other areas of policy development and that it adopt a whole-of-government approach to pharmaceutical policy issues, requiring consideration of health, fiscal and industry development questions.

#### **Recommendation 5**

That the federal government consult closely with industry and State Governments in relation to the design of any future assistance to the pharmaceuticals industry.

### **Changing shape of the pharmaceuticals industry**

It is important to ensure that the pharmaceuticals industry remains innovative. The OECD argues that a country's innovative capacity may be more important to its long term sustainable economic growth than is any particular technology breakthrough or industrial sector. "While development and adoption of ICT appears to have been a key driver of growth in the 1990s, other technologies – biotechnology, nanotechnology, or something entirely different – may create new industries and reinvigorate established industries in the future. Countries that experience the highest levels of growth are likely to be those that can most rapidly develop new products, processes and services based on these new technologies and apply them most effectively to other sectors of the economy."<sup>34</sup>

It is questionable whether the PIIP, in its current form, encourages innovation to occur in the pharmaceuticals industry as well as a similar program could. Commitments are entered into at the start of a five year process, with limited ability for companies to adapt within the PIIP process to new innovations emerging during that time. Pharmaceutical companies that missed out on the

<sup>34</sup> *Science, Technology and Industry Outlook. Drivers of Growth – Information Technology, Innovation and Entrepreneurship*, OECD 2001, p 52.

competitive process of allocating PIIP entitlements in 1999 have had no further chance to obtain support, despite any innovative advances they may have made or any investment or new manufacturing opportunities that emerged in the subsequent years. The Productivity Commission should address this when considering the structure of any future incentive program, particularly for a longer term program.

The Victorian Government considers that the PIIP in its current form does not provide support to a broad enough range of stakeholders in the pharmaceuticals industry.

**Recommendation 6**

That the new PIIP scheme be available to more pharmaceutical companies, recognising that PBS price factors impact across pharmaceutical companies.

**Recommendation 7**

That the design and administration of a modified PIIP permit new companies to enter the scheme and participating companies to extend their activity after the initial allocation, with multiple entry points over a ten year period.

The PIIP does not provide any direct incentives to smaller biotechnology companies to innovate. These small companies will be critical to the future of the development of pharmaceuticals in Australia. The pharmaceuticals industry is changing its structure rapidly – large pharmaceutical companies are increasingly looking for partnerships with small biotechnology companies to fill gaps in their drug development pipelines. International pharmaceutical companies are merging to try to reduce costs associated with drug development and marketing. A number of products with significant market shares are coming off-patent in the near future. New markets are appearing and expanding for a range of reasons – the global population is ageing; the mapping of the human genome is bringing new possibilities in drug design.

Australia's small biotechnology companies and research institutions hold valuable intellectual property in these areas. The Victorian Government urges the Productivity Commission to recognise the need for policies and programs that encourage adding value in Australia to that intellectual property base. These small companies and research institutions currently receive no direct support from the PIIP. While it may be argued that there are other mechanisms of support for these groups, these programs do not necessarily reward additional investment, production and R&D in the pharmaceutical industry, despite biotechnology companies and research institutions delivering many of these outcomes.

The Victorian Government urges a recognition of the vital role that biotechnology companies are playing in developing drugs for the global pharmaceutical market. There is a need to provide assistance, including access to finance, to Australian biotechnology SMEs to grow to sustainable sizes. Measures are required to encourage Australian biotechnology companies to take potential drug products further down the drug development pipeline in Australia, to maximise the economic benefit of the intellectual property developed here.

It is also important to note that there are commercial opportunities for goods and services within the supply chain itself. Many of these are and will in the future be met by Australian biotechnology companies.

The current PIIP program may provide some indirect support to biotechnology firms via PIIP recipients engaging in R&D collaborations with them. It is difficult to obtain comprehensive data on the extent of collaborations in Australia between pharmaceutical companies, biotechnology

companies and/or research institutes. Much of this is commercial-in-confidence information.<sup>35</sup> Unpublished data from publicly available sources indicates that biotechnology to biotechnology alliances are growing – have these been rewarded by the PIIP?<sup>36</sup>

The Victorian Government considers that the Productivity Commission should examine what proportion of additional R&D spend under the PIIP program has flowed to entities not directly recipients of the scheme. However, it will also be important to assess whether that economic return has been of long term benefit to Australia or whether intellectual property assets have been ceded too early in the value chain.

The Victorian Government considers that, recognising the changing structure of the pharmaceuticals industry, a new PIIP should be structured to provide benefits to a wider range of stakeholders in that industry, while recognising that the prime justification for the program is compensation for low product prices.

Lower than average world prices for pharmaceuticals in Australia may discourage pharmaceutical companies from undertaking production and R&D activities. It needs to be recognised also that a smaller pharmaceutical industry also discourages a range of other companies, drawing expertise from and providing services to the drug companies. Smaller companies are becoming increasingly important in the industry. Research collaboration within the product development chain involves both research organisations at the discovery end and specialist biotechnology and preclinical and clinical services companies in product development. Any new PIIP needs to recognise these relationships and the importance of strengthening the whole development chain. The new PIIP and related policies should encourage the activities of small biotechnology companies in Australia directly, as well as indirectly through support for pharmaceutical companies.<sup>37</sup>

#### **Recommendation 8**

That the new PIIP scheme design be sufficiently flexible to reward small Australian biotechnology companies and research institutes, where they contribute to the pharmaceuticals development process through increased production value add and research and development.

The possibilities offered by personalised medicine and other scientific developments should be an important consideration for the Productivity Commission in determining whether the PIIP would be an effective form of intervention in the future. While an enormously complex issue, how will the PBS handle personalised medicine and, consequently, what pricing impact will there be on the pharmaceuticals industry? This issue will become more pressing as the science advances.

The Victorian Government urges the Productivity Commission to examine the impact of the development of personalised medicine on pharmaceutical pricing in Australia and any flow-on effects on any new PIIP scheme design.

---

<sup>35</sup> A 1996 survey of 14 pharmaceutical companies found that those companies had 571 strategic alliance relationships with 261 organisations. Only 19 of these relationships were with companies, as opposed to organisations such as hospitals (320) and medical research funding bodies (81). 37 medical research institutes were involved with 83 relationships in total – *Strategic Industry Research Foundation*, 1996, p 3, cited in *1999-2000 Facts Book*, APMA, p 16. More recent research on publicly known alliances was discussed on 16 September 2002 at a Centre for Strategic Economic Studies Forum in Melbourne (*Development Paths for Australian Biomedical Companies*, Bruce Rasmussen, unpublished study), and some specific examples – some stimulated by participation in the PIIP - are discussed in *op cit. n. 9*, p 37.

<sup>36</sup> *Development Paths for Australian Biomedical Companies*, Bruce Rasmussen, unpublished study, discussed at a Centre for Strategic Economic Studies Forum in Melbourne on 16 September 2002.

<sup>37</sup> *Op cit. n. 21*, pp 38-42.

**Recommendation 9**

That the new PIIP scheme design be sufficiently flexible to take into account the development of personalised medicine.

A key component of the development of Australia's pharmaceuticals industry base is the development of new export opportunities. With domestic consumption accounting for approximately one percent of the global pharmaceutical market, it is important that Australian pharmaceutical manufacturers have access to global markets to ensure sustainability.

**Recommendation 10**

That the new PIIP scheme contribute to Australia capturing new opportunities in manufacturing, including biologicals and recombinant proteins.

**Recommendation 11**

That the federal government ensure that the new PIIP scheme is compliant with WTO obligations.

A skilled and experienced workforce at all stages in the drug development pipeline is critical in building the pharmaceutical industry. While Victoria, and indeed Australia, has an excellent education system and a good skills set for many areas of the pharmaceuticals industry, there is a critical need to ensure that those skills capabilities are maintained and expanded and any gaps are filled. The Victorian Government has committed to form a Biotechnology Skills Taskforce to address these issues at a State level.

A significant skills gap is the lack of commercial skills in Australian universities, research institutions and some small biotechnology companies. One way to address this may be to encourage movement of employees between the public and private sectors, with appropriate conflict of interest controls in place, transferring skills and knowledge in the process. GlaxoSmithKline recently proposed a "brokerage" scheme to rotate researchers through various entities – academic, local business, international business and government bodies.<sup>38</sup> The new PIIP scheme could have industry internships for public sector researchers as a condition for funding.

**Recommendation 12**

That the federal government consider including skills targets under any new PIIP scheme.

**The international outlook and sustaining competitive performance**

The Australian pharmaceuticals industry, as part of the global industry, is subjected to the same pressures being applied to the industry worldwide. The Productivity Commission must ensure that the right signals encouraging increased investment in R&D and production value added are sent to the international pharmaceutical industry. The disadvantages caused by low PBS prices need to be offset to create a favourable investment climate. Abandoning PIIP without any scheme to replace it has the potential to undo much of the good work achieved by the scheme and its predecessor, Factor (f).

Pharmaceutical company advocates argued after the commencement of the PIIP program that "Australia needs to be viewed as an international competitive location for pharmaceutical industry investment, and PIIP helps to enhance that image."<sup>39</sup>

<sup>38</sup> *Op cit. n. 24*, pp 8-9.

<sup>39</sup> *APMA briefing papers – Pharmaceutical Industry Investment Program (PIIP)*, Australian Pharmaceutical Manufacturers Association (now Medicines Australia), September 1999, p 2.



But not all pharmaceutical companies receive PIIP payments. Merck Sharp Dohme, not a PIIP recipient, argues that the combined effect of the PBS process and price outcomes result in reduced local revenue and an inability to predict forecast growth with any confidence. This means the company is not confident about the return on any future potential R&D investment and is not in a strong position to lobby its parent company for that investment.<sup>40</sup>

PIIP should be extended to a wider range of companies, as recommended above.

Investment signals to pharmaceutical companies' global headquarters are vitally important in attracting increased investment into the Australian pharmaceutical industry. While some investment will follow existing operations (and the PIIP is very important for this), footloose investment in the pharmaceutical sector is another matter. While the PIIP is important for this, it is not sufficient by itself, particularly when compared with incentives offered by other countries.

The Victorian Government urges the Productivity Commission to consider policy and program measures in addition to the PIIP in intervening in the pharmaceutical industry on the global level. This is not to rule out an extension of the PIIP or a related program in some form, which the Victorian Government considers appropriate, but rather to urge the Commission to look at other options as well.

What is needed, in addition to a revised PIIP, to encourage international investment in the pharmaceuticals industry in Australia, thus building the domestic base? It needs to be acknowledged by federal and state governments that Australia often fails to attract large international investments in the pharmaceutical industry. This occurs not because Australia is not a world class location for these developments, but rather in competition for these projects we lose out to other nations prepared to modify taxation regimes and offer other incentives. The reality is that currently Australia does not fare well in the competitive market to attract this investment.

A recent survey by industry associations found that for R&D, pricing and reimbursement were ranked as the most important factors influencing multinational corporation headquarters' decisions to investment. Regulatory issues were also ranked very highly, with operational costs, taxation incentives and human resources and infrastructure high. For manufacturing, pricing/reimbursement issues and the taxation environment were ranked as most important, with geographic distance and time zone issues of high importance. Australia was ranked poorly in terms of the taxation environment and incentives.<sup>41</sup>

Investment incentives are by no means the sole consideration of international investors when determining the location of an R&D facility or manufacturing base. A recent survey of senior biotechnology R&D leaders and business executives in Australia and overseas revealed that a multitude of factors are relevant to presenting a compelling "value proposition" for investment, and that costs *per se* are not apparently the most important.<sup>42</sup>

Incentives do, however, have a crucial role to play at the margins.<sup>43</sup> Governments around the world have recognised this. Many are offering a range of investment incentives. The incentives offered by Australia, including the \$300m PIIP – with one entry point over 5 years - and the R&D

---

<sup>40</sup> *Op cit. n. 23*, p 3.

<sup>41</sup> Pharmaceutical Industry Action Agenda survey, cited in *Op cit. n. 23*, p 4.

<sup>42</sup> *Benchmarking Study of R&D Costs in Selected Segments of Australian Biotechnology*, Ernst & Young, Hay Group, and Strategic Industry Research Foundation, January 2001, p 28.

<sup>43</sup> The World Investment Report, 1996, cited in *Investment attraction policies – a briefing paper*, Coopers & Lybrand Policy and Economics, 1997, p 23.

tax concession, are simply not of the same magnitude as offers made by countries such as Singapore and Ireland.

Singapore, for example, offers

- Tax and grant incentive schemes to encourage biomedical science industrial activity;
- R&D grants and manpower training for companies to “jumpstart” local operations; and
- Various tax incentives for manufacturing or service activities.<sup>44</sup>

In 2001 alone, several major pharmaceutical investments in Singapore were announced, including:

- Merck Sharp & Dohme’s global manufacturing facility for asthma and arthritis active pharmaceutical ingredients, and plans for a formulation facility, with total capital investment of over S\$900 million;
- Schering-Plough’s construction of a S\$225 million lyophilisation plant for two new products - a Hepatitis C drug and an anti-inflammatory agent for rheumatoid arthritis;
- Novartis’s announcement of a tropical diseases research centre, projected to spend S\$220 million on research over 5-10 years; and
- Eli Lilly’s announcement of its first systems biology R&D centre outside the US, projected to spend S\$260 million on research over 5 years.<sup>45</sup>

These investments, together with other recent developments, have meant Singapore now claims capabilities in primary manufacturing - chemical synthesis of pharmaceutical active ingredients, and process development – as well as capabilities in secondary manufacturing, formulation and finishing, and lyophilisation. Companies with existing manufacturing facilities have also continued to increase their production capacities in Singapore.

Ireland has similar stories of success. It offers:

- A 10% corporate tax rate until 31 December 2002 for manufacturing and qualifying services. From 1 January 2003, a rate of 12.5% will apply to all trading profits;
- Other taxation fiscal incentives, such as patent royalty tax exemption, capital allowances and expenditure on scientific research;
- Non-repayable financial grants, for capital, employment, training, and R&D;<sup>46</sup>
- Quick and duty-free access to European markets;<sup>47</sup> and
- A one-stop shop providing advice and assistance.<sup>48</sup>

Ireland is a key location for the pharmaceutical and chemical industry in Europe. Overseas companies employ 20,000 people and export US\$32 billion annually, representing over 29% of total exports and making Ireland one of the world’s largest pharmaceuticals and fine chemicals exporters.<sup>49</sup>

---

<sup>44</sup> BioMed-Singapore.com website.

<sup>45</sup> *Biomedical Sciences Industry Maintained Growth Trajectory in 2001*, Joint Economic Development Board Biomedical Science Group and Biomedical Research Council/Agency for Science, Technology & Research Industry Briefing 2002 press release, 6 February 2002.

<sup>46</sup> *Achieve European Competitive Advantage – Guide to tax and financial incentives in Ireland*, Ireland Industrial Development Agency, June 2001.

<sup>47</sup> *Facts about Ireland 2002*, Ireland Industrial Development Agency.

<sup>48</sup> *Achieve European competitive advantage in healthcare*, Ireland Industrial Development Agency, March 2000.

<sup>49</sup> IDA Ireland website ([http://www.idaireland.com/industry/pharmaceutical\\_industry.asp](http://www.idaireland.com/industry/pharmaceutical_industry.asp)).

Ireland estimates total Irish investment by the overseas pharmaceutical sector at US\$12 billion. The sector is diversified, with investment in fine chemical plants producing bulk active materials and new investments in finished product pharmaceutical operations. Forty-seven finished pharmaceutical plants are now in operation.<sup>50</sup> Collaborative research projects with universities are also common.

The Victorian Government considers that Victoria rates well on most of the factors in the Ernst and Young survey cited above, for biotechnology manufacturing as well as for biomedical R&D. A study by PriceWaterhouseCoopers found that Victoria's global position is extremely competitive for international investors in these areas, with the State providing the best global infrastructure, real estate and living environment of all competing locations.<sup>51</sup>

However, many investment decisions are made on the margins. Australia does offer distinctive skills, knowledge and innovation in the biomedical area. But there is an urgent need for the federal government to accept that incentives, whether fiscal, financial or other measures, are a reality of the global pharmaceutical industry. They must be sufficiently targeted and flexible and of a scale that allows Australia to compete with other locations offering a generous range of incentives. The federal government must take a leadership role in securing major pharmaceutical manufacturing projects for Australia, including through the provision of significant financial incentives.

A recent financial benchmarking study by PWC Consulting looked at the upfront costs of attracting a high profit margin biopharmaceutical project to Victoria as against Ireland, Singapore, Puerto Rico and Switzerland. The study found that Victoria has an advantageous cost structure with lower site, building construction, utilities and white collar labor costs than in the benchmarking countries. However, with corporate tax as the major cost driver in the cost structure, in the benchmarking countries, the company would be able to benefit from either a considerably lower corporate tax rate (Ireland and Puerto Rico) or an outright tax exemption (Switzerland and Singapore) making these locations very attractive for this type of tax sensitive project. The study found that this could readily be addressed with the offer of a cash grant. Increasing the upfront incentives package on fixed asset investment can greatly enhance the competitiveness of Victoria for the project up to the point where it surpasses the other locations.<sup>52</sup>

The federal government must recognise that without incentives, it is unlikely that any state can successfully attract high value pharmaceutical investment into Australia given the international competition for such investment.

There is a range of incentives that the federal government could contemplate in relation to attracting pharmaceutical activities to Australia. Fiscal incentives could include a reduction of the standard corporate income tax rate, tax holidays, further value-added based incentives and export-based incentives. Financial incentives could include direct subsidies to cover part of capital, production or marketing costs of an investment project, subsidised loans and loan guarantees. Other incentives could include subsidised dedicated infrastructure, and assistance with training.

The Victorian Government concludes that despite the clear cost and quality advantages of Victoria as an investment location, incentives are necessary in the current global market, to attract new

---

<sup>50</sup> *Ibid.*

<sup>51</sup> The Victorian Government would be happy to make this PWC Consulting study available to the Productivity Commission on a confidential basis if requested.

<sup>52</sup> *Financial Benchmarking for Bio-Pharmaceutical Project for the Department of State and Regional Development of Victoria*, PWC Consulting, 13 June 2002. The Victorian Government would be happy to make this study available to the Productivity Commission on a confidential basis if requested.

investment from the pharmaceutical industry. This is particularly true for attracting investment in the high value and innovative components of the value chain as well as large scale manufacturing projects.

Australia needs to learn from international experience. The Productivity Commission should examine investment incentives offered by other countries to build their pharmaceutical industry and assess them in the Australian context

In addition, the federal government should ensure that Invest Australia better co-ordinate its biotechnology and pharmaceutical activities (beyond events) with State-based investment attraction agencies

### **Recommendation 13**

That, in addition to support provided through any PIIP-like scheme, the federal government agree to offer investment incentives to attract appropriate investment from international pharmaceutical companies at all stages of the industry value chain (discovery R&D, preclinical development, clinical trials and manufacturing).

### **Other policy and program measures**

The terms of reference for the Productivity Commission's evaluation of the PIIP are sufficiently wide to propose alternative actions to the PIIP to ensure a sustainable pharmaceutical industry in Australia. The Victorian Government considers that this opportunity should not be missed.

While the Wills Review identified a virtuous cycle in medical research, there are still serious deficiencies in parts of that cycle, resulting in missed opportunities to add value to the excellent medical research occurring in Australia. If a new PIIP alone was implemented by way of intervention in the pharmaceuticals industry in Australia, opportunities would continue to be missed. A range of measures is required to equip Australia's pharmaceuticals industry to add value to intellectual property generated in Australia and extract that value for Australia's benefit.

### ***Increase inter-government co-operation and co-ordination***

It should be recognised that a range of alternative policy and program measures is already being implemented in relation to the development of a sustainable pharmaceuticals industry in Australia. In Victoria, the Biotechnology Strategic Development Plan for Victoria, launched in June 2001, aims to make Victoria one of the world's top five locations for biotechnology by 2010, for the vibrancy of its industry and quality of its research. There are over 60 major initiatives in the Strategic Plan, covering areas from skills, infrastructure, commercialisation, building the corporate base, and government leadership and support.<sup>53</sup>

The manufacturing component of the pharmaceuticals industry is addressed in the Victorian Government's \$27 million *Agenda for New Manufacturing*. The agenda builds on the State's existing manufacturing strengths and aims to accelerate innovation, grow exports, champion manufacturing, create high-performance workplaces, build skills, achieve environmentally sustainable manufacturing and attract investment.

Other State Governments have biotechnology industry development initiatives underway, most notably, South Australia, Queensland and New South Wales. The Commonwealth Government's National Biotechnology Strategy, currently under review, is a useful high level document, but

---

<sup>53</sup> The full document can be downloaded from [www.biotechnology.vic.gov.au](http://www.biotechnology.vic.gov.au).

there is a need for the federal government to show more leadership in the sector, particularly in relation to investment attraction activities.

#### **Recommendation 14**

That the federal government align its biotechnology and pharmaceutical industry development policies and programs with those of the various State and Territory Governments, and show leadership in relation to biotechnology investment attraction activities.

#### ***Enhance Australia's preclinical capability***

While the Biotechnology Innovation Fund and the pre-seed fund initiatives, together with a wide range of State Government commercialisation programs, are addressing very early stage developments in the drug development value chain, there are serious deficiencies preventing small Australian biotechnology companies from developing Australian intellectual property at the preclinical capability and clinical trial stages. Issues of manufacturing, marketing and distribution are a further step-up in complexity.

In many cases, small biotechnology companies may need to partner with international pharmaceutical companies with expertise in these areas. Shared infrastructure – eg IT – may also be another mechanism used to shorten biotechnology companies' products' time to market. The difficult issue will be how best to maximise returns for Australia from the development of Australian intellectual property.

The Victorian Government recently sponsored a forum entitled "Maximising Australia's Preclinical Capacity", aimed at identifying ways of increasing Australia's share of the global pharmaceuticals industry by addressing needs and opportunities at the preclinical stage of drug development. A range of recommendations was made, designed to ensure action in this area.<sup>54</sup>

The federal government has been working with the pharmaceuticals industry since May 2001 on the development of an action agenda for the pharmaceuticals industry. The Victorian Government hopes that when the action agenda is released the federal government will show leadership in determining its implementation.

#### **Recommendation 15**

That the federal government work with industry and the State Governments to identify interventions in the preclinical arena that would result in additional investment, production and research and development, and uses the findings of the "Maximising Australia's Preclinical Capacity" forum as a starting point.

#### ***Enhance Australian company access to clinical trials***

Australia has a generally excellent clinical trials infrastructure, and many multinational trials have Australian centres. However, development of potential pharmaceutical products through the clinical trial phases is a difficult issue for some Australian biotechnology companies.

Initiatives improving access to finance (at mid- and later stage) and regulatory expertise are required in this area to enable more Australian biotechnology companies to participate and grow to sustainable levels. The R&D START program, if re-opened, could be considered as a potential source of funds for early phase clinical trials, as well as the private sector.

---

<sup>54</sup> *Maximising Australia's Pre-clinical Capabilities Forum Discussion Paper*, SDA Biotech, August 2002.

Sustainable business models will be required, to encourage start-up companies to become strong, multiproduct companies. Australia should aspire to grow companies in Australia that can take product all the way to market, or at least registration domestically. These should grow alongside large pharmaceutical companies, which will remain crucial to the development of the sector and to ensuring that Australians have access to pharmaceutical products.

**Recommendation 16**

That the federal government work to encourage Australian biotechnology companies to take potential pharmaceutical products through at least the early phase clinical trials.

***Address PBS listing difficulties where appropriate***

As discussed earlier, some pharmaceuticals industry advocates are concerned that there is a cost-containment imperative operating around the PBS, resulting in fewer Australian patients being able to access the same therapies as their counterparts in other developed countries, and price erosion occurring after listing.

The challenge of the Pharmaceutical Benefits Pricing Authority (PBPA) in reviewing PBS prices is to secure a reliable supply of pharmaceutical products at the most reasonable cost to Australian taxpayers and consumers whilst maintaining a sustainable pharmaceutical industry in Australia.<sup>55</sup>

The Victorian Government wishes to ensure that Victorian patients have affordable access to essential medicines through the PBS. We urge that the federal government ensure that the PBS listing process is thorough and timely, without unnecessary delays, with increased transparency where appropriate. GlaxoSmithKline contend that there is a lack of clarity of process and interaction in relation to the listing and reimbursement process in Australia, which is “of grave concern to those who wish to attract additional pharmaceutical R&D to Australia.”<sup>56</sup>

The Victorian Government suggests that the Productivity Commission consider interventions into the pharmaceuticals industry through the PBS listing process as part of its evaluation. A range of issues could be addressed, including the following:

- Whether any global flow-on effect of PBS prices in Australia prevents products being listed in Australia;
- Whether the impact of the Therapeutic Group Premium (TGP) Policy which leads to a TGP on all products in a group when one product goes off-patent is justified;
- Whether the assumptions, including dosage, underlying Weighted Average Monthly Treatment Costs (WAMTC), are appropriate;
- What the impacts on Australian companies are of TGP and WAMTC price reductions being greater than PIIP payments;
- Whether a lack of CPI adjustments for PBS prices (possibly resulting in a decline in R&D returns) is justified;
- Whether PBS price decreases for products over time make it more difficult for PIIP entitlement recipients to reach PVA targets and whether measures should be introduced to address this;
- Whether productivity savings should be considered in economic analyses of PBS products;

<sup>55</sup> *Pharmaceutical Benefits Pricing Authority (PBPA) Annual Report For the year ended 30 June 2001*, p 7.

<sup>56</sup> *Op cit. n. 24*, p 6.

- Whether the PBS listing process delivers certainty to the industry, with price declines following reviews;
- What the implications would be if PBS prices for new innovative medicines were increased, paid for by decreasing PBS prices for off-patent medicines; and
- Whether further increases in transparency in methods and procedures used by the PBAC and the PBPA are desirable.

In addition, Medicines Australia has proposed a number of options for improving the effectiveness of the PBS.<sup>57</sup> The Victorian Government, while not endorsing the options, urges the Productivity Commission to examine them under the terms of reference for its evaluation of the PIIP.

Medicines Australia has also proposed a number of options addressing issues of sustainability of the PBS in the context of the overall health care system.<sup>58</sup> It argues that the federal government should give consideration to increasing government expenditure for the PBS up to the OECD average.<sup>59</sup> The Victorian Government is committed to fiscal responsibility and would therefore urge the Productivity Commission to examine that proposition closely before considering recommending it to the federal government.

The Australian Institute of Health and Welfare concedes that there is no definitive relationship between what a country spends on health and the health status of its population.<sup>60</sup> Clearly, the fact that the US spent nearly double on health expenditure than Australia per capita in 2000 does not mean Americans are twice as healthy as Australians. On the other hand, PBS expenditure, in some cases, may slow down expenditure in other health areas. Medicines Australia, then the APMA, estimated that the use of medicines developed by the pharmaceuticals industry results in savings to the health budget of hundreds of millions of dollars, with millions of Australians saved from hospitalisation, surgery and death.<sup>61</sup> This savings issue is something the Productivity Commission may wish to address.

#### **Recommendation 17**

That changes should be contemplated where appropriate to the pharmaceutical listing process to overcome difficulties being experienced, while retaining the integrity of the Pharmaceutical Benefits Scheme.

#### ***Remove trade barriers (including regulatory barriers) to overseas markets***

For Australia's pharmaceutical exporting capacity to continue to increase, the federal government will need to work to ensure that export markets are not blocked unreasonably. As the OECD states, "[n]ational standards and procedures can help exporters, because transparent rules facilitate trade. But they can also reduce international competition, distort markets and prevent firms, notably foreign firms, from entering markets."<sup>62</sup> Regulatory harmonisation is an important component of this issue. Australia should continue to monitor developments at the International Conference on Harmonisation. The Victorian Government considers that the federal government must continue to be involved in international fora where frameworks that shape regulatory, as well as patenting and trade, issues are determined.

<sup>57</sup> *Op cit. n. 29*, pp viii-x.

<sup>58</sup> *Ibid*, pp vii-viii.

<sup>59</sup> *Ibid*, p 9.

<sup>60</sup> *Health Expenditure Australia 2000-01*, Australian Institute of Health and Welfare, September 2002, p 55.

<sup>61</sup> *1999-2000 Facts Book*, APMA, p 51.

<sup>62</sup> *Modern Biotechnology and the OECD*, Policy Brief, OECD, June 1999, p 6.

**Recommendation 18**

That the federal government increase its efforts to ensure trade barriers (including regulatory barriers) are removed from overseas markets

***Improve generic export opportunities***

When the federal government announced the PIIP, it said that “two of the most important factors which shape investment in the pharmaceutical industry on an international basis are: the extent of price controls and the competitiveness of a country’s patent regime.”<sup>63</sup>

The Victorian Government considers that the federal government should explore ways of increasing generic medicine manufacture in Australia for export, where appropriate, and welcomes the federal government’s current review of pharmaceutical patent extension policy and springboarding. Any action in this regard would, of course, need to be undertaken with regard for Australia’s strong commitment to internationally accepted intellectual property standards.

**Recommendation 19**

That the federal government examine interventions relating to patent protection to encourage the growth of generic manufacturing in Australia for export.

***Australia’s taxation regime***

Anecdotal evidence continues to be that Australia’s taxation position is uncompetitive as an international investment location. A recent taxation discussion paper, *Growing our knowledge economy*, argued for various taxation amendments.<sup>64</sup> In addition, the draft Pharmaceutical Industry Action Agenda identifies a range of possible taxation reforms. While the Victorian Government does not necessarily endorse the positions taken in either paper, we encourage the Productivity Commission to identify the proposals in the papers as possible alternative mechanisms and assess them under the terms of reference for this evaluation.

**Recommendation 20**

That the federal government examine options for introducing taxation measures assessed by the Productivity Commission as possible alternative mechanisms under the terms of reference for this evaluation

<sup>63</sup> *New policies promote investment in Australia’s pharmaceutical industry*, press release 87/97, the Hon John Moore MP, 8 April 1997.

<sup>64</sup> *Growing our knowledge economy*, Ernst & Young, 2002. Note that funding support was provided by the Victorian Government Department of State and Regional Development.



## Conclusion

This policy contribution concludes that a comprehensive strategy, based on a suitable mix of policies, is required in relation to development of the pharmaceuticals industry in Australia.

The Victorian Government considers that a replacement for the current PIIP will be an integral part of that mix. There is a continuing need for a scheme to provide price compensation as an incentive for pharmaceutical activity in Australia. We propose a replacement PIIP with the following key policy features:

- Long term policy certainty
- More than one entry point in time
- Recognising the wide range of players contributing to the pharmaceuticals industry, including small biotechnology companies and research institutes
- Creating the ability for Australian intellectual property to be taken further down the drug development pipeline in Australia
- Encouraging new manufacturing capability
- Internationally competitive as an investment incentive
- Flexible enough to adapt to scientific developments
- R&D (including collaboration), value added manufacture, and skills targets.

In addition to the PIIP, the Victorian Government recommends that the Productivity Commission examine additional interventions in two areas:

- Internationally competitive investment attraction measures, to attract footloose investment in the pharmaceuticals industry where that investment is of strategic value to the future development of the Australian pharmaceuticals industry (including the growth of Australian biotechnology companies); and
- Focused pharmaceutical and biotechnology sector development support, addressing issues such as access to finance, skills, preclinical capacity, PBS listing, trade barriers, and taxation.