

**Deloitte Insight Economics for the Department
of Innovation, Industry, Science and Research**

**Evaluation of the
Pharmaceuticals
Partnerships Program (P³)**

FINAL REPORT

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Acronyms

ABS	Australian Bureau of Statistics
ANAO	Australian National Audit Office
API	Active Pharmaceutical Ingredient
CIE	Centre for International Economics
COMET	Commercialising Emerging Technologies
DIISR	Department of Innovation, Industry, Science & Research
DITR	Former Department of Industry, Tourism and Resources
E7	Brazil, China, India, Indonesia, Mexico, Russia and Turkey
EIU	Economist Intelligence Unit
EU	European Union
G7	Britain, Canada, France, Germany, Italy, Japan, & the United States
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
ICH	International Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use
IP	Intellectual Property
MNC	Multinational Corporation
P³	Pharmaceuticals Partnerships Program
PBS	Pharmaceutical Benefits Scheme
PIIP	Pharmaceutical Industry Investment Program
R&D	Research & Development

Key Findings

Appropriateness of P³

At the time of its introduction, the Pharmaceuticals Partnerships Program (P³) addressed some identified market failures that particularly impacted upon the pharmaceuticals industry. Specifically, it addressed:

- the lack of generally available support for Research & Development (R&D) by Multinational Corporations (MNCs) where Intellectual Property (IP) ownership was held overseas;
- perceived limitations in private funding available for local biotechnology firms to undertake product development R&D; and
- sub-optimal levels of R&D partnerships between companies, and between companies and medical research institutes.

The first of these issues was of particular concern for the pharmaceuticals sector given the strong preference by pharmaceuticals MNCs to hold IP centrally. However it is not clear that the latter two issues are unique to the pharmaceuticals sector. The appropriateness (at the time of its introduction) of a sector specific policy intervention such as P³ therefore relied upon a combination of the need to address the needs of MNCs and upon a judgement as to whether the strategic significance of the pharmaceuticals and biotechnology industry justified the introduction of a sector specific program.

Since the introduction of P³, an important change to the 175 per cent Premium R&D Tax Concession partly addresses the issue of access to general R&D support for MNCs (they still cannot access the 125 per cent R&D Tax Concession). This change weakens (but does not completely remove) the case for the appropriateness of P³ into the future, insofar as the most *sector specific* market failure has now been largely addressed. The case for the appropriateness of a future sector specific intervention now must largely rest on whether the strategic significance of the pharmaceuticals and biotechnology industry is seen to justify such special treatment.

While assessing the ‘strategic significance’ of a particular industry is a somewhat subjective exercise, and is one for Government policy makers to determine, there does not appear to be compelling evidence available to suggest that spillovers for pharmaceuticals/biotechnology R&D are, on the whole, systematically higher than those that would be expected from R&D in other high technology and high innovation intensity industries.

It is important to note here that the question of appropriateness of a sector specific program is not the same as the question of whether there are still market failures in relation to industry R&D that continue to impact upon the pharmaceuticals sector as they do on other sectors. Such continuing market failures, for instance in relation to small companies that are pre-profitable and therefore do not benefit from the R&D Tax Concessions, may provide justification for continuation or expansion of Government programs that provide general support for emerging technology intensive companies. For instance, general programs such as the R&D Tax Offset, COMET and the Innovation Investment Fund may well be appropriate mechanisms to address market failures that impact upon the pharmaceuticals industry.

Effectiveness of P³

The key findings from the evaluation of the effectiveness of P³ in achieving its stated policy objectives are:

Increase in pharmaceuticals R&D activity in Australia

There has been an increase in R&D expenditure amongst successful participants in the program. Evidence does suggest that firms awarded P³ grants have expanded their R&D expenditure as a result of the program. For instance, successful participants' R&D spend has grown at a higher rate than the average for the sector as a whole. Stakeholders have also reported that the program has induced additional investment, including influencing the location of foreign direct investment to Australia. Round 3 appears to have had a higher inducement rate for attracting new R&D expenditure than Rounds 1 and 2.

The number of multinational firms with regional or global R&D operations in Australia

P³ does not appear to have resulted in MNCs establishing new regional or global R&D operations in Australia. However, it is possible that P³ has had a role in all MNCs with regional or global R&D operations in Australia retaining these operations in Australia over the past three years. P³ has positively influenced the level of R&D that MNCs with existing regional or global R&D operations in Australia have undertaken in Australia.

The number and quality of linkages and new collaborations

In relation to collaborations and partnerships, P³ is reported by stakeholders to have had a generally low to moderate impact. Strongest positive impacts were seen in relation to the development of partnerships with universities and medical research institutes. Participants in Round 3 tend to report higher positive impacts relating to collaborations and partnerships from P³ than do participants in Rounds 1 and 2, suggesting that these collaborations and partnerships are viewed as being of higher quality.

The quality of R&D undertaken by participants

Projects awarded funding under P³ tend to be at an earlier stage of development in the pharmaceuticals value chain than the industry average. Therefore P³ has, on average, supported investment in projects that could be expected to deliver higher spillover benefits for the community than the industry average. In the absence of ongoing monitoring of the scientific quality of projects, the shift towards earlier stage and higher spillover R&D is the best available proxy for the quality of R&D being undertaken. Feedback from participants in Round 3 suggests that Round 3 has had a 40 per cent greater impact on the level of spillover benefits than did Rounds 1 and 2 and hence could be regarded as having supported higher quality R&D.

The level of benefit to the Australian economy of P³

The net economic impact of P³ is discussed in detail separately below.

Encouraging the development of medicines for the global markets

In relation to developing medicines for global markets, stakeholders report P³ as having only a modest impact to date, with the strongest impact seen to be in assisting participants in gaining new IP. Again, participants in Round 3 tend to report higher positive impacts from P³ relating to the development of medicines for the global market than do participants in Rounds 1 and 2.

Unsurprisingly, given the timeframes for medicines development and the fact that the majority of P³ funding has supported early stage R&D and clinical trials, the impact of the program in advancing the objective of developing medicines for global markets is not rated highly by participants. This is not a criticism of the program as such, but rather may suggest that the true impacts in this area may take several more years to emerge.

Overall conclusions regarding effectiveness of P³

Leaving aside the question of the net economic impact of the program, which is discussed below, the program can be assessed as having made some positive contribution in relation to its objectives, with the strongest contribution being made to the attraction of new high quality R&D expenditure. It would also appear that the changes made to the program between the first two Rounds and Round 3 have increased the extent to which the program has made a positive contribution in relation to each of its key objectives.

Across the three rounds of the program, the number of applications has declined but the success rate of applications has increased. This reflects participants gaining progressively greater understanding of the requirement of the program and them better targeting applications to the program objectives. The higher success rate in Round 3 can therefore be interpreted as reflecting an increase in the average quality of applications for that round when compared to earlier rounds.

Efficiency of P³

The review team agrees with the ANAO's finding that P³ has been managed in an efficient manner. This holds in relation to both the efficiency of the application process and the efficiency of ongoing compliance processes.

Efficiency in relation to program administration costs, application costs and compliance costs all seem to be well within the acceptable performance range for Government programs of this type.

Net public and economic impact of P³

Before considering the net public and economic impact assessment conducted in this study, it is important to place in context what benefits from P³ are captured in this form of analysis and what potential benefits are not captured in the analysis. Pharmaceuticals research generates a range of impacts that can be clearly captured in the 'market' sphere – it can directly lead to productivity gains, increased production, exports and employment. Not all of these benefits in the market sphere will be captured by the private entity undertaking the research, with some 'spilling over' to deliver a wider economic benefit of the community. The public and economic impact analysis of P³ in this study is focused only on capturing these 'market' sector privately and publicly captured economic benefits resulting from P³.

It must be openly acknowledged that this represents only a partial accounting of the total beneficial impacts that may be associated with the pharmaceuticals research supported by P³. Research, in addition to generating impacts in the market sector over the short to medium term, can also generate a range of longer term beneficial impacts to society. For instance, if pharmaceuticals research leads to better treatment of illness ten or fifteen years from now, this would confer significant economic and non-economic benefits to the community. Better health outcomes will increase labour force participation and productivity, things that fall within the 'market' sphere, but will also have a profound 'non-market' value, namely, the value we place on living longer and healthier lives. While there are attempts now being made in economic theory, such as through contingent choice valuation methodologies, to place an 'economic' value on profoundly non-market goods such as the personal value we place on life and health, such approaches are beyond the scope of this study.

The public and economic impact assessment of P³ in this study should therefore be viewed for what it is, an attempt to capture the costs and benefits of P³ over a limited time horizon where only impacts clearly within the ‘market’ sphere are factored into the calculations. As such, it is necessarily only a partial accounting for the potential long terms societal costs and benefits that may result from P³.

Key findings

Based on the three different modes of impact analysis (detailed in Sections 4.5.1, 4.5.2 and 4.5.3), a diversity of results are produced:

- When the assumptions used by CIE are maintained and net public impacts calculated using current available performance data, the net public cost/benefit of P³ is calculated to be between minus \$95.9 million and positive \$87.9 million. The ‘expected’ result is minus \$11.1 million. Given the scale of the program and the uncertainties surrounding the assumptions, this should be interpreted as suggesting that the expected public cost/benefit of P³ is close to neutral when the CIE assumptions are used.
- When some of the assumptions used by CIE are altered to reflect more recently available information and net public impacts are calculated using currently available performance data, the net public cost/benefit of P³ is calculated to be between minus \$96.4 million and positive \$85.7 million. The ‘expected’ result is minus \$23.8 million. Given the scale of the program and the uncertainties surrounding the assumptions, this should be interpreted as suggesting that under this methodology the expected public cost/benefit of P³ is likely but not certain to be moderately negative.
- The application of the methodology (and assumptions regarding inducement rates, spillover rates and financing costs) used by the Productivity Commission in its 2003 review of the PIIP to the specifics of P³ results in an estimated net economic benefit for P³ of positive \$9.8 million. If the methodology of the Productivity Commission is matched to the CIE assumptions regarding inducement rates, spillover rates and financing costs, the estimated net economic benefit for P³ is negative \$21.0 million. If the methodology of the Productivity Commission is matched to the ‘alternative’ Deloitte assumptions regarding inducement rates, spillover rates and financing costs the estimated net economic benefit for P³ is negative \$4.7 million. Given the scale of the program and the uncertainties surrounding the assumptions, this range of results when applying the Productivity Commission methodology should be interpreted as suggesting that the expected public cost/benefit of P³ is close to neutral.

Given the variation in results that flow from the different methodologies and assumption approaches (and the inherent uncertainty around the selection of these assumptions), with mid-point impact estimates ranging from of -\$23.8 million to +\$9.8 million, we believe that the most appropriate overall conclusion to draw in relation to the quantifiable public and economic impact of P³ is that, while the balance of probability is towards a small negative impact, the actual overall public and economic impact of P³ is likely very close to neutral. Reading more into the results than this would be falling into the trap of attributing ‘false precision’ to the mid-point impact estimates.

While the public costs and public benefits of P³ are of primary interest for the purposes of the program review, it should be noted that a private net benefit exceeding \$100 million is expected to be generated by the program, with between half and two thirds of this benefit expected to accrue to Australian owned firms.

It should also be stressed that the public and economic benefits able to be captured in this study are limited to clearly 'market' sphere benefits that are expected to be delivered over the short to medium term. As such, the analysis represents only a partial accounting of the potential total long term benefits from P³.

Policy and program options for future consideration

This evaluation suggests that, based on recent changes to the eligibility rules for the 175 per cent Premium R&D Tax Concession and the estimated cost effectiveness of the program, there is not a compelling case for P³ to be continued past 2009 in its current form.

One of the challenges for this review, and especially the question of possible options for a future program, is that there is considerable uncertainty about the future mix of Commonwealth programs to support innovation. The Commonwealth Government has launched the *Review of the National Innovation System*. The review will, amongst other things, be looking at ways of reducing the number of innovation programs which currently exist at both the Commonwealth and State/Territory levels. The review guidelines and terms of reference note that there are now 169 Commonwealth and State innovation programs.

The nature and level of R&D taxation concessions to be applied in the future is also a key agenda item for the *Review of the National Innovation System*.

Any successor to P³ would need to be developed within the context of general measures designed to support innovation and the R&D taxation concessions in particular. Against this background, it is difficult to make recommendations about a future program for pharmaceuticals/biotechnology. Instead we have sought to identify a number of options for consideration by policy makers.

There are five core options set out below for the Government to consider in relation to what, if any, sector specific policies should succeed P³. Government may wish to consider:

1. Not replacing P³ with any new industry specific program, but rather relying upon general measures to provide incentives for industry R&D activity.

The negative of this option would be that it would effectively represent a decrease in the incentives currently available to the pharmaceutical/biotechnology industry to undertake R&D in Australia. The 175 per cent Premium R&D Tax Concession somewhat mimics the incentives provided by P³, but at a lower incentive rate (22.5 cents in the dollar via the concession versus 35 cents in the dollar after tax via P³) than the incentive offered in Round 3.

A reduction in support available for pharmaceuticals R&D would be expected to lead to somewhat lower levels of R&D activity being undertaken. However, if general support for R&D is increased as a result of the recommendations from the recently commenced *Review of the National Innovation System*, this concern may be avoided.

2. Continuing with P³ in its current form.

This evaluation suggests that based on the first three years of the program and its estimated cost effectiveness, notwithstanding the recent improvements to the program, there is not a compelling case for P³ to be continued past 2009 in its current form. This conclusion is further confirmed when account is taken of the relative merits of the use of sector specific rather than general policy instruments to encourage R&D.

3. Refining the design of P³ to increase the inducement rate of the program and drive step change additional R&D investment by large pharmaceuticals companies.

In relation to the expected net economic impact of this option, increasing the inducement rate to levels higher than Round 3 and focusing only on supporting basic research and early stage clinical trial projects would be expected to improve the net economic benefit of the program when compared to P³.

For this option to be justified, a case would need to be established that this sector specific initiative would be expected to yield higher economic returns than would a similarly designed initiative open to project submissions from all industry sectors. It is not clear that such a case currently exists.

4. Refining the design of P³ to implement a smaller scheme focused only on Australian emerging pharmaceuticals/biotechnology companies. The R&D Tax Concession would, under this approach, be relied upon as the primary mechanism to encourage investment by larger companies.

In relation to the net economic impact of such a program, the focus on small to medium sized Australian companies doing early stage R&D would preclude capture of any benefits associated with inducement of foreign direct investment. However, the focus on early stage R&D only would result in higher spillover rates for funded activity than the average for P³.

As with option 3, for this option to be justified, a case would need to be established that this sector specific initiative would be expected to yield higher economic returns than would a similarly designed initiative open to project submissions from all industry sectors. It is not clear that such a case currently exists.

5. Introducing a new scheme whose purpose is to facilitate only ‘partnership’ investments in pharmaceuticals related multi-party access infrastructure where the partnerships involve pharmaceuticals companies and the public research sector.

The net economic impact of such a program may potentially be higher than P³ as it could achieve higher levels of inducement and also higher spillover benefits through providing long term infrastructure that would benefit multiple parties over a prolonged period of time.

As with options 3 and 4, for this option to be justified, a case would need to be established that this sector specific initiative would be expected to yield higher economic returns than would a similarly designed initiative open to project submissions from all industry sectors. It is not clear that such a case currently exists.

It is important to note that these options are not intended to represent a collection of different proposals put forward by stakeholders. The options are based on the review team’s consideration of the views of stakeholders, analysis of P³ performance and consideration of the principles of good program design that have been set out by the Productivity Commission.

Findings

Noting the current *Review of the National Innovation System* and its potentially significant impact on a range of Government policies impacting the business R&D environment, we make the following three findings regarding the development of a post P³ program:

- **Finding 1:** P³ should not be renewed in its current form when it ends in June 2009.
- **Finding 2:** No decision should be taken on the development of a successor program until after the release of both the Green Paper from the *Review of the National Innovation System* review panel and the subsequent release of a White Paper response from the Government.
- **Finding 3:** As a precondition to development of any sector specific program to support pharmaceuticals sector R&D, compelling evidence should be presented to demonstrate why such a program should be developed in preference to a generally available program.

1 Project objectives and methodology

This chapter provides a brief outline of the project objectives, methodology and report structure.

1.1 Project objectives

Deloitte Insight Economics has been commissioned by the Department of Innovation, Industry, Science and Research (DIISR) to provide an independent evaluation of the first three years of the Pharmaceuticals Partnerships Program (P³). Through this project, the appropriateness, effectiveness and efficiency of P³ are evaluated. In conducting this evaluation the following matters have been considered:

- increasing the pharmaceuticals R&D activity undertaken in Australia, including the amount, type and quality of new activity taking place;
- the number of multinational firms with regional or global R&D operations in Australia;
- the number and quality of linkages and new collaborations within the industry and international engagement of Australian companies;
- the quality of R&D undertaken by participants;
- the level of benefit, including the net public and economic benefit, to the Australian economy, using the generalised ‘spillover’ benefits approach, as adopted by the CIE in the first evaluation of P³;
- encouragement of the development of medicines for global markets; and
- the extent to which the changes made to the program design as a result of the first year evaluation had an impact on the quality and quantity of applications for Round 3 of P³.

1.2 Project methodology

To assess the appropriateness, effectiveness and efficiency of P³, the project team undertook a methodology involving secondary research of existing literature and primary research of the industry through extensive stakeholder engagement.

- *Literature and data review* — The project team reviewed public research reports and private department documents and company data related to P³ to develop an evidence base for assessing the appropriateness, effectiveness and efficiency of P³. Appendix C provides a list of the public research reviewed over the course of the project.
- *Stakeholder engagement* — The project team undertook an online survey and stakeholder consultations to obtain primary data of the impacts and impressions of P³ by the industry:

- Online survey — An online survey was developed in consultation with DIISR. The survey was developed from the first year evaluation questionnaire to provide time series data for some questions but also introduced specific questions to elicit key information from three survey sub-groups: P³ participants, unsuccessful P³ applicants, and non-P³ applicant companies.

A total of 29 responses to the online survey were received. Appendix B contains the complete list of survey respondents. Overall, the response rates for firms that received grants under Round 1 was 91 per cent¹ and firms successful in Round 2 had a response rate of 57 per cent. However, those firms from Rounds 1 and 2 not responding had either declined the grant or have subsequently withdrawn from the program. There has been a 100 per cent response rate from firms that were successful under Round 3.

Overall, for the seventeen firms that are still participants in the program there was a 100 per cent response rate to the survey. In addition, one third of successful applicants that either declined the grant or have withdrawn from the program responded (noting that although Janssen-Cilag terminated its participation under Round 1, it did so in order to participate in Round 3). Ten firms that were unsuccessful in being awarded a grant or did not apply for a grant also responded to the survey.

- Stakeholder consultations — Consultations were also conducted with over 30 individuals drawn from 21 organisations², including P³ participants, unsuccessful applicants, eligible non-applicant companies, industry associations, and relevant Government committees and agencies such as AusIndustry. Appendix B contains a list of those organisations and individuals consulted.

The project team synthesised this primary and secondary research to evaluate P³. Appropriateness was evaluated in terms of whether there is a need for Government action and whether P³ was designed appropriately to meet these needs. This was informed by primary research and stakeholder consultations. Effectiveness was assessed in terms of whether P³ had met its objectives, and whether the economic benefits of the program exceeded the cost. The levels of spillover and quality of the R&D generated by the project were assessed based on survey responses and consideration of Productivity Commission data about average rates of spillover that have been observed for different types of R&D. Efficiency was assessed by benchmarking Government and industry costs under P³ compared to other comparable programs administered by AusIndustry.

Having conducted an evaluation of P³, the project team also considered the policy case for a successor program, based on survey information and stakeholder views, and has set out a number of options for the Government's consideration in relation to the nature of a post P³ program.

¹ The Round 1 response rate is 100 per cent if CSL responding on behalf of Zenyth, which withdrew, is included in the calculation.

² If the employer of members of committees are counted as organisations rather than counting the committee as the organisation for all its members, the number of organisations consulted is 28.

1.3 Report structure

The P³ evaluation is structured in the following way:

- Key Findings: This sets out the key findings regarding the appropriateness, effectiveness and efficiency of P³ and the economic impact of the program.
- Chapter 1: Project overview — Sets out project objectives, methodology and report structure.
- Chapter 2: The Australian pharmaceuticals industry — Evaluates Australia's position within the global pharmaceuticals industry, the economic impact of the Australian industry and drivers of R&D investment.
- Chapter 3: The pharmaceuticals industry policy environment — Outlines the historic policy approaches to pharmaceuticals investment attraction in Australia, the evolution of P³ and other policy measures that provide incentives for industry R&D.
- Chapter 4: Review of P³ — Provides an assessment of the appropriateness, effectiveness and efficiency of P³ and analyses the overall public and economic impact of the program.
- Chapter 5: Options for the future — Considers options for future action once P³ concludes.
- Appendix A — Other R&D incentives in Australia.
- Appendix B — Stakeholder consultations and survey respondents.
- Appendix C — References.

2 Global and Australian pharmaceuticals industry

This chapter outlines major trends in the global pharmaceuticals industry, identifies key features of the Australian pharmaceuticals industry and considers the drivers of investment in R&D (both discovery and clinical trials). This chapter is included to provide some broader context for the review of P³.

2.1 Key trends in the global pharmaceuticals industry

The pharmaceuticals industry, which undertakes the development, production and supply of pharmaceuticals products needed to save lives, prevent disease and otherwise assist in maintaining quality of life, is an outstanding example of a knowledge-based industry with a very direct relationship with scientific research advances.

The average cost of discovery and development of a new medicine is estimated to be more than \$1 billion with the average development time for new medicines being 12-15 years. Only five out of 10,000 compounds investigated are tested in clinical trials.³

The leading companies have major investments in their corporate R&D facilities and have one of the highest R&D-to-sales intensities of all industries, typically lying in the range of 15 to 20 per cent.⁴ A process of concentration has been underway for some time with large scale merger and acquisition activity marking the history of the current industry leaders.

Until comparatively recent times, the market capitalisation of the largest pharmaceuticals companies was such as to make them among the biggest companies by market capitalisation in the world.

A more difficult business environment is facing the research-based pharmaceuticals companies due to competition from generics manufacturers (as the patent protection on large selling drugs expire) and the declining productivity of R&D as the industry's ability to produce new blockbuster drugs has declined. This has led to a series of adjustments being made by a number of the world's leading pharmaceuticals companies.

Notwithstanding current challenges, the pharmaceuticals industry remains large: six of the top 40 companies in the world by market capitalisation are in the pharmaceuticals industry, with the leading company, Pfizer, having a market capitalisation of \$179 billion at 30 March 2007.⁵ While recent years have been challenging for the global industry, the longer term potential for the industry to grow remains strong given the ageing population (raising demands for a range of drugs for treatment of chronic diseases), increasing global incomes (raising capacity to pay for medicines) and emerging new technologies (which may open scope for development of many new medicines).

³ Medicines Australia, *Industry*, Retrieved 21 January 2008 from <http://www.medicinesaustralia.com.au/pages/page4.asp>

⁴ Pharmaceutical Research Manufacturers of America, *Pharmaceutical Industry Profile 2007*, March 2007.

⁵ Forbes, *The Forbes Global 2000*, Retrieved February 2008 from <http://www.forbes.com/2005/03/30/05f2000land.html>

Global spending on prescription medicines exceeded US\$600 billion in 2005. Between 1998 and 2005, sales almost doubled, while the industry growth rate between 2002 and 2005 averaged over 12 per cent.⁶ This growth has been driven by a number of factors, including the ageing population and increased health spending.

Seven of the top 20 global companies by R&D expenditure in 2007 were in the pharmaceuticals and biotechnology sectors.⁷

The US comprises about 45 per cent of the pharmaceuticals market worldwide, while Europe comprises about 25 per cent.⁸ Emerging markets such as China, Russia, South Korea and Mexico, while still relatively small, are showing very high growth rates and their importance is expected to increase rapidly in coming years.

The top ten pharmaceuticals companies account for around half of world sales, with industry concentration significantly higher than a decade ago (when the top ten represented only 28 per cent of the global market).⁹

The top ten pharmaceuticals companies by 2006 sales are shown in Table 2.1.

Table 2.1: Top Ten Pharmaceuticals Companies by 2006 Sales

Rank	Company	Sales (US\$ m)	Growth (%)	Market Share (%)
1	Pfizer	45,083	1.8	8.6
2	GlaxoSmithKline	36,947	8.9	7.1
3	Sanofi-Aventis	35,605	4.9	6.8
4	Novartis	28,868	17.9	5.5
5	Hoffmann-La Roche	26,560	21.4	5.1
6	AstraZeneca	25,741	10.5	4.9
7	Johnson & Johnson	23,267	4.2	4.4
8	Merck & Co.	22,636	2.8	4.3
9	Wyeth	15,638	9.8	3.0
10	Eli Lilly & Co	14,816	7.5	2.8

Source: Wood Mackenzie's Productview™ March 2007, *Global Company Sales 2006*, available at www.p-d-r.com/ranking/2006_Company_Sales.pdf

Five of the top ten companies are headquartered in the US, two in the UK, two in Switzerland and one in France.

⁶ IMS Health, www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_77491316,00.html

⁷ UK Department of Innovation, University and Skills in conjunction with the UK Department for Business Enterprise and Regulatory Reform, *The 2007 R&D Scoreboard: the top 850 UK and 1250 global companies by R&D investment*, available at www.innovation.gov.uk/rd_scoreboard/

⁸ IMS Health, www.imshealth.com/ims/portal/front/articleC/0,2777,6599_3665_77491316,00.html

⁹ Wood Mackenzie's Productview™ March 2007, *Global Company Sales 2006*, available at www.p-d-r.com/ranking/2006_Company_Sales.pdf

The industry is a large performer of R&D. Its R&D intensity, measured in terms of expenditure on R&D as a share of sales, is high and tending to rise. Expenditure on R&D in the US, Europe and Japan (home to all of the major pharmaceutical manufacturers) increased from US\$45 billion in 2000 to over US\$67 billion in 2005.¹⁰

As an example of the importance of R&D to the leading companies, GlaxoSmithKline spends US\$7 billion on R&D and employs 16,000 people on its R&D activities. Its main centres of R&D are in the UK and the US.¹¹

It is likely, however, that the industry faces a growing challenge in maintaining its financial performance. The number of new molecular entities in the pipeline is falling, and the rapidly approaching expiry of patents on the blockbuster drugs with sales exceeding \$1 billion, mean that pharmaceuticals companies may be forced to rethink the established models and concepts of drug discovery, development and economics. Competition from manufacturers of generic drugs is intensifying as major patents expire and national governments and regional governments seek to reduce the costs of pharmaceuticals in their health care budgets.

Two shifts are likely to have a profound impact on drug discovery and development. First, the costs of basic research have increased in recent years as universities – the location of a large share of fundamental scientific research – have tended to commercialise IP. Second, the move away from traditional biopharmaceuticals and the rise of genomic drugs and personalized medicine which, while it does not appear to have transformed the industry as much, and in such a short time, as some suggested would be the case, is likely to be an important factor in coming decades.

In a recently released report on the pharmaceuticals industry, *Pharma 2020: The Vision – Which path will you take?*, PriceWaterhouseCoopers (PWC) suggest that, based on macroeconomic modelling, the industry value could more than double by 2020, when it could be worth in the order of \$1.3 trillion.¹²

A crucial factor driving this growth will be high rises in demand for pharmaceuticals in the 'E7' countries – the emerging economies of Brazil, China, India, Indonesia, Mexico, Russia and Turkey. PWC modelling projects that real GDP of the E7 economies will triple between 2004 and 2020, compared to growth of 'G7' economies – Britain, Canada, France, Germany, Italy, Japan, & the United States – in the same period of around 40 per cent. The E7 group spent a lower proportion of GDP on medicines than the G7 countries – 0.94 per cent compared to 1.31 per cent – and it is likely that this proportion too will rise as the E7 countries become wealthier in the coming decades. Spending on pharmaceuticals products in the emerging economies will therefore increase dramatically relative to the current levels, to the G7 spending, and to other expenditure.¹³

The clinical advances associated with longer life spans and population ageing will also have an impact on demand for pharmaceuticals and the health system as a whole. Chronic conditions represent a growing proportion of disease burden, requiring long term use of medication. Many of these chronic diseases, particularly in the wealthy countries, are non-communicable. Alongside a growing interest in disease prevention as well as cure, this is likely to significantly alter the nature of pharmacological treatment.

¹⁰ German Association of Research Based Pharmaceutical Companies, *Statistics 2006*, VFA www.vfa.de/en/statistics/innovation/.

¹¹ GlaxoSmithKline, available at <http://www.gsk.com.au/research-development.aspx>, viewed March 2008.

¹² PriceWaterhouseCoopers, 2007, *Pharma 2020: The Vision – Which path will you take?* p.5.

¹³ Ibid. p.4.

In addition to demographic changes, epidemiological shifts will alter the nature of pharmaceuticals treatment, and of drug products. Climate change is another potential driver of shifts in pharmaceuticals demand. Changing weather – including global warming and the increased occurrence of extreme events – may alter disease patterns. It is thought that new epidemiologies for old diseases such as malaria and asthma may emerge as a result of climate change. In this context, the need to manage the risk of devastating pandemics has resulted in a revival of pharmaceuticals vaccines.¹⁴

In response to these demand changes, it is likely that models of discovery and development in the pharmaceuticals industry will be reconfigured.

In the past, the high costs and risks, and the long lead times involved in drug development were offset by the prospect of blockbuster drugs. To be viable, these products must be sold on a global scale. These barriers to entry and the requirements of compliance with international regulatory regimes have contributed to a model of drug development which is highly vertically integrated. Typically, the pharmaceuticals business model has consisted of centralised discovery R&D operations, globally dispersed clinical trial facilities and sales offices, and a small number of high volume manufacturing plants.

While this model remains the dominant one in the industry, there are signs of some divergent trends, in both innovation and drug development models.

Instead of placing big bets on a few small molecules, it is likely that there will be a bigger spread of drug leads pursued with the implication that the range of clinical trials conducted by companies will tend to increase. This may provide new opportunities for the conduct of clinical trials in Australia.

Pharmaceuticals firms are developing partnerships with external parties, particularly research-intensive biotechnology firms, universities and research institutes. The volume of corporate alliances in the pharmaceuticals industry increased markedly during the late 1990s and the early years of this century.¹⁵ While this trend should not be overstated, it is nonetheless significant.

Strategic alliances between pharmaceuticals companies and small biotechnology firms, universities and research institutes typically establish licensing arrangements for new compounds. The resource rich pharmaceuticals companies provide development expertise and funding, while the smaller firms provide specialist expertise.¹⁶

As well as shifts in the model of innovation, a trend of outsourcing of development processes has emerged in recent years. Increasingly, clinical trial activities are outsourced to contract research organisations, generally choosing those with the most attractive combination of cost effectiveness, high skill levels, and strategic or regulatory benefits.

¹⁴ Center for Health and the Global Environment, 2005, *Climate Change Futures: health, ecological and economic dimensions*, Harvard Medical School.

¹⁵ Rasmussen, B., 2002, *The role of pharmaceutical alliances*, Centre for Strategic Economic Studies, Working Paper no.2, p.5.

¹⁶ Ibid. p.16-17.

2.2 Distinguishing features of the Australian industry

The dimensions of the Australian pharmaceuticals industry depends on the scope ascribed to it. In the Australian Pharmaceuticals Industry Fact Sheet,¹⁷ DIISR, adopting a broad definition, defines the industry as comprising bio-medical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling and distribution.

In 2005-06 the industry, using DIISR's definition, had a turnover of around \$18 billion and in 2004-05 employed around 34,000 people (including 15,000 in manufacturing). Exports were approximately \$3.9 billion in 2007 making pharmaceuticals Australia's second largest manufactured export after automobiles and automotive components. In 2005-06, the industry spent around \$752 million on R&D.¹⁸

Around 60 per cent of the jobs in the pharmaceuticals industry are located in New South Wales and Victoria. The industry average wage is \$65,400, which is over 36 per cent higher than the average level in the manufacturing sector of \$47,900.¹⁹

Medicines Australia, the industry association with coverage of the majority of Australian medical and pharmaceuticals originator companies, reports on its website that its 49 member companies had a turnover in 2006 of almost \$10 billion and employed over 10,000 people in terms of direct employment. In 2007 the member companies had exports of \$2.5 billion which represented about 72.5 per cent of total medicinal and pharmaceutical manufactured exports.²⁰ In 2006 their member companies spent \$340 million on R&D which represented about 3.5 per cent of the total Australian Business Expenditure on R&D (BERD).²¹

In this highly trade exposed sector, over 60 per cent of domestic demand is met by imported product. At the same time, 51 per cent of local production is exported. Australia's major export markets are currently South Africa, New Zealand, Taiwan, Korea, Thailand and the UK.²²

While the pharmaceuticals industry is one of the largest contributors to BERD in Australia, the R&D intensity of Australia's pharmaceuticals industry is below the levels achieved in the world centres of the industry in the US, Europe and Japan. This is due to the tendency of the leading multinational companies to concentrate their R&D expenditure, especially on discovery R&D, in their home countries and the US which are located close to the world centres of fundamental medical and health research. A significantly higher proportion of pharmaceuticals BERD in Australia (42 per cent compared with 34 per cent in the US) is on

¹⁷ Department of Innovation, Industry, Science & Research, *Australian Pharmaceuticals Industry Fact Sheet*, available at <http://www.innovation.gov.au>.

¹⁸ Department of Innovation, Industry, Science & Research, *Australian Pharmaceuticals Industry Fact Sheet*, available at <http://www.innovation.gov.au>.

¹⁹ ABS, 8221.0, *Manufacturing Industry, Australia 2005-06*, p.21, 24.

²⁰ Medicines Australia, *Australian Pharmaceutical Industry At A Crossroad?, Report of the 2007 Medicines Australia Member Economic Survey*, 2008, p.2, 3 and 4.

²¹ Medicines Australia, *Australian Pharmaceutical Industry – Facts at a glance, Research and Development*, May 2007, p.1-2.

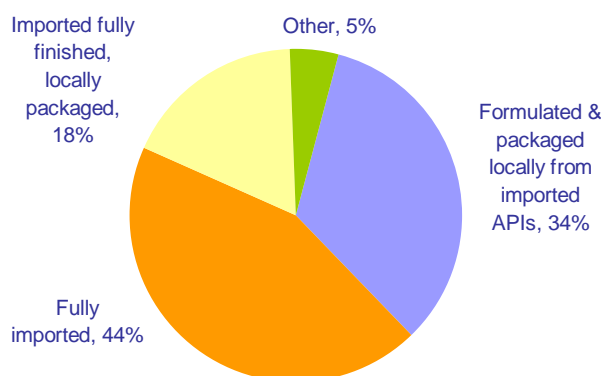
²² IBIS World, *Industry Report – Medical and Pharmaceutical Product Manufacturing in Australia*, 2008, p.6.

clinical trials.²³ P³ is an initiative designed to address this situation and increase R&D spend in Australia.

Formulation and packaging account for the majority of Australian manufacturing activity, although there is a small amount of active pharmaceutical ingredient (API) manufacturing. API manufacturing in Australia is generally small scale and specialised, and is dominated by the synthesis of alkaloids such as morphine and codeine. Companies involved in the production of APIs from Tasmanian poppy crops include GlaxoSmithKline (although in late 2006 this capacity was slashed from 5000ha to 500ha) and Tasmanian Alkaloids. Other producers of APIs in Australia include CSL and the Institute for Drug Technology Australia (in partnership with Pfizer and other clients).

Australian activity is mainly in secondary manufacturing, including the formulation and packaging of product. The active ingredients are mostly imported, with passive ingredients and packaging produced locally. These operations are much larger in scale than local API production, reflecting the strategic value for the major global players in having a regional hub. Figure 2.1 illustrates the very small amount of primary manufacture which occurs in Australia.

Figure 2.1: Australian Role in Manufacture of Pharmaceutical Products 2001-02



Source: Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, AusInfo, Canberra, p.1.5.

The Australian pharmaceuticals manufacturing industry is made up of at least 300 companies, both local and multinational subsidiaries. The industry is not overly concentrated, with the largest five companies estimated to have between 30 and 40 per cent market share while the top ten account for around 60 per cent of sales. In line with global trends, however, industry concentration has been rising in recent years.²⁴

Subsidiaries of MNCs in Australia include Alphapharm, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Janssen-Cilag, Merck Sharp & Dohme, Novartis, Pfizer, Roche and Servier.

In 2006-07 the top 10 suppliers contributed over two-thirds of the value of total sales made to the PBS. In 2006-07, there were over 168 million scripts processed through the PBS, at a cost to Government of \$6.4 billion.²⁵

²³ The Allen Consulting Group, *Drivers of Pharmaceutical Industry Investment*, September 2006, p.54-55.

²⁴ IBIS World, *Industry Report – Medical and Pharmaceutical Product Manufacturing in Australia*, 18 May 2007, p.9.

²⁵ Pharmaceutical Benefits Pricing Authority, 2007, *Annual Report 2006-07*, p.19.

Table 2.2: Suppliers' Shares of PBS Sales by cost, 2006-07

	Share of PBS sales by cost (%)
Pfizer	16.0
AstraZeneca	8.6
Alphapharm	8.2
Sanofi-Aventis	8.2
GlaxoSmithKline	6.5
Merck Sharp & Dohme	4.9
Bristol-Myers Squibb	4.4
Arrow	3.9
Eli Lilly	3.5
Wyeth	3.3

Source: Pharmaceutical Benefits Pricing Authority, 2007, *Annual Report 2006-07*, p.28.

Table 2.3: Suppliers' Shares of PBS Scripts by volume, 2006-07

	Share of PBS scripts by volume (%)
Alphapharm	15.8
Pfizer	12.5
Sanofi-Aventis	9.2
AstraZeneca	6.9
Sigma	5.6
GlaxoSmithKline	5.1
Arrow	4.2
Bristol-Myers Squibb	4.0
Merck Sharp & Dohme	3.7
Servier	3.4

Source: Pharmaceutical Benefits Pricing Authority, 2007, *Annual Report 2006-07*, p.29.

The Australian biotechnology industry currently includes 470 core biotechnology, companies, up from 190 in 2001.²⁶ The market capitalisation value of Australian Securities Exchange listed Australian biotechnology companies was estimated to be around \$24.9 billion at the end of the fourth quarter of 2007. CSL alone accounted for approximately 80 per cent of biotechnology market capitalisation.²⁷

2.3 Drivers of investment

2.3.1 Broad considerations

The pharmaceuticals industry is one of the leading contributors to the process of globalisation in which technology and capital is placed around the world in pursuit of the best commercial advantages and leading firms have tightly run globally integrated operations and supply chains. The old model tended to see the leading research-based pharmaceuticals companies conducting the great bulk of their discovery R&D in their country of origin in major corporate research facilities. Clinical trials were more likely to be undertaken both inside and outside the companies' countries of origin. Manufacturing of active ingredients was centralised, again in the country of origin, while formulation and packaging plants were located in end markets.

In more recent times, the situation has changed in important respects. A great deal more discovery R&D is being conducted outside the original corporate laboratories – this has involved many European origin companies establishing major R&D facilities in the US and also supporting extra-mural research in the universities and medical research institutes.

An important basis for location choice in pharmaceuticals R&D and manufacturing will be the cost competitiveness of operational inputs. Australia is generally a low overall cost environment relative to the US and the EU but ahead of only Japan in Asia. The 2005 survey conducted by the Economist Intelligence Unit found that, according to international pharmaceuticals executives, Australia was ranked ahead of Japan, the UK, Germany and the US, but below India and Singapore in terms of input costs, including salaries and utility costs.²⁸

Australia and Singapore were judged to have highly skilled workforces, although India, in spite of a lower rate of appropriately qualified scientists and researchers, has a larger overall pool due to its bigger population. Australia has a strong biomedical research base, and this has contributed to its being viewed as an attractive location for clinical trials. It also has a heterogeneous population, an important characteristic in conducting clinical trials.

Medicines Australia has suggested that Australia has strong research and medicines discovery capability, but is weak on medicines development, commercialisation, and manufacturing for trials/commercial production.²⁹

Given the global mobility of investment, the presence or otherwise of Government support for R&D will be a factor in company decisions on where investment is located.

²⁶ Hopper, K. and Thorburn, L., 2007, *2007 BioIndustry Review*, p.2.; Ernst & Young, 2001, *Australian Biotechnology Report*, for Commonwealth of Australia, p.7.

²⁷ DIISR, February 2008, *Biotechnology Business Indicators*, p.1, available at www.innovation.gov.au

²⁸ Economist Intelligence Unit, *Benchmarking Study of the Characteristics of the Australian and International Pharmaceutical Industries*, September 2005, p.7.

²⁹ Medicines Australia September 2006, *Submission To The Productivity Commission Study Into Public Support For Science And Innovation In Australia*, p.11.

2.3.2 Discovery R&D decisions

Discovery R&D involves the innovation end of drug development, from initially identifying drug targets and proceeding through to a smaller number of clinical candidates. In general, this involves developing new drugs in one of two categories, small molecules and biologicals.

The key drivers of discovery R&D investment decisions are those which lead to good ideas, rather than market considerations. Scientific track records and productivity, as well as access to specialised resources of expertise or facilities, are generally more important than cost in these decisions. In a small proportion of cases, discovery R&D location choices may be on the basis of strategic advantage, for example, to build brand profile in an emerging regional market.

Not surprisingly, the major centres of discovery R&D tend to be in the US, Western Europe and Japan where the world's leading medical and health research facilities are located. The US has proved to be a major magnet for discovery R&D as a result of the large amounts of funding for medical and health research being provided by the National Institutes of Health, the large and well-funded medical research institutes at major universities and the attractive regulatory environment. The leading European pharmaceuticals companies have virtually all opened major discovery research facilities in the US.

A number of trends suggest that patterns of discovery R&D spending will shift in coming years. One of the most important of these changes is the decline of the blockbuster business model, and the rise of partnering. The drying up of blockbuster discovery, and the fragmentation of drug populations, has resulted in growing pressure on pharmaceuticals companies' R&D productivity. One response to this has been an increasing level of outsourcing, in-licensing, and partnerships between the leading pharmaceuticals companies and smaller R&D and pre-clinical firms. This alliance activity was at its highest levels during the early 1990s, and more recently the trend appears to have slowed somewhat. Similarly, it does not appear likely that collaboration with small firms and in-licensing will replace in-house discovery R&D altogether, although the proportion will be more substantial than has traditionally been the case.

Another factor involved in this shift from the traditional drug discovery model has arisen as, for a range of reasons, basic researchers at universities are increasingly moving to capture the value of their work. One of the drivers of this move is the increasing push towards, and growing capabilities in, research commercialisation at universities. Universities are recognising that, rather than simply identifying drug targets (which are then developed by pharmaceuticals companies), commercial returns are generated by being involved in the discovery processes through to the later stages of a compound's development.

While the bulk of discovery R&D decisions are driven by research quality related factors, there are nonetheless some other factors to come into play, including the availability of external partnering options, the IP regulatory environment, and the broader innovation environment. For example, the generous taxation incentives for R&D in Ireland and Singapore have played a role in attracting investment into these countries' biomedical research industries. In the Australian context, P³ has been the primary mechanism for delivery of support to multinational pharmaceuticals companies to undertake discovery R&D in Australia.

2.3.3 Clinical trial R&D decisions

Clinical trial R&D includes all testing from Phase I on, through testing on healthy human subjects, small scale tests on patients (Phase II), and finally to Phase III, pre-market large scale testing in patient populations.

Decisions about clinical trial R&D investments, while driven by scientific quality factors, are more likely than pre-clinical R&D decisions to be affected by cost considerations, given that many locations have the basic capabilities needed. Criteria for clinical trial R&D location choice include:

- the capacity to undertake high quality trials;
- the timeliness/speed of clinical trials;
- the cost of clinical trials; and
- the safety of clinical trials in terms of their conformance with good clinical practice (GCP) guidelines and international standards.

The cost effectiveness of clinical trials is affected by the costs involved in recruiting participants, the ethics and regulatory approval process, and of staffing and location costs in conducting the investigations. The costs of trials are correlated with the speed with which they can be completed, and this implies in turn a faster path to market and a longer patent duration (which impacts on profits).

Trends in clinical trial R&D investment have been underpinned by a deeper shift in the sector, which has seen increased complexity arising from higher levels of scrutiny of clinical trial quality, which necessitates greater information collection and linkage. At the same time, the decline of the blockbuster drug and the rise of more fragmented drug treatment populations have meant that more clinical trials must take place, to increasingly rigorous standards.

Higher global expectations for clinical trial quality have been more clearly articulated in recent years, and there has been progress towards world harmonisation of GCP standards. Australian clinical trials must now conform to regulatory requirements in line with the International Harmonisation on Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). One effect of this trend is that it has reduced inconsistencies between countries in terms of quality outcomes from clinical trials. As such, while nations such as Australia have formerly been able to rely on non-cost factors to offset cost disadvantages in comparison to developing countries, this is likely to be less of a factor in the future, most particularly in relation to Phase III trials and bioequivalence studies (cost is a more important driver for later stage clinical trials than for early stage clinical trials – where quality of research infrastructure and time taken to commence the trial are more important factors). Highlighting this point, two P³ participants have withdrawn from the program because they chose to locate these parts of R&D in cheaper international locations.

All of these factors – greater focus on cost controls, the increasing complexity of clinical trials, and improved levels of quality assurance – have contributed to a trend of outsourcing of clinical trial R&D. Increasingly, pharmaceuticals companies can choose from among a large number of locations which meet the benchmark criteria, and can conduct cost effective clinical trials with high quality outcomes.

At the moment, Australia is generally well positioned in relation to other potential sites for clinical trial R&D. The 2005 EIU survey found that, across a number of indicators of the attractiveness of various countries, Australia scored very well, particularly for the low average costs of trials, a large number of recognised clinical trial sites, and a high percentage of timely completions. Overall, the EIU ranked Australia second (Singapore first) of the seven countries considered, having particular cost advantages over Germany, Japan, the UK and the US. While costs were lower in both Singapore and India, at the time of the study it was felt that Australia's non-cost advantages outweighed these factors when compared to India.³⁰ Increasingly, however, many countries are competitive in these areas, and this means that pharmaceutical companies can be more strategic about location choices. If Australia's overall attractiveness as a location for clinical trials declines against lower cost countries, in the absence of increased levels of support for this activity, Australia's share of the clinical trials market would be expected to decline.

³⁰ Economist Intelligence Unit, 2005, *Benchmarking study of the Characteristics of the Australian and International Pharmaceuticals Industries*, p.7.

3 Policy environment for the pharmaceuticals industry

This chapter identifies the reasons why the pharmaceuticals industry has been the focus of policy attention in Australia, the policy frameworks that have been applied and their rationales, and where P³ sits in the broader set of policies intended to support R&D and its commercialisation.

3.1 Policy attention

Over the last 20 years the Australian pharmaceuticals industry has been the focus of special policy attention. This has shown itself in the adoption of three policy frameworks that have operated in that period:

- 1988-1999: Factor f;
- 1999-2004: Pharmaceutical Industry Investment Program (PIIP); and
- 2004-2009: Pharmaceuticals Partnerships Program (P³).

The objective of the three programs has been to improve the environment for the development of the Australian pharmaceuticals industry. The nature of the programs has changed over time to reflect changing attitudes to the source of market failure that needed to be addressed and the underlying realities in the Australian pharmaceuticals industry and the global context in which it finds itself.

While Factor f and the PIIP supported both investment in manufacturing and R&D, P³ is focused on R&D and partnerships. Factor f and the PIIP were targeted at pharmaceuticals companies with production and/or R&D activity, however P³ also applies to biotechnology companies often at a reasonably early stage of development. The nature of the three programs is considered in the following sections.

In view of the fact that the pharmaceuticals industry has been the subject of ongoing policy intervention in the last two decades, it is important to understand why this has been so.

The first set of reasons relate to the nature of the industry itself. As was explored in Chapter 2:

- The pharmaceuticals industry is a leading example of a knowledge-based industry which builds its product portfolio directly on the foundation of advances in science in general and medical science in particular. Its products are aimed at aspects of human health ranging from those which are designed to save lives to those which improve the quality of life. Pharmaceuticals are an important part of the health care system as a whole.
- Reflecting its knowledge-base, the industry is highly R&D intensive. The leading research-based pharmaceuticals companies are typically spending between 15 to 20 per cent of their sales revenue on R&D making it one of the most R&D intensive industries in the economy. The leading companies also operate large corporate laboratories that undertake a mix of discovery and applied R&D.
- The pharmaceuticals industry is one of the largest contributors to BERD.

- The industry is one of the largest employers of R&D personnel who generally hold tertiary qualifications and, in many cases, advanced degrees.
- In recent years the increasing tendency for the leading pharmaceuticals companies to support extra-mural research in universities and medical research institutes as well as emerging technology-based companies has strengthened linkages with the publicly funded research agencies. The pharmaceuticals companies represent a path to market for public sector research.
- The industry has also been building a network of strategic alliances with emerging technology based companies who are in the early stages of commercialising new products and processes.
- The leading companies with their large market capitalisations and global marketing/sales and supply systems are valuable partners for emerging technology based companies.
- As global corporations, the leading pharmaceuticals companies have a global network of manufacturing, R&D, supply chain and marketing facilities. They account for an important part of foreign direct investment.
- The growth prospects for the pharmaceuticals industry to 2020 and beyond remain strong.

Because of the above characteristics of the industry, governments in many countries and regions place a high value on attracting investment by the world's leading pharmaceuticals companies. While the attractive features above no doubt exist in relation to the pharmaceuticals and biotechnology industries, and explain why many governments are prepared to offer inducements for investment in this sector, it is important to note that the pharmaceuticals and biotechnology industries are not unique in this regard. Many countries that have supported pharmaceutical and biotechnology industry development have also placed a high value on attracting investment and supporting sectoral development in other high tech industries – such as aerospace, precision tooling, medical devices and information technology.

In effect, it is high tech industries in general, rather than the pharmaceuticals and biotechnology industries in particular, that are seen by many countries as being industries that warrant particular focus due to the range of benefits they are seen to deliver to the economy.

It is not only the above factors, however, that have explained the particular policy interest in the pharmaceuticals industry. It has been argued that the operation of the PBS, through the impact it has had on average pharmaceutical prices in Australia, has the potential to hold back the development of the Australian industry. This was an important aspect of the philosophy underlying the Factor f and PIIP schemes.

Another sector specific factor has been the very considerable public investment in medical and health research in the Universities and medical research institutes and the recognition that the leading pharmaceuticals companies represented a strategic asset in terms of providing a pathway to markets for IP developed in Australia.

3.2 Past Australian pharmaceutical investment policies

3.2.1 Factor f (1988-1999)

Rationale and objectives

The Factor f scheme was designed to encourage investment in pharmaceuticals manufacturing and R&D. The program was initiated in response to concerns that the monopsony purchasing power of the PBS would drive down pharmaceuticals prices and discourage investment within the industry. At the time of its commencement there was concern in Australia that some pharmaceuticals companies were intending to cease their Australian manufacturing operations and that the industry was under investing in R&D.

Program design and administration

Under the Factor f scheme, notional price increases could be granted to specific products sold on the PBS. Prices could not be raised above what would be expected in a normal market without PBS price suppression.

To be eligible for funding under Factor f (Phase I) participants were required to:

- achieve a ratio of exports to imports of one half within three full company financial years of acceptance of the Pharmaceutical Benefits Pricing Authority's (the Authority) offer of price increases;
- increase exports by 33 per cent in real terms within three full company financial years of acceptance of the Authority's offer of price increases;
- spend a minimum of three per cent of turnover on R&D; and
- increase spending on R&D by 33 per cent in real terms within three full company years of acceptance of the Authority's offer of price increases.

Participants were also required to undertake both manufacturing and R&D activities within Australia.

To be eligible for Factor f (Phase II), companies needed to satisfy the following eligibility criteria (one within three years of entry into the Scheme, the other within five years):

- increase value added in Australia on pharmaceutical production by 50% over a three year period; and,
- achieve a level of R&D spending equal to 3% of turnover and maintain R&D spending at 3% for the remainder of the Scheme.

In addition to this, some participants were approved under the qualitative criteria. These companies were unable to meet the quantitative criteria but their proposed activity was internationally competitive and likely to lead to significant net benefits to Australia. Activity considered under the qualitative criteria included:

- new active ingredient production;
- new investment in production plant, facilities or equipment;
- expenditure on new R&D projects;
- new production for export and domestic sale;

- commitment to best manufacturing practice through measures such as benchmarking, quality program and workplace reform;
- establishment of Australia as a centre for operations in the Asia/Pacific region; and
- other internationally competitive activity.

Once the qualitative or quantitative criteria were met, the proposal then had to be recommended by the Authority to the Ministers for Industry, Science & Technology and Health, Housing and Community Services for their approval. If the Ministers approved the recommendation, the company was admitted to Phase II of the Scheme.

Payments made under Factor f were subject to a capped percentage of value added activity and R&D payments were dependant on whether or not the company was claiming the then 150 per cent tax concession for R&D.³¹

Phase one of Factor f, which commenced in 1988 and concluded in 1995, cost \$157 million of an initial government allocation of \$198 million.³² A second phase, operating from 1992 through to 1999, received an additional allocation of \$820 million. In total the program cost government \$948 million. There were ten participants in Phase I of the program and eleven in Phase II.³³

Participants

Phase I participants

- Bristol-Myers Squibb Pharmaceuticals
- CSL
- Cyanamid Australia
- F H Faulding
- Glaxo Australia
- ICI Australia
- Merck Sharp & Dohme
- Schering-Plough
- Sigma Pharmaceuticals
- SmithKline Beecham

³¹ The Industry Commission, 1996, *The Pharmaceutical Industry: Industry Commission Inquiry Report*, The Commonwealth of Australia, p.104-105.

³² Ibid, p.110.

³³ Department of Industry Tourism and Resources, 2001, *Pharmaceuticals Industry Action Agenda: Local Priority — Global Partner*, Commonwealth of Australia, p.24.

Phase II participants

- 3M Pharmaceuticals (Australia)
- AMRAD
- Astra Pharmaceuticals
- CSL
- F H Faulding
- Fisons
- Glaxo Australia
- Merck, Sharp & Dohme
- Pfizer
- Upjohn
- Wellcome Australia

Outcomes

Factor f, according to the Industry Commission and stakeholders, produced significant benefits by generating a greater level of pharmaceuticals industry activity than would have occurred without the intervention. It was reported that the program improved the perception of Australia as a favourable environment for investment and may even have resulted in greater pharmaceuticals activity than would have occurred without PBS price suppression.

To meet their Factor f targets, participants undertook \$224 million in additional investment in Phase I and an estimated \$380 million in Phase II. The program is estimated to have directly created 1000 jobs.³⁴

The major criticism of Factor f was the strict eligibility criteria, which excluded some key companies from participating. Further criticism related to the timeframe of the program, which was described as too short and failed to reflect the lengthy period of time required to move a pharmaceutical product through discovery and development phases and into manufacture.

3.2.2 PIIP (1999-2004)

Rationale and objectives

Due to the success of the Factor f program, and in recognition of ongoing pharmaceuticals price suppression by the PBS, the Commonwealth Government initiated the Pharmaceutical Industry Investment Program (PIIP). PIIP operated from 1999 to 2004. Like Factor f, the PIIP's primary objective was to induce domestic activity lost due to price suppression.

The guiding principles of the PIIP were to: increase the total level of pharmaceuticals R&D and production value added activity (PVA) undertaken in Australia; encourage the growth in scale and in scope of existing pharmaceuticals activity; and encourage activities that are internationally competitive and of benefit to Australia. Applicants participated in a competitive selection process in which they were required to outline how the elements of their program activities would contribute to meeting the guiding principles.

³⁴ Industry Commission, 1996, *The Pharmaceutical Industry*, Report No. 51 p.126.

Program design and administration

PIIP was smaller in scale and expenditure than its Factor f predecessor, attributed partly to the continuing benefits of that program.

Under PIIP, companies received higher notional PBS price increases on nominated PBS products that were paid in the form of grants to companies. In return those companies agreed to meet certain criteria for undertaking additional value-added manufacturing and R&D activities within Australia. The activities that could earn price increases were broadly classified into two streams, PVA/R&D activity targets and broad activity commitments. To be considered by the PIIP, PVA activities were required to be undertaken in Australia and only R&D expenditure relating to domestic activity could constitute eligible expenditure.

Companies' entitlements were calculated as 20 per cent of both PVA and R&D eligible expenditure with a cap of \$60 million for an individual company over the five year period. Only additional expenditure, greater than that recorded in a base year, was eligible for compensation, with price increases calculated up to, but not above, the average European Union price for the relevant product. The PIIP offered grants in lieu of actual price increases for products listed on the PBS to compensate for price suppression.

Participants

- AMRAD
- Bristol-Myers Squibb
- CSL
- Eli Lilly
- Mayne Pharma
- GlaxoSmithKline
- Janssen-Cilag
- Pfizer
- Pharmacia

Outcomes

The nine companies that participated in the program received \$246 million and in turn provided \$1.74 billion in increased PVA and R&D activities.³⁵

PIIP received similar criticism to Factor f, owing to the similarities in the programs, including that there were too few participants, funding was fully committed up-front and that only PBS suppliers could participate.

In reviewing the PIIP, the Productivity Commission found that the rationale for assistance to the pharmaceuticals industry based on price suppression was 'less persuasive than conventionally claimed', and that the costs of PIIP had outweighed its benefits. This finding reflected the Productivity Commission's judgement that there were few, if any, spillover benefits associated with pharmaceuticals manufacturing activities. The Productivity Commission accepted that there were spillover benefits with R&D and that PIIP had induced a significant amount of additional R&D investment in Australia.

³⁵ Pharmaceutical Benefit Pricing Authority, 2005, *Annual Report for the year ended 30 June 2005*, p.17.

The Productivity Commission concluded that it was extremely difficult to reach a confident conclusion regarding inducement rates and that their estimates using different approaches ranged from 25 to 73 per cent. However, they did conclude that “the empirical analysis suggests that PIIP has induced a significant amount of new R&D and, to a lesser extent, value added production”.³⁶ The Productivity Commission concluded that the payments for R&D under PIIP were likely to have had a net economic benefit.

Following its draft report which recommended against the continuation of special support for the pharmaceuticals industry, in its final report, after taking into account the fact that the leading pharmaceuticals companies were unable to access the R&D tax concession as a result of the beneficial ownership of IP rules, the Productivity Commission suggested that, as this provision of the R&D tax concession was unlikely to be changed, a case existed for a new R&D focussed PIIP. The Productivity Commission maintained its draft report recommendation that no special support (grants or raised prices) should be provided for pharmaceuticals manufacturing in lieu of price suppression.

3.3 P³ (2004-2009)

3.3.1 Rationale and objectives

P³ was introduced in 2004 and is specifically targeted toward increasing the amount of pharmaceuticals R&D undertaken within Australia. The program is a replacement of PIIP and incorporates many of the recommendations from the review of that program, including a move away from production subsidies towards a stronger R&D focus. The objectives of P³ include to:

- increase the level and quality of new pharmaceuticals R&D undertaken in Australia;
- increase the number and quality of linkages within the industry; and
- improve the international engagement of local firms.

P³ promotes increased high-quality pharmaceuticals R&D, the development of medicines for global markets and partnerships and collaborations between multinational corporations and local companies.

To be eligible for P³, a company is required to be incorporated, part of the pharmaceuticals industry, have at least three years experience in undertaking eligible pharmaceuticals R&D activities in Australia (Rounds 1 and 2 only) or in Australia or overseas (Round 3) and increase its R&D expenditure above a calculated base level. Applicants to the program are subjected to a competitive assessment process and are assessed against criteria including: past performance and capabilities of the applicant, scope and nature of partnerships and linkages arising from its activities, technical merit and the overall level of benefit likely to be provided to the Australian economy.

The program initially operated by offering participating companies undertaking eligible R&D activities a 30 cents in the dollar taxable grant for R&D expenditure above a base level, calculated as an average of the past three years eligible R&D expenditure (the agreed baseline). Companies' payments are capped at \$10 million and P³ monies can be expended by companies over a five year period with funds designated for particular approved projects able to be transferred to other substitute projects that are approved by the program delegate. In response to a review by the Centre of International Economics (CIE), the rate of the taxable grant for round three was raised to 50 cents in the dollar and the allowable expenditure cap for intellectual property protection doubled to \$200,000.

³⁶ Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, research report, p.xxi.

3.3.2 Program design and administration

P³ has had three entry rounds commencing on 1 July 2004, 1 July 2005 and 1 July 2007. Eleven, seven and six companies were offered grants in Rounds 1, 2 and 3 respectively. Subsequently, five companies have withdrawn from P³ and one selected company declined the offer. Initially \$150 million was allocated to be spent over the five years of the program. In Round 1, grants were approved for a total of \$87.1 million and in Round 2, \$46.8 million,³⁷ however one company declined the offer in Round 2, leaving the total approved grants at \$36.8 million. Round 3 grants, which commenced in July 2007, were approved for a total of \$28.1 million. It is noted that, although total awarded grants listed above exceed \$150 million, the program has not exceeded its allocated funding, rather the additional monies awarded under Rounds 2 and 3 were the result of funds surrendered through either company underperformance or withdrawal. Actual expenditure on the program will be dependant on companies' eventual R&D expenditure and the meeting of P³ requirements.

AusIndustry has had responsibility for the program through its Innovation and Collaboration Programs Branch. This responsibility has covered the full cycle of the program beginning with its communication and promotion to the pharmaceuticals industry and the assessment of applicants against the eligibility criteria (assessment of the merit of applications, including technical advice, is undertaken by the Pharmaceuticals Committee of Innovation Australia). Upon approval, successful applicants negotiate funding agreements with AusIndustry and are then subject to their compliance requirements.

AusIndustry manages participants' compliance to ensure that the grant funding is being used appropriately and that each participant is meeting the relevant conditions. There are three main mechanisms for achieving this end: making variations to funding agreements; the compliance management strategy; and ad-hoc reviews. Variation to funding agreements exists to allow for changes in the R&D portfolio of participants, addressing the difficulties that are inherent in forecasting R&D projects and expenditure. The compliance management strategy is the basis for determining a participant's risk rating; risk treatments; the activities undertaken at different levels of compliance and the number of times those activities should occur. The activities that AusIndustry undertakes to manage compliance at this level include site visits and reviews of participant's quarterly and annual reports. Ad hoc reviews are set out in the Program Guidelines for Rounds 1 and 2, and are triggered by a number of participant performance measures. The ad hoc review requirement was replaced in the Program Guidelines for Round 3 (applicable only to Round 3 entrants) by the requirement that the Program Delegate may review a company's performance at any time during the program as a result of quarterly reporting or as part of the annual assessment.

3.3.3 Participants

Round 1 successful participants

- **Acrux DDS (VIC)** — Acrux is an Australian drug delivery business developing and commercialising a range of patient-preferred pharmaceutical products for global markets, using patented technology to administer drugs through the skin.
- **ChemGenex Pharmaceuticals (VIC)** — ChemGenex Pharmaceuticals Limited was formed in 2004 from the merger of AGT BioSciences of Melbourne and ChemGenex Therapeutics of California. ChemGenex uses genomic and proteomic technologies from discovery through to clinical development. Its focus is to develop targeted medicines for the treatment of cancer, diabetes and obesity.

³⁷ Invest Australia, 2005, "\$46 Million Awarded to Leading Health R&D Projects," *Inflow*, Issue 8, 20 April. Available at http://investaustralia.gov.au/media/INFLOW_Issue_8_05.pdf.

- **Zenyth Therapeutics (VIC) *withdrawn*** — Zenyth Therapeutics became a wholly owned subsidiary of CSL in November 2006. Zenyth had previously developed new therapies for inflammation and cancer.
- **CSL (VIC)** — Headquartered in Melbourne, CSL Limited is a global, specialty biopharmaceutical company that develops, manufactures and markets products to treat and prevent serious human medical conditions, with a particular focus on blood plasma.
- **Eli Lilly Australia (NSW) *withdrawn*** — Eli Lilly Australia is the Australian operation of US company Eli Lilly & Co. Eli Lilly products are used to treat many conditions including depression, schizophrenia, attention-deficit hyperactivity disorder, diabetes and osteoporosis.
- **Janssen-Cilag (NSW) *now a Round 3 participant*** — Janssen-Cilag Australia is a research-based pharmaceutical company, employing 330 staff in Australia and providing prescription medicines for a range of conditions in the areas of mental health, neurology, women's health, haematology, gastroenterology and pain management.
- **Mayne Pharma (VIC) *now Hospira*** — Mayne Pharma Limited was recently acquired by US pharmaceutical company Hospira. Its main focus is on the development, manufacture, sale and distribution of oncology medicines.
- **Merck Sharp & Dohme Australia (NSW)** — Merck Sharp & Dohme Australia manufactures and distributes medicines for high cholesterol, osteoporosis, arthritis, asthma, high blood pressure and HIV/AIDS and other conditions. It produces over \$1 billion worth of medicines each year for both the local and overseas markets.
- **Novogen (NSW)** — Novogen is an Australian company, formed in 1992. Its main business involves developing drugs to treat degenerative diseases and disorders including cancer, heart disease, osteoporosis, rheumatoid arthritis and inflammatory bowel disease.
- **Pharmaxis (NSW)** — Pharmaxis is a specialist pharmaceutical company undertaking the research, development and commercialisation of human therapeutic products that address chronic respiratory and autoimmune diseases.
- **Servier Laboratories (VIC) *withdrawn*** — Servier Australia is the local subsidiary of Servier, a French research-based pharmaceutical entity, specialising in ethical pharmaceuticals. Servier employs 200 people in Australia, undertaking clinical research including the management of Phase I, II, III and IV clinical trials and sales and marketing. Servier products treat diseases including cardiovascular, diabetes and osteoporosis.

For Round 1, in addition to the 11 successful applications, there were 15 unsuccessful applications. The success rate for Round 1 applicants was therefore 42.3 per cent.

Round 2 successful participants

- **Alchemia (QLD) *withdrawn*** — Alchemia Limited is a listed Australian biotechnology company. The company has particular expertise in chemistry, which it has applied to the discovery and development of human therapeutic products.
- **Alphapharm (NSW) *withdrawn*** — Alphapharm is owned by the US entity Mylan Laboratories. It develops, manufactures, markets and distributes prescription medicines and medicines only available at pharmacies, with a particular focus on generic medicines.

- **CBio (QLD)** — CBio Limited is an Australian biopharmaceutical company established in 2000. Operations include the development and commercialisation of treatments for inflammatory and autoimmune disorders.
- **Peplin Limited (QLD)** — Peplin Limited is an Australian headquartered company with development operations in California and a manufacturing facility in Southport, Queensland. Peplin is developing products to treat types of skin cancer.
- **Pfizer Australia (NSW)** — Pfizer Australia is the Australian operation of the global pharmaceutical firm. Pfizer Australia employs more than 1500 staff undertaking functions including manufacturing, R&D and marketing.
- **Prana Biotechnology (VIC) *declined*** — Prana Biotechnology is an Australian company established in 1997. The company's research is focused on developing disease modifying therapeutics for the treatment of common neurological disorders, with a focus upon Alzheimer's, Parkinson's and Huntington's diseases.
- **Starpharma (VIC)** — Starpharma is a leader in the development of nanotechnology-based pharmaceuticals and, through its US-based subsidiary Dendritic Nanotechnologies, a range of life science and industrial uses. It is currently trialling drugs for the prevention of genital herpes and HIV. Starpharma is listed on the Australian Securities Exchange.

It should be noted that Prana Biotechnology Ltd did not take up the offer to participate.

For Round 2, in addition to the seven successful applications, there were six unsuccessful applications. The success rate for Round 2 applicants was therefore 53.8 per cent.

Round 3 successful participants

- **Peptech (NSW) *now Arana Therapeutics*** — Arana Therapeutics is an Australian biotechnology company dedicated to developing and providing antibody and peptide-based human therapeutic products for the treatment of diseases in the areas of cancer and inflammation and products for fertility control in animals.
- **Janssen-Cilag (NSW)** — Janssen-Cilag Australia is a research-based pharmaceutical company, employing more 330 staff in Australia and providing prescription medicines for a range of conditions in the areas of mental health, neurology, women's health, haematology, gastroenterology, and pain management.
- **Progen Industries (QLD)** — Progen Pharmaceuticals Limited is an Australian and US listed company undertaking the discovery and development of small molecule-based cancer therapeutics.
- **Tissue Therapies (QLD)** — Tissue Therapies Limited was incorporated in 2002 to commercialise tissue culture and repair technology from the Queensland University of Technology in Brisbane, Australia. Operations include developing biomedical technologies for wound healing, tissue and various cell culture applications.
- **Vital Health Sciences (VIC)** — Phosphagenics began as an ASX listed investment company, Greenchip Development Capital. In 1999 the company redirected its investment program into the biohealth and plastics industries and changed name to Vital Capital Limited (VIT). Vital Health Sciences Ltd (VHS) was the major biohealth investment of VIT. In 2004 the shareholders approved distribution of the company's other investment Petrecycle in its actual form, the acquisition of the outstanding shares of VHS and a change of name to Phosphagenics Limited. VHS became a 100% owned subsidiary of Phosphagenics.

- **GlaxoSmithKline Australia (VIC)** — GlaxoSmithKline Australia is the Australian operation of the global pharmaceutical company of the same name. It has divisions in pharmaceuticals and consumer healthcare and undertakes activities including manufacturing and R&D in Australia.

For Round 3, in addition to the six successful applications, there were two unsuccessful applications. The success rate for Round 3 applicants was therefore 75 per cent.

3.3.4 First year evaluation outcomes

In its 2005-06 review of the first year of P³'s operation, the CIE found that P³ showed positive signs of improving the level of pharmaceuticals R&D in Australia and that the structure of the program had led to more novel research avenues. CIE predicted that P³ would, by the time of its conclusion, make a positive contribution to the Australian pharmaceuticals industry and a small contribution to the Australian economy. CIE concluded that the program had been somewhat effective in targeting spillovers but less successful in:

- achieving a significant shift in the focus of the R&D;
- promoting early stage partnerships; and
- changing MNC's R&D investment location.³⁸

3.4 Generally available R&D incentive programs

The special programs for the pharmaceuticals industry need to be seen in the context of the broader, generally available programs designed to provide support for business R&D and research commercialisation. In a real sense, pharmaceuticals companies have a choice whether they utilise support under P³ in preference to support in principle available under alternative R&D related programs.

As is discussed in Chapter 5, the recently commenced *Review of the National Innovation System* will be investigating the full range of R&D incentive programs in Australia and may (or may not) recommend reforms to these arrangements in its report to Government.

3.4.1 Large Companies

For companies with turnovers greater than \$100 million the two accessible R&D programs are the 125 per cent R&D Tax Concession and the 175 per cent Premium R&D Tax Concession.

At the time of the Productivity Commission's review of the PIIP, multinational companies headquartered outside Australia were in effect excluded from the 125 per cent (and 175 per cent Premium) R&D Tax Concession as a result of the rules relating to the holding of beneficial ownership of IP – only where beneficial ownership was held in Australia was it possible for companies to access the 125 per cent R&D Tax Concession.

³⁸ Centre for International Economics, 2006, *Pharmaceuticals Partnerships Program – First Year Evaluation*, p.50.

Unlike the multinational companies, large Australian companies were able to access the 125 per cent (and the 175 per cent Premium) R&D Tax Concession and therefore were able to choose whether they would apply for support under P³ or the R&D tax concession. On the face of it, the higher after tax grant rate delivered by P³ of 21 cents in the dollar compared to 7.5 cents for the 125 per cent R&D Tax Concession made it an attractive option. However, the 175 per cent Premium R&D Tax Concession offered a higher concession rate of 22.5 cents in the dollar. The cap of \$10 million for a five year program meant that it was likely they would actually make use of both support options (the main company in this category, CSL, was successful under the first round of P³). The rules of the R&D tax concession, which has a clawback arrangement to reduce the benefit of the concession where a company receives a grant from another government program on activity claimed under the concession, rules out the possibility of double-dipping.

The situation became somewhat different following the decision in 2007 to relax the rules on the beneficial ownership of IP for the purposes of the 175 per cent Premium R&D Tax Concession (although not for the 125 per cent R&D Tax Concession). In these circumstances, it becomes possible for MNCs headquartered outside Australia to apply for the 175 per cent Premium R&D Tax Concession. In principle, the MNCs now find themselves in the same position as Australian-owned companies as far as the 175 per cent Premium R&D Tax Concession is concerned – they have a choice between accessing P³ or the 175 per cent Premium R&D Tax Concession or both.

3.4.2 Small to Medium Sized Companies

Small to medium sized companies in this context refers to companies whose turnovers are less than \$100 million per annum. Programs that are relevant for small to medium sized companies, especially those at an early stage in their development are the Commercialising Emerging Technologies (COMET) program and the Pre-Seed Fund.

Small to medium sized firms can also access the 125 per cent R&D Tax Concession and the 175 per cent Premium R&D Tax Concession. Small companies can also access the R&D Tax Offset announced in the 2000-01 Budget.

The R&D Tax Offset is available to eligible Australian companies with an annual group turnover of less than \$5 million and R&D group expenditure of up to \$1 million. Smaller companies in tax loss, that would otherwise carry forward R&D related tax losses, can realise these losses as a cash equivalent payment when their tax return for the relevant year is processed.

A fuller discussion of the general programs available to support R&D and other aspects of innovation and a comparison of them with P³ is set out in Appendix A. It also shows a comparison between the support provided under P³ and the 175 per cent Premium R&D Tax Concession.

4 Review of P³

This chapter provides a formal review of P³ based on the first three years and projected outcomes to the program's conclusion in 2009 using an appropriateness, effectiveness and efficiency framework.

4.1 Assessment overview

Good public policy and government program design should focus on obtaining the maximum economic, social and environmental benefits for the funding involved. There is a range of design principles that facilitate achieving this outcome.³⁹ Such design principles also provide a good basis against which to assess the appropriateness, effectiveness and efficiency of a government funded program, such as P³. Principles of good design, as described by the Productivity Commission, are:

- target the source of the problem (objectives/rationales);
- inducement (additionality);
- contestability;
- consistency;
- funding duration;
- avoidance of risks;
 - adverse interactions with other programs;
 - unforeseen liabilities for government; and
 - strategic behaviour by firms.
- administrative and compliance efficiency;
- accountability and transparency;
- cost effectiveness;
- compliance with international obligations; and
- evaluation, monitoring and reporting.⁴⁰

In reviewing P³, a standard appropriateness, effectiveness and efficiency framework has been applied whilst also considering these good design principles.

Appropriateness is assessed by considering whether Government actions, in this case P³, have targeted an identified or prioritised need, or set of needs, to deliver a net gain to society, or to correct a market failure. Appropriateness is also considered in the light of whether continued government involvement is required.

³⁹ Productivity Commission, 2007, *Public Support for Science and Innovation*, Research Report, Productivity Commission, Canberra, p.373.

⁴⁰ Ibid p.373.

Effectiveness is assessed in terms of the extent to which the outcomes achieved are different to those that would have been achieved in the absence of P³. Particular points addressed in assessing effectiveness include: whether the P³ objectives have been met and the extent to which P³ has generated additional economic outcomes (additionality criterion).

Efficiency is assessed in terms of whether a program meets its intended objectives in a way that minimises costs, including administrative costs for government and stakeholders. Evaluation of the efficiency of P³ addresses: the extent to which inputs have been minimised and/or outputs maximised while achieving the P³ objectives.

Following a discrete assessment of appropriateness, effectiveness and efficiency, the overall economic impact of P³ is considered.

4.2 Appropriateness of P³

4.2.1 Addressing market failures

Reflecting the policy interest in the development of the pharmaceuticals industry in Australia and the special issues it faces (the market for prescription drugs is decisively influenced by the PBS), since 1988 there have been three sector-specific programs directed at supporting investment in the pharmaceuticals industry.

These programs all share the objective of increasing investment in R&D, which is the life blood of the pharmaceuticals industry and the source of productivity-enhancing spillovers. Unlike the two previous programs (Factor f and PIIP), P³ does not provide support for investment in manufacturing. P³ does however have an explicit aim of supporting the development of research partnerships between the leading pharmaceuticals companies and Australian emerging biotechnology/pharmaceuticals companies and centres of medical and health research.

While Factor f and the PIIP were limited to companies producing products listed on the PBS, P³'s eligibility was wider, in that it also applied to emerging biotechnology companies with a focus on human health products.

P³ has three primary objectives:

- promoting an increase in the amount and quality of pharmaceuticals R&D;
- the development of medicines for the global market; and
- partnerships and collaborations between multinational corporations and local companies.

The design of P³ was influenced by the findings of the Productivity Commission's review of the PIIP.

A major conclusion reached by the Productivity Commission was that the price suppression that might or might not be associated with the PBS did not warrant a program designed to offset the effects of price suppression.

The Productivity Commission found in their final report that a sector-specific successor to PIIP was warranted on the grounds that there was a particular market failure for business R&D in pharmaceuticals because the then R&D Tax Concession excluded intellectual property where the beneficial ownership of which was not held in Australia. Rather than recommending the general rectification of this problem by changing the R&D Tax Concession, the Commission suggested a successor to PIIP that focussed only on business R&D and that would provide an incentive for multinational pharmaceuticals companies to invest in more, and more novel, R&D in Australia.

The Productivity Commission recommended against providing support for pharmaceuticals manufacturing activities on the basis that they did not offer any special spillovers in addition to those associated with the manufacturing industry more generally.

As already noted, P³ applied not only to multinational companies that were affected by the requirements of the R&D tax concession in terms of the beneficial ownership of IP, it also applied to emerging Australian biotechnology/pharmaceuticals companies. The rationale for this extension might be either that such companies were facing particular market failures in terms of accessing risk capital to expand their businesses, or that they were perceived to be strategically important to the future of the pharmaceuticals industry.

On the basis of the rationale provided by the Productivity Commission for a successor program to PIIP, a special scheme would remain appropriate as long as the particular market failure it identified remained present. The requirement concerning the beneficial ownership of IP remains as it was at the time of the Productivity Commission's review for the frontline 125 per cent R&D Tax Concession. However, new arrangements have been introduced for the 175 per cent Premium R&D Tax Concession for IP held by the MNCs. *Prima facie*, while this change would appear to directly address, at least partly, the market failure that provided an important rationale for the introduction of P³, it does not fully address the market failure identified by the Productivity Commission.

A second rationale for P³ was to encourage R&D partnerships. It is thought that partnerships, between companies and between companies and publicly funded research organisations, can enhance the productivity of R&D activities and accelerate the generation and application of new knowledge. Underlying this rationale is the judgement that, left to itself, the market will not necessarily lead to optimal investment in partnership activity due to the lack of full benefit capturability by the partnership participants. It should be noted that there are general Commonwealth Government programs available that provide funding support to partnerships between industry and Universities. For instance, the ARC Linkage Grants and the Co-operative Research Centres Program both explicitly target the formation of such partnerships. The R&D Tax Concessions also provide support for R&D involving partnerships but they do not specifically target or preferentially provide support for partnership activities.

Taken together, these rationales for P³ retain some validity, albeit with lesser force than was the case in 2004 due to the changes made to the 175 per cent Premium R&D Tax Concession. The positive spillovers associated with R&D would lead to societally sub-optimal levels of investment in R&D (including in partnerships) in the absence of Government policy intervention.

Box 4.1 sets out the general market failures associated with R&D funding.

Box 4.1 Market failures associated with R&D

The market failures associated with Research and Development (R&D) and the role for government funding for R&D have long been recognised and documented in economic literature. Market failure is a term used to describe a situation in which markets do not efficiently allocate goods and services. The term market failure is also often used to describe situations where market forces do not serve the perceived public interest – in this case the market will produce either more or less of a good than is optimal from the perspective of the society.

The primary market failure that results in the private sector undertaking R&D at a societally sub-optimal level is that the outputs of R&D – new knowledge and skills – have public good characteristics.⁴¹ That is, the outputs of R&D are, at least to a degree, non-rivalrous and non-excludable. Consumption by one party of the knowledge produced by R&D does not reduce the amount of that knowledge available for consumption by others. It is also, despite the various mechanisms for protection of intellectual property, almost impossible to fully exclude parties that did not invest in the generation of knowledge from accessing and benefiting from the new knowledge. The funding of R&D by one party will therefore generate some positive externalities that can be enjoyed by the wider community.

The research and development stages are the highest risk phases for project success and are where spillovers from innovation (that cannot be captured by the innovator) are potentially greatest. Failure to capture these spillovers provides the rationale for Government involvement, such that the spillovers are captured and disseminated throughout industry and wider community.

The Productivity Commission has recently stated the following that:

“The strongest case for public support based on spillovers occurs:

- for basic research in science, especially where most governance and funding mechanisms concentrate on the highest quality and most efficient diffusion practices; and
- where businesses are engaged in novel R&D activities induced by support that, either spill over cheaply to others, or that trigger cycles of innovation by rivals. The spillover benefits will be greatest when there are many potential domestic beneficiaries (generic technologies, or many potential users of the technology because of industry structures).

Spillovers not only provide a rationale for public support, but pinpoint other policies that are important in increasing the effectiveness of the innovation system. These include measures that reduce the costs of absorption (such as skill upgrading); that facilitate research cooperation; and that provide new mechanisms for the legal distribution of knowledge in a digital world (for example, copyright and journal publishing models).”

Productivity Commission, 2007, *Public Support for Science and Innovation*, p.73.

The above arguments, however, do not provide a rationale for a sector *specific* program such as P³. In general it is preferable to use sector-neutral rather than sector-specific policy instruments to address market failures that cut across all sectors. This is because sector specific programs introduce distortions between sectors, encouraging investment in one sector at the expense of other sectors. It is preferable that such inter-sectoral distortions be avoided where possible.

⁴¹ As with most areas of economic activity, market failures such as information asymmetries will also be present to some degree in relation to innovation activity.

For a sector specific program to be appropriate therefore, one of two conditions must hold:

- there needs to be not only a market failure that effects the sector but this market failure needs to be specific to that sector; or
- the development of the sector is seen to be of such strategic priority that the introduction of a sector specific program is seen as an acceptable cost of supporting the sector's growth.

Given that the market failures impacting upon pharmaceuticals R&D do not appear to be unique to the sector (although the beneficial ownership of IP was a particularly important issue for the pharmaceuticals sector given the ownership structure of the industry and the strong tendency for pharmaceuticals companies to hold IP at head office), the appropriateness of a sector specific program such as P³ rests significantly upon a judgement as to whether the strategic significance of the sector warrants a special program supporting it.

It is important to note here that the question of appropriateness of a sector specific program is not the same as the question of whether there are still market failures in relation to industry R&D that continue to impact upon the pharmaceuticals sector as they do on other sectors. Such continuing market failures, for instance in relation to small companies that are pre-profitable and therefore do not benefit from the R&D Tax Concessions, may provide justification for continuation or expansion of Government programs that provide general support for emerging technology intensive companies Australia, as a relatively small market for many innovation intensive products, may systematically struggle to attract the attention of potential R&D investors. A clear Government commitment to supporting R&D investment may assist in boosting the visibility of Australia for investment in R&D to the decision makers within MNCs.

4.2.2 Appropriateness of the program design and administration

P³ has a number of key design features, some of which are similar to PIIP and some of which are different.

The focus of P³ is on R&D activities and partnerships. It differs in this respect from PIIP which also provided support for manufacturing but did not explicitly aim to support partnerships. The case for supporting R&D and partnerships remains stronger than the case for supporting manufacturing. The spillovers associated with R&D and partnerships are typically much larger than those associated with manufacturing activities.

In line with the good program design principles articulated by the Productivity Commission, both P³ and the PIIP involved competitive selection processes rather than being entitlement programs. In principle, this ought to result in higher quality R&D (and partnerships) being supported than would be the case with an entitlement scheme. Part of the higher quality ought to be a somewhat greater inducement effect as entitlement schemes tend to provide support for business-as-usual activities.

While PIIP was limited in terms of company eligibility to companies providing products listed on the PBS, P³ has widened the scope to include companies who have at least three years experience undertaking eligible pharmaceuticals R&D activities in Australia (or in the case of Round 3 in Australia, overseas, or both). The change in eligibility to include non-PBS suppliers reflected a desire to encourage high quality additional pharmaceuticals R&D from across the entire industry value chain and not just amongst PBS suppliers.

"The rationale for allowing emerging Australian companies to participate in the program was in part a recognition that high quality R&D is performed by companies at any stage of the

value chain and not just by established companies. In doing so it partially addressed some of the market failures associated with emerging companies in accessing capital."⁴²

Both the PIIP and P³ have aggregate and company funding caps. For the PIIP, \$300 million was provided over five years to support both production value added and R&D, while for P³ a maximum of \$150 million was to be provided over five years to support R&D.

The individual company funding cap for P³ was set at \$10 million compared to the funding cap of \$60 million per company with the PIIP (companies that received support under the PIIP got a little over \$30 million each on average). On the face of it, this number is essentially arbitrary, being driven by the total level of funding for the program (\$150 million over five years) and the desire to ensure wider participation than had been the case with the PIIP. In principle, while a case can be made for an aggregate funding cap (as a way of controlling expenditure), it is harder to see the justification for an individual company funding cap with a competitive program. The only rationale seems to be that there is a virtue in diversity itself. It is notable that in the third round of P³ companies that got support received up to \$10 million over two years rather than the five years in Rounds 1 and 2.

The rate of grant provided under Rounds 1 and 2 of P³ was a taxable grant of 30 cents in the dollar (which translates to an after tax incentive of 21 cents) for each dollar of additional R&D performed above a base level. This exceeds the after tax benefit provided by the 125 per cent R&D Tax Concession of 7.5 cents in the dollar. In Round 3 the grant rate was lifted to a taxable 50 cents in the dollar (which translates to an after tax incentive of 35 cents in the dollar) for each dollar of additional R&D performed above the base level of R&D. The changes to the 175 per cent Premium R&D Tax Concession, which did not occur until after the close of Round 3, mean that the MNCs would be able to access support of around 22.5 cents in the dollar under that scheme. If the grant rate had not been raised in Round 3, P³ would have offered a lower incentive to multinational companies compared to that subsequently available through the 175 per cent Premium R&D Tax Concession.

A further program design feature shared by P³ and the PIIP was the condition that support was provided only to the increase in R&D over a calculated base level. The case for such a condition is that it is more likely to achieve higher levels of additionality than a scheme which supports all R&D. The 175 per cent Premium R&D Tax Concession embodies a similar philosophy, although it does use a different methodology to calculate the base.

Another significant program design feature of P³ is that its support applies to a portfolio of R&D activities rather than particular projects. This is designed to allow greater flexibility and to better match the approach used by companies to manage their R&D activities. It does require companies in the scheme to forecast their likely future R&D investments, and requires a way of dealing with unplanned changes in the mix of activities in a given R&D portfolio.

The final special program design feature of P³ is that it provides support for partnerships between beneficiary companies and other biotechnology/pharmaceuticals companies and medical research institutes.

P³ is administered by AusIndustry, with decisions on which companies receive support and for how much, being decided by the program delegate who makes funding offers based upon the advice of the Pharmaceuticals Committee of Innovation Australia (previously the Industry R&D Board). The Pharmaceuticals Committee assesses applications against the program's four merit criteria:

1. the applicant's track record and capabilities;
2. the scope and nature of the applicant's partnerships and collaborations;

⁴² Background on the rationale for this change in scope provided by DIISR.

3. the technical merit of the proposed activities; and
4. the level of benefit to the Australian economy.

These criteria are clearly aligned to the program's objectives and hence are appropriate selection criteria.

Summary of appropriateness assessment

At the time of its introduction, the P³ addressed some identified market failures that particularly impacted upon the pharmaceuticals industry. Specifically, it addressed:

- the lack of generally available support for R&D by MNCs where IP ownership was held overseas;
- perceived limitations in private funding available for local biotechnology firms to undertake product development R&D; and
- sub-optimal levels of R&D partnerships between companies, and between companies and medical research institutes.

The first of these issues was of particular concern for the pharmaceuticals sector given the strong preference by pharmaceuticals MNCs to hold IP centrally. However it is not clear that these the latter two issues are unique to the pharmaceuticals sector. The appropriateness (at the time of its introduction) of a sector specific policy intervention such as P³ therefore relied upon a combination of the need to address the needs of MNCs and upon a judgement as to whether the strategic significance of the pharmaceuticals and biotechnology industry justified the introduction of a sector specific program.

Since the introduction of P³, an important change to the 175 per cent Premium R&D Tax Concession partly addresses the issue of access to general R&D support for MNCs (they still cannot access the 125 per cent R&D Tax Concession). This change weakens (but does not completely remove) the case for the appropriateness of P³ into the future, insofar as the most sector specific market failure has now been largely addressed. The remaining sector specific market failure now only relates to multinational pharmaceuticals companies that hold IP offshore not being able to access the 7.5 cents in the dollar support for the R&D base in the way that companies that hold IP in Australia can. The case for the appropriateness of a future sector specific intervention now must largely rest on whether the strategic significance of the pharmaceuticals and biotechnology industry is seen to justify such special treatment.

While assessing the 'strategic significance' of a particular industry is a somewhat subjective exercise, and is one for Government policy makers to determine, there does not appear to be compelling evidence available to suggest that spillovers from pharmaceuticals/biotechnology R&D are systematically higher than those that would be expected from R&D in other high technology and high innovation intensity industries.

4.3 Effectiveness of P³

Assessing the effectiveness of P³ involves evaluating the performance of P³ in its first three years of operation to assess the extent to which P³ funding is achieving its policy objectives of:

- A. increasing the pharmaceuticals R&D activity undertaken in Australia, including the amount, type and quality of new activity taking place;
- B. the number of multinational firms with regional or global R&D operations in Australia;
- C. the number and quality of linkages and new collaborations within the industry and international engagement of Australian companies;

- D. the quality of R&D undertaken by participants;
- E. the level of benefit, including the net economic benefit, to the Australian economy, using the generalised ‘spillover’ benefits approach, as adopted by the CIE in the first evaluation of P³; and
- F. encouragement of the development of medicines for global markets.

The extent to which the changes made to the program design as a result of the first year evaluation had an impact on the quality and quantity of applications for Round 3 of P³ is also considered.

Analysis of the effectiveness of P³ in contributing to the promotion of these inter-related objectives, and the extent to which the changes made to the program as a result of the first year evaluation had an impact on the quality and quantity of applications received for Round 3, is discussed in the following sub-sections:

- Additional, high quality pharmaceuticals R&D activity in Australia (relates particularly to objectives A, B and D) ;
- Development of medicines for global markets (relates particularly to objectives C and F); and
- Partnerships and collaborations (relates particularly to objectives C and D).

The assessment of performance in these areas is then used as a basis for assessment of the inducement rate for R&D expenditure (relates to objectives A and B) associated with P³ and the level of spillovers generated by the program (relates to objectives C and D).

The net economic impact of P³ (objective E) is separately assessed in Section 4.5 and draws particularly on the analysis of inducement rates and spillovers.

4.3.1 Additional, high quality pharmaceuticals R&D activity in Australia

P³ impact on inducing additional pharmaceuticals R&D activity in Australia

In order to establish whether P³ has been effective in attracting additional pharmaceuticals R&D activity to Australia, it needs to be shown that not only has the activity increased, but also that this increased activity, or part thereof, would not have occurred in the absence of P³. Expenditure on R&D is used as a proxy for the level of R&D activity.

Change in pharmaceuticals R&D expenditure in Australia

To date, firms that were successful in being awarded funding under Rounds 1 and 2 of P³ have reported an actual nominal increase (over baseline forecasts) in R&D expenditure of \$132.9 million over the three year period July 2004 to June 2007. Over this same period, baseline nominal expenditure has been \$525.9 million, suggesting that expenditure by participant P³ firms increased by a nominal 25.3 per cent.⁴³ Successful Round 3 participants are yet to report on a full year under P³.

A nominal increase in R&D expenditure of 25.3 per cent does not accurately reflect the increase in activity due to inflation in the costs of performing R&D over this time period. Therefore, the increase in real expenditure (in constant 2004-05 price year terms) is more reflective of the increase in observed activity. Using the observed changes in the Consumer Price Index⁴⁴ over the period, the actual increase in real expenditure is \$127.3 million.

⁴³ Analysis of P³ GLAM Database data provided by AusIndustry.

⁴⁴ Australian Bureau of Statistics, September 2007, *Consumer Price Index, Australia*, Cat. No. 6401.0.

Table 4.1: Changes in pharmaceuticals R&D expenditure by P³ participants (\$ million)

	2004-05	2005-06	2006-07	Total
Baseline R&D Expenditure	161.9	209.8	154.3	526.0
Actual Audited R&D Expenditure	178.7	269.5	210.5	658.8
<i>Additional nominal R&D Expenditure under P³</i>	<i>16.8</i>	<i>59.8</i>	<i>56.3</i>	<i>132.8</i>
<i>Per cent increase over baseline</i>	<i>10.4%</i>	<i>28.5%</i>	<i>36.5%</i>	<i>25.3%</i>
<i>Additional real R&D Expenditure under P³ (2004-05 price year)</i>	<i>16.8</i>	<i>57.5</i>	<i>53.0</i>	<i>127.3</i>
<i>Real (2004-05 price year) per cent increase over baseline</i>	<i>10.4%</i>	<i>27.4%</i>	<i>34.3%</i>	<i>24.2%</i>

Source: Analysis of AusIndustry data

Australian Bureau of Statistics (ABS) data on business expenditure on pharmaceuticals R&D showed that R&D expenditure has grown from \$575.9 million in 2003-04 to \$722.8 million in 2005-06 (in constant 2004-05 price year terms), representing a 25.5 per cent increase of \$146.9 million (in 2004-05 constant price year terms).⁴⁵ However, this includes the R&D expenditure from P³ participants. When the P³ participants' expenditure is excluded from the figures, the rest of the pharmaceutical industry actually increased its R&D expenditure by \$72.6 million (~12.5 per cent in real terms). At the same time, the expenditure from P³ participants increased by a real \$74.3 million. Note that ABS data for 2006-07 has not yet been released.

Based upon the evidence of R&D expenditure within the Australian pharmaceuticals industry, it is evident that the amount of R&D expenditure by P³ participants grew at a faster rate than the rest of the industry between 2003-04 and 2005-06. At face value this suggests that P³ has had a strong role in increasing pharmaceuticals R&D expenditure in Australia. However, when considering the changes from year to year, P³ participants have outperformed the rest of the industry in only one of the two years analysed. Therefore, it is considered that a longer time horizon of data is required in order to establish the extent to which P³ participants have consistently outperformed the rest of the industry in terms of the growth in R&D expenditure.

⁴⁵ Data provided by DIISR on R&D expenditure for Australian Standard Research Classifications 670400 (Human Pharmaceutical Products) and 730100 (Clinical Health).

Table 4.2: Australian pharmaceuticals R&D expenditure (\$ million constant 2004-05 prices)

	2003-04	2004-05	2005-06	Change in R&D expenditure	% Change
Australian pharmaceuticals industry R&D expenditure	575.9	648.5	722.8	146.9	25.5%
<i>Industry less P³ participants' expenditure</i>	409.9	469.8	463.6	53.7	13.1%
P ³ participants' R&D expenditure	166.0 ⁽¹⁾	178.7	259.2	93.2	56.1%

Source: Analysis of data supplied by DIISR and AusIndustry

(1) This is based upon the agreed base line expenditure, which is the average of the previous three years expenditure.

The issue of underperformance of successful firms

Although it is clear that pharmaceuticals R&D has increased as a result of P³ and that a portion of the increased R&D would not have occurred in the absence of the program, the actual increase has fallen short of that expected given the commitments made in the applications for P³. Total expenditure was forecast to be \$705.5 million over the period 2004-05 to 2006-07 after adjusting forecasts for withdrawal of firms from the program. Actual expenditure has only been \$658.8 million, 93.4 per cent of that forecast.

If the forecasts for firms which have withdrawn from the program were included in the analysis the underspend figure would be higher. However, as no actual data is provided for post withdrawal spending, it is not possible to calculate the extent to which performance is below forecast when adjusting for the withdrawal of companies from the program.

Table 4.3: Underperformance against forecasts in P³ applications (\$ million)

	2004-05	2005-06	2006-07	Total
Baseline expenditure ⁽¹⁾	161.9	209.8	154.3	526.0
Forecast R&D expenditure from applications ⁽¹⁾	201.0	269.9	234.6	705.5
Actual expenditure	178.7	269.5	210.5	658.8
Underspend	22.3	0.4	24.1	46.8

Source: Analysis of data supplied by AusIndustry and data within the CIE Survey

(1) Includes the values for companies that have withdrawn from the program.

Note figures may not sum due to rounding

Although there has been lower R&D expenditure than initially anticipated, the situation has improved since the first evaluation, in which it was concluded that only 50 per cent of forecast additional expenditure had occurred⁴⁶ (although the information in Table 4.3 suggests that the underspend in the first year was 57 per cent). This improvement in the expected expenditure shortfall suggests that firms have been able to utilise the mechanism that allows for firms to carry forward overspends or 'catch up' for underspends in the previous year. This appears to be an effective mechanism of the program.

⁴⁶ Centre for International Economics, 2006, *Pharmaceuticals Partnerships Program: First Year Evaluation*, prepared for the Department of Industry, Tourism and Resources, p.viii.

The underspend that has been observed has been significantly influenced by the withdrawal from the program by a number of firms, including both MNCs and smaller firms. For smaller companies, if their central project falls over, they generally do not have the project pipeline to replace it.

The carryover provisions for P³ have been more restrictive than were in place for PIIP, with the intention of reducing the extent to which funds become ‘tied up’ and unavailable for use to encourage other firms to undertake R&D. This has however allowed some funds un-used from Rounds 1 and 2 to be recycled for use in Round 3 of the program.

Possibly in response to the tightening of carryover provisions when compared to PIIP, some companies felt that the rules around the use of this mechanism were now overly restrictive. This can be best summarised in the words of a successful applicant’s comment received in the online survey:

“Forecasting R&D projects, by their very nature, is difficult. In our case the expenditure that occurred later in the program was not able to be claimed as the earlier underspends had expired.”

The respondent also called for the “ability to carry forward and carry back expenditure to all years within the grant”.

However, given that few companies have consistently spent close to or above their spending targets, in relation to carry forward of over-spend in particular it is not clear that this has materially impacted upon the effectiveness of the program.

Ability of P³ to influence the location in which pharmaceuticals R&D is conducted

As discussed in chapter 2, selection of a location at which to undertake pharmaceuticals R&D is influenced by a number of ‘economic factors’ typically used when making non-R&D based investment decisions (such as cost) as well as a number of ‘strategic factors’ (such as R&D track record). The type of company (e.g. multinational pharmaceuticals company versus a small biotechnology company) and the stage of development on which the firm is focused or the stage at which an individual project is, also play important roles in the choice of location for R&D to be conducted.

Responses to the survey indicate that P³ has had a significant impact on the choice of location in which to conduct the R&D. The survey found that two-thirds of successful Round 3 respondents said that the additional expenditure under P³ was a relocation of planned investment from abroad and that it was new R&D in Australia, whilst all respondents said that the additional expenditure was an extension of planned investment in Australia.

The responses from firms successful in Round 3 suggest that the higher grant rate and shorter timeframe have had a significant impact on the choice of location at which to conduct R&D. From the CIE evaluation, it was found that for firms successful in Rounds 1 and 2, slightly less than half of respondents reported relocating investment from abroad and that the new expenditure was new R&D for Australia, whilst just over half said that the additional expenditure was an extension of planned investment in Australia.

While P³ has clearly influenced MNCs to locate additional R&D activity to Australia, it does not appear that it has induced MNCs that previously did not have regional or global R&D operations in Australia to establish such operations in Australia. Consultations with Medicines Australia suggest that the number of their MNC members with ‘regional or global R&D operations’ in Australia has remained steady at nine over the past three years. Discussions with staff in multiple State and Commonwealth Government investment

attraction agencies also did not result in identification of any MNCs newly establishing such operations in the past three years.

Factors influencing the locality decisions of companies

MNCs typically operate across the entire pharmaceuticals value chain, and conduct R&D at any individual stage in a location that is of most benefit to the firm, whilst Australian based companies may only target specific stages along the value chain.

In response to the survey, one firm noted that “investments in basic medical research will continue to be made on a case by case basis depending upon the quality of the science”. This highlights the difficulty associated with relocating discovery (basic) R&D. Typically, discovery R&D is conducted where there is a proven track record of research capability.

Other more minor factors that influence the location of where discovery research is conducted include whether there is an established critical mass of skilled resources, infrastructure and favourable tax and patent laws.

Given the physical characteristics required for discovery R&D, it is very difficult to relocate, particularly under a program that limits the grant to any individual firm of AUD\$10 million, is of a relatively short term nature, and does not provide certainty of the amount of Government funding as payment is contingent upon the extent to which R&D spending exceeds base-line levels.

Clinical trials are significantly more flexible in where they can be located. As such, it is cost, quality, speed and safety standards which affect the decision on where to conduct clinical trials R&D. Australia is well-positioned to compete on these grounds, and P³ helps support Australia’s position as a competitive place to conduct clinical trials.

In providing comments in the survey, a firm noted that “investments in clinical research will continue but with reduced growth due to international competition”. Another firm, which withdrew from the program, said that “it became very difficult to increase [R&D expenditure] from the base achieved under PIIP [and that] growth in R&D has been impacted by shifts in some activities to Asia and increasing competition within the corporation on a cost and speed basis”. These comments highlight the global competition by countries wanting to attract pharmaceuticals R&D.

For MNCs, satellite offices compete internally for R&D funding and projects. Some MNCs, when interviewed as part of the stakeholder consultations felt that, while P³ was not the decisive factor in decisions on funding projects in Australia, it did help support the business case. Primarily P³ was seen to have sent the signal to headquarters that the Australian Government is interested in, and supportive of, the pharmaceutical industry.

Conditions of the pharmaceuticals market in host countries can also play a role in the R&D decisions of MNCs, particularly in the case of Australia as a comparatively small market place. Until recently the pricing structure of the PBS was raised as a major deterrent for some firms, but the PBS reforms may change this perception of the Australian market in the future.

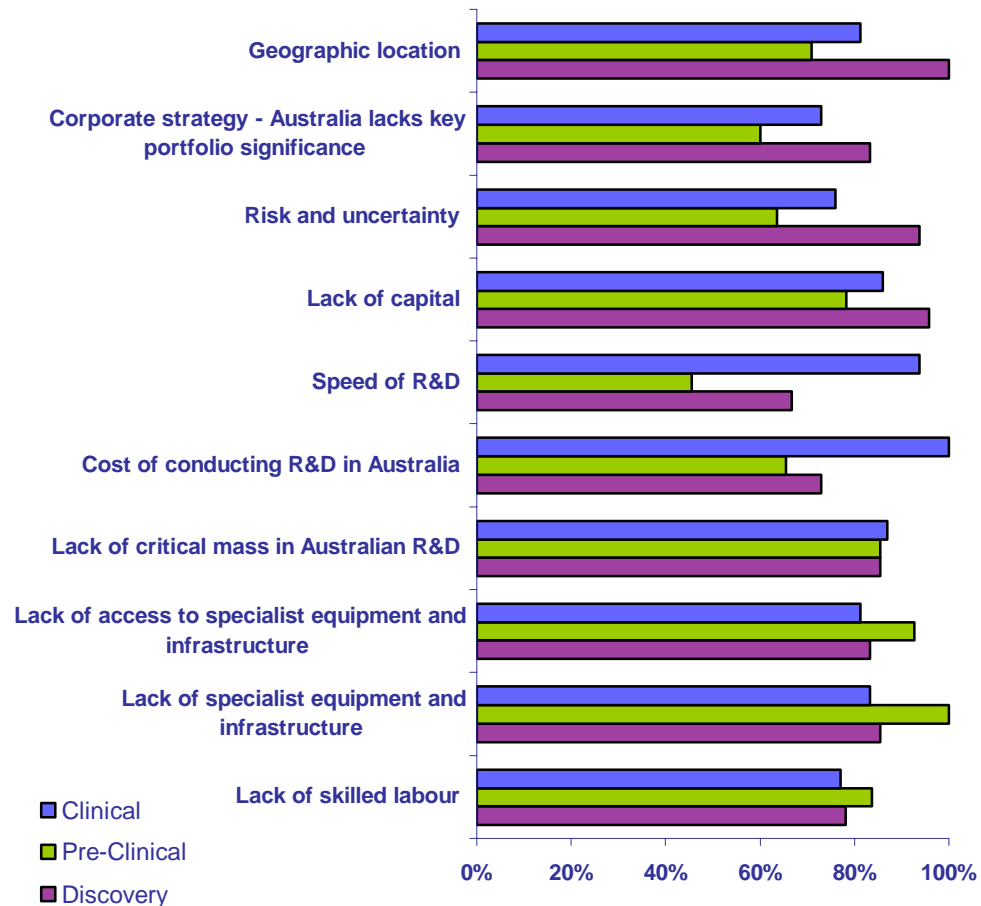
Factors constraining companies from conducting more R&D in Australia

Factors constraining firms from conducting more R&D in Australia have been identified in the survey. The top ten constraining factors are presented in Figure 4.1 below. The results have been normalised such that the most important factor is represented by a ranking of 100 per cent.

The results indicate that for discovery, pre-clinical and clinical trials, the most important factor is the lack of specialist equipment and infrastructure, with other important factors

including lack of skilled labour, lack of access to specialist equipment and infrastructure, lack of critical mass in Australia and lack of capital.

Figure 4.1: Top ten factors constraining firms from conducting more R&D in Australia



Source: Deloitte 2007 Pharmaceuticals Partnerships Program survey

While P³ does not directly address all of the factors which have been identified as most constraining additional pharmaceuticals R&D investment in Australia, it is clear that by providing additional funding into the R&D system it indirectly contributes to improvements in relation to many of them.

Throughout the stakeholder interviews, a number of firms suggested that there is a lack of capital for the required equipment and infrastructure, and called for the option to propose a large scale R&D facility to establish critical mass. Such a suggestion was made by both small and medium sized firms and larger firms.

The need for capital to fund equipment and infrastructure resonates in the approach being adopted by State Governments in attracting R&D funding. Queensland and Victoria in particular have provided significant infrastructure funding to medical research institutions.

P³ impact on the quality of pharmaceuticals R&D activity in Australia

It is clear that there has been an increase in the R&D activity in Australia as a result of P³, and that a sizeable (but difficult to quantify, as is discussed in 4.3.4) portion of this increase in expenditure would not have occurred in the absence of P³. The inducement rate is not, however, the only important driver of the effectiveness of the program. The quality and

novelty of the R&D undertaken is also a very important aspect in assessing the effectiveness of the program.

The competitive application process used to select recipients of P³ funding and the extent to which the Pharmaceuticals Committee of Innovation Australia can identify higher quality or more novel projects, would suggest that the grants awarded would be to projects that were of a higher quality or of a more novel nature. Therefore, it could be expected that projects awarded P³ funding are able to deliver greater spillover benefits than the average project. The evidence for this is presented in the following sections.

One of the merit criteria used by Innovation Australia (through the Pharmaceuticals Committee) to assess applications was the *Technical Merit of Proposed Activities*. This criteria aimed to assess whether the proposed activities were of a high technical merit. Quality and novelty were not explicit criteria, but were captured through measures such as:

- the degree of innovation (relating to novelty);
- activities involving leading edge technologies, techniques or skills (relating to novelty);
- the level of technical risk and the robustness of strategies to manage that risk (relating to quality); and
- whether the research is conducted to global practice standards (relating to quality).⁴⁷

In reviewing the Pharmaceuticals Committee's rating of the Round 3 applicants, it is clear that the committee also focused upon the track record of companies, the quality and novelty of that record and the quality of partnerships and collaborations.⁴⁸ The stage of development at which proposed projects were also factored into the rating decisions.

The quality of some projects was also questioned due to the companies' inability to demonstrate an understanding of technical risks, the development of risk mitigation strategies and understanding of regulatory requirements. In the Committee's assessment of one firm, it was quite clear that the Committee had doubts over the novelty of proposed projects, and that they did not demonstrate a successful track record in managing pharmaceuticals R&D in the proposed fields.

From the Committee's assessment of applications, it is clear that the quality and novelty were critical elements in their decision. To the extent that low quality and novelty projects ranked lowly in the Committee's assessment and did not receive P³ funding, P³ has improved the overall level of funding for projects that are of a higher quality or more novel. As such, it would appear likely to have increased the overall quality profile of industry R&D.⁴⁹

4.3.2 Development of medicines for global markets

Developing new medicines for global markets is a long process, typically requiring between 10 and 15 years to go from the lab to the consumer.⁵⁰ Much of this time is spent in the conduct of discovery and clinical trials R&D (as opposed to manufacturing and registration). As such, given that P³ focused more on the earlier stages in the pharmaceuticals value chain,

⁴⁷ Innovation Australia, *Assessment Framework – Pharmaceuticals Partnerships Program*

⁴⁸ Information provided by DIISR.

⁴⁹ The ANAO in their audit of the Management of the Pharmaceuticals Partnerships Program noted that there is no collection of information relating to the quality of research across the industry, and that without such data it is difficult to assess whether P³ has increased the quality of R&D being undertaken, or whether the increase is of the same quality as the industry. However, while data is not collected on the scientific merit of projects, from the community's perspective it is reasonable to treat projects with higher spillover benefits as being a proxy for higher quality projects.

⁵⁰ PhRMA, 2007, *Pharmaceutical Industry Profile 2007*, available at www.phrma.org.

the program has not been running sufficiently long enough for the individual projects to progress to manufacturing, and global marketing. It is noted that a small proportion of P³ expenditure was allocated to later stages in product development, which may have already contributed to the development of new medicines.

There are a number of indicators which can be used to determine the extent to which projects under P³ have progressed through the different stages of development towards the objective of developing medicines for global markets. A summary of these measures is shown in Table 4.4. Data is not yet available for firms successful in Round 3.

Table 4.4: Number of new patents and licenses from firms participating in P³

	2004-05	2005-06	2006-07	Total
Pharmaceuticals registrations	8	135	317	460
Patents	135	93	100	328
Licenses	21	9	9	39

Source: AusIndustry

Over the period that P³ has been running, there has been a significant increase in the number of pharmaceuticals registrations from firms successful in gaining P³ grants and a relatively steady flow of patents awarded (in jurisdictions including Australia, the United States, Europe, Japan and China). There have also been a total of 39 licenses granted over the first three years of P³. While these have not yet translated to a large scale increase in medicines available on the global markets, they are encouraging early indicators that this may occur in the future.

It is important to note here that the recent increase in pharmaceuticals registrations from firms successful in gaining P³ grants may not primarily be a consequence of P³ as these recent product registrations will tend to relate to R&D that commenced many years prior to the operation of P³. While P³ grants may have been involved in taking some products through the final trial stages, it would not be expected that the earlier stage R&D activity funded by P³ would yet be flowing through to product registrations. The recent increase in product registrations may in fact be taken more as evidence of the impacts of P³ predecessor programs that supported the research projects in their early stages perhaps a decade or more ago than as a direct outcome of P³ to date (much as product registrations five or ten years from now may in fact relate to P³ supported activity).

The impact of P³ on new discoveries, patents and licenses can be measured through responses to the survey. Table 4.5 presents the average responses to survey questions (from successful applicants) about the impact that P³ has on developing new medicines for global markets, using a rating scale of zero (no progress/impact) to five (significant progress/impact).

Over the past three years, most progress was reported to have been made on gaining new intellectual property (on average) and P³ has been cited as an important factor in this progress.

There is significant variation in the impact of P³ on the development of new medicines between firms successful in Rounds 1 and 2 and those successful in Round 3. P³ is seen to have had a greater impact in shortening the development cycle for Round 3 firms relative to firms in Rounds 1 and 2. P³ is however seen to have had a greater impact on increasing the probability of discovery and improving the efficacy of existing molecules or active ingredients/compounds for Round 1 and 2 firms.

Table 4.5: Impact of P³ on new R&D, discoveries, patents and licenses

	Rounds 1 and 2	Round 3
Shorter time scale upon which pharmaceuticals are available		
Extent of achievement over past three years	0.8	1.7
Significance of P ³ to achieve this outcome	0.6	1.8
Increased probability of discovery		
Extent of achievement over past three years	0.9	1.7
Significance of P ³ to achieve this outcome	0.8	1.8
Discovery of new molecules or active ingredients/compounds		
Extent of achievement over past three years	1.4	2.7
Significance of P ³ to achieve this outcome	1.1	2.7
Improved efficacy of existing molecules or active ingredients/compounds		
Extent of achievement over past three years	0.4	1.7
Significance of P ³ to achieve this outcome	0.7	1.5
Gained new intellectual property		
Extent of achievement over past three years	1.4	1.0
Significance of P ³ to achieve this outcome	1.1	1.2
Increased number of drugs registered		
Extent of achievement over past three years	1.6	1.7
Significance of P ³ to achieve this outcome	1.2	1.8

Source: Deloitte 2007 Pharmaceuticals Partnerships Program survey

The average survey response for the extent of achievement in relation to new R&D, discoveries, patents and licenses was 1.2 for Rounds 1 and 2 and 1.5 for Round 3. In relation to the significance of P³ to achievement of these outcomes, the average survey response was 1.1 for Rounds 1 and 2 and 1.6 for Round 3.

Unsurprisingly, given the timeframes for medicine development and the fact that the majority of P³ funding has supported early stage R&D and clinical trials, the impact of the program in advancing the objective of developing medicines for global markets is not rated highly by participants. This is not a criticism of the program as such, but rather may suggest that the true impacts in this area may take several more years to emerge.

4.3.3 Partnerships and collaborations

As is discussed in Table 4.8, partnerships and collaborations play an important part in generating spillover benefits from pharmaceuticals R&D expenditure by exposing researchers to new technologies and the potential for breakthroughs at the ‘interfaces’ between researchers in discovery R&D. Table 4.9 shows that P³ on average had a moderate impact on improving the networks among domestic researchers for successful Round 3 applicants, and that this effect had been slightly lower for Rounds 1 and 2.

The actual number of research collaborations and contracted research organisations established by firms successful in receiving funding under P³ is shown in Table 4.6. The number of research collaborations more than doubled between 2005-06 and 2006-07, whilst the number of contracted research organisations saw a 27 per cent increase between 2004-05 and 2005-06.

Table 4.6: Number of research collaborations and contracted research organisations

	2004-05	2005-06	2006-07	Total
Research collaborations	38	39	88	165
Contracted organisations	191	243	252	686

Source: AusIndustry

One potential reason for the increase in collaborations could be a result of the factors constraining companies from undertaking more R&D in Australia. The survey identified that the three most important factors (in order of priority) that are constraining companies from undertaking more R&D (Discovery, Pre-clinical and Clinical Trials) in Australia are:

- lack of specialist equipment and infrastructure;
- lack of capital;
- lack of access to specialist equipment and infrastructure.

The development of partnerships and collaborations is one way in which firms can address two of these constraints (relating to equipment and infrastructure) through the sharing of resources (both human capital and physical infrastructure).

The impact that P³ has had on collaborations and partnerships was addressed in the survey. Respondents were asked to rate the extent of achievement over the past three years (against various measures of collaborations and partnerships) and the significance of P³ in achieving the outcome on a scale of zero (no progress/impact) to five (significant progress/impact). Table 4.7 presents an overview of the average responses.

From the survey, the three areas where P³ has had the greatest influence is in:

- facilitating new relationships with universities and research institutes;
- facilitating new relationships with non-competing companies; and
- facilitating new relationships with hospitals.

The extent of achievement in these areas was of a moderate level. The average survey response for the extent of achievement in relation to partnerships and collaborations was 1.3 for Rounds 1 and 2 and 1.7 for Round 3. In relation to the significance of P³ to the achievement of these outcomes, the average survey response was 1.0 for Rounds 1 and 2 and 1.7 for Round 3.

Table 4.7: Impact of P³ on collaborations and partnerships

	Rounds 1 and 2	Round 3
Facilitated new relationships with universities and research institutes		
Extent of achievement over past three years	2.0	2.8
Significance of P ³ to achieve this outcome	1.7	2.8
Facilitated new relationships with hospitals		
Extent of achievement over past three years	1.9	2.7
Significance of P ³ to achieve this outcome	1.9	2.3
Facilitated new relationships with non-competing companies		
Extent of achievement over past three years	1.4	2.7
Significance of P ³ to achieve this outcome	1.5	2.7
Facilitated new relationships with competing companies		
Extent of achievement over past three years	0.8	1.2
Significance of P ³ to achieve this outcome	0.7	1.3
Facilitated new relationships with customers		
Extent of achievement over past three years	1.1	0.8
Significance of P ³ to achieve this outcome	0.8	0.8
Facilitated new relationships with suppliers		
Extent of achievement over past three years	1.3	1.7
Significance of P ³ to achieve this outcome	1.0	1.7
Increased collaboration with overseas research centres		
Extent of achievement over past three years	1.6	0.7
Significance of P ³ to achieve this outcome	0.6	0.7
Increased collaboration with Australian biotechnology firms		
Extent of achievement over past three years	0.6	2.2
Significance of P ³ to achieve this outcome	0.8	2.5
Increased collaboration with pharmaceuticals MNEs		
Extent of achievement over past three years	0.6	0.8
Significance of P ³ to achieve this outcome	0.2	0.8

Source: Deloitte 2007 Pharmaceuticals Partnerships Program survey

Whilst it is clear that there has been a moderate increase in partnerships and collaborations by participants in P³, and that P³ has played a role in this increase, stakeholders consulted have not suggested that P³ has led to the widespread establishment of new large scale and long lasting partnerships.

In terms of the quality of partnerships, stakeholders interviewed did not indicate that collaborations and partnerships were significantly or systematically different in nature than those that may have been entered into in the absence of P³. Stakeholders reported that P³ enabled more and larger collaborations and partnerships rather than fundamentally different types of collaborations and partnerships. However, given that participants in Round 3 tend to report higher positive impacts relating to collaborations and partnerships from P³ than do participants in Rounds 1 and 2, this could be seen to suggest that these partnerships and collaborations are viewed as being of higher quality.

4.3.4 Induced pharmaceuticals R&D expenditure in Australia

Although the evidence presented above shows that P³ has been associated with an increase in pharmaceuticals R&D expenditure, the observed real increase in R&D expenditure of \$127.3 million to the end of June 2007 does not necessarily represent the expenditure that has been induced by P³. A portion of the increase in expenditure may have occurred regardless of P³ or, conversely, in the absence of P³ expenditure may have actually fallen (a prospect raised by several industry stakeholders consulted). The level of induced pharmaceuticals R&D expenditure, and hence pharmaceuticals R&D activity, is the additional R&D expenditure undertaken in Australia due to the incentives created by P³, excluding that which would have occurred regardless of P³.

A *prima-facie* expectation is that the rate of induced R&D expenditure from Round 3 of P³ may have been greater than that for Rounds 1 and 2, given the increase in the taxable grant rate from 30 cents in the dollar to 50 cents in the dollar and the \$10 million cap only applying over two years (rather than five for Round 1 and four for Round 2).

In order to estimate the inducement rate of firms participating in Round 3 of P³, successful firms were contacted individually and asked to identify what proportion of individual projects would not have proceeded in the absence of P³. Responses to this question identified an inducement effect for Round 3 across a range of 14 per cent to 30 per cent. The average inducement rate from the responses was 22 per cent (which is also the mid point between the upper and lower bounds by coincidence).⁵¹ This figure seems very low compared to findings relating to inducement in both the initial CIE review of P³, which estimated that the inducement rate was between 25 per cent and 54 per cent for Rounds 1 and 2 of the program, and the Productivity Commission's evaluation of the PIIP, which found an expected inducement rate in relation to the R&D component of the PIIP of 60 per cent.

Several stakeholders noted that it was very hard for them to estimate what may have happened in the absence of the P³ grant they received, noting that they could only base the assessment on comparing what their plans had been prior to announcement of Round 3 and what they have subsequently done. This, of course, implies that plans would not have changed without P³, something that may or may not actually be the case. The Productivity Commission has also repeatedly stressed the inherent difficulty in establishing inducement rates for R&D incentives.

⁵¹ The methodology developed by CIE in the 2006 evaluation of P³ applied weightings to a number of survey responses in order to establish the inducement rate. Using this approach in analysing the 2007 survey, an inducement rate of 89.5 per cent is established. This level of inducement was considered to be very high when compared to other studies of inducement for R&D programs, and successful firms were re-interviewed and directly asked to identify the level of inducement.

The Productivity Commission's assessment of inducement rates for the 125 per cent R&D Tax Concession further highlights the significant difficulties and uncertainties associated with establishing inducement rates. They have estimated that a range for the inducement rate is between 4.5 per cent and 10 per cent for the 125 per cent R&D Tax Concession.⁵²

A separate recent survey of the impact of R&D assistance on company behaviour identified from survey respondents that had there not been the 125 per cent R&D Tax Concession, 14 per cent of projects would not have continued, suggesting an inducement rate of 14 per cent for that program, higher than the estimate established by the Productivity Commission.⁵³

Given the difficulties associated with inducement rate estimation, it is important that a wide range is tested and the mid-point estimate really should be viewed as a 'reasonable estimate' rather than as a precise and reliable figure. Our approach to establishing upper bound, lower bound and expected inducement rates for P³ is detailed below.

Establishing an upper bound inducement rate

The CIE analysis of the upper bound was based on weighting a number of responses to survey questions. The questions included in the weighting were:

- Consideration of P³ on investment (30%)
- Impact if unsuccessful (20%)
- Impact on total planned R&D (10%)
- P³ at 50 per cent impact on funding (10%)
- Type of R&D induced (30%)

It is not clear why the final two questions have been included in this weighting of survey responses. Question 4 was a yes/no question about a hypothetical future program and question 5 focuses on the characteristics of induced R&D rather than the quantity induced. If these questions are taken out of the CIE weighting formula, the weighted upper bound inducement rate for Rounds 1 and 2 would be 43 per cent rather than 54 per cent. We believe that the 43 per cent represents the more reasonable upper bound estimate for Rounds 1 and 2 based on the stakeholder survey results from that study.

In relation to Round 3, given that the after tax incentive rate is 35 cents per dollar versus 21 cents per dollar of additional R&D for Rounds 1 and 2 (a ratio of 1.67:1) it may be reasonable to assume that the upper bound for inducement rate for Round 3 would also be commensurately higher, at 72 per cent versus 43 per cent for Rounds 1 and 2.

The upper bound for Round 3, while still high when compared to much of the literature surrounding inducement rates, is not seen to be implausibly high given that all Round 3 participants have indicated that projects funded under P³ have involved an extension of planned investment in Australia and two thirds suggested that it involved a redirection of resources to Australia from overseas. It is also in line with the Productivity Commission's upper bound estimate for induced R&D under PIIP of 73 per cent.⁵⁴

⁵² Productivity Commission, 2006, *Public Support for Science and Innovation*, Draft Research Report, Productivity Commission, Canberra, p.9.14, 9.15.

⁵³ Department of Industry, Tourism and Resources, 2007, *How R&D Assistance Influences Company Behaviour*.

⁵⁴ Productivity Commissions, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, p.5.30.

Establishing a lower bound inducement rate

The lower bound of the CIE inducement rate estimate (25 per cent) was established by consideration of what R&D unsuccessful applicants subsequently undertook. They found that 75 per cent of unsuccessful Round 1 and 2 applicants ended up actually undertaking as much or more R&D than they planned in their application. From this CIE concluded that “this suggests that a lower bound on inducement is around 25 per cent, that is, of the additional investment, 75 per cent would have occurred anyway”. We do not believe that this conclusion necessarily follows from the analysis – the general circumstances may have altered in numerous ways for unsuccessful applicants which could have more influence on observed spending patterns than whether or not a P³ grant was received.

In this review we have adopted a different approach to the establishment of a lower bound inducement rate for Rounds 1 and 2 and for Round 3.

If it is assumed that increasing the rate of incentive would be expected to lead to a commensurate increase in the inducement rate, lower bound estimates for the inducement rates for Rounds 1, 2 and 3 may be derived by scaling up the lower bound inducement rate of 4.5 per cent that the Productivity Commission has found in relation to the 125 per cent R&D Tax Concession. For Rounds 1 and 2, with an after-tax incentive rate of 21 cents per dollar compared to 7.5 cents per dollar for the 125 per cent R&D Tax Concession, the lower bound estimate for inducement rate would be $(21/7.5) \times 4.5$ per cent. This gives a lower bound estimate of 13 per cent for these Rounds. For Round 3, with an after-tax incentive rate of 35 cents per dollar compared to 7.5 cents per dollar for the 125 per cent R&D Tax Concession, the lower bound estimate for inducement rate would be $(35/7.5) \times 4.5$ per cent. This gives a lower bound estimate of 21 per cent for Round 3.

Given that a number of stakeholders consulted in this review expressed the view that a grant that counts to the revenue line is more attractive to them than a tax concession of the same theoretical value, these lower bound estimates should be viewed as being quite conservative.

Establishing an expected inducement rate

Given uncertainties in the assessment of inducement rates, the most that can be concluded in relation to the expected inducement rate for P³ is that it will fall somewhere between the upper and lower bound estimates. In establishing a designated ‘expected’ inducement rate for P³, we have taken the mid-point estimate of the inducement rate ranges.

For Rounds 1 and 2 this mid-point is 28 per cent while for Round 3 the mid-point inducement rate estimate of is 47 per cent.

4.3.5 Impact of P³ in generating spillover benefits

The impact of P³ on the quality and novelty of pharmaceuticals R&D undertaken in Australia is an important outcome from the program as such projects are more likely to lead to greater improvements in the medicines developed and available to the public. They are also important because of the ‘spillover’ benefits that result from R&D.

Spillover benefits occur when a third party benefits from an activity of another firm but does not pay for the benefit (a positive externality). Knowledge, created through R&D, is a commonly cited spillover benefit.

If, as a result of P³, pharmaceuticals R&D undertaken in Australia was of either a higher quality or was more novel, or both, than would have otherwise been the case, then P³ potentially generated significant spillover benefits for the Australian economy.

The funding of pharmaceuticals R&D may also deliver spillover benefits that are not related to the quality or novelty of projects. Specific spillover benefits that may result from P³ are discussed in Table 4.8.

Table 4.8: Spillover benefits from pharmaceuticals R&D

Spillover benefit	Description of benefit
Development of new technologies	When an innovation is made, it may not be possible to completely exclude this new knowledge from others. The easier it is for other firms to access the innovation, the larger the benefit.
Diffusion and absorption of new knowledge	The ability of firms to identify and adopt new technologies increases the speed at which the productivity gains from these new technologies are realised. The establishment of networks can facilitate the speed at which new technologies are diffused. More highly educated employees can increase the capacity of firms to absorb and adopt new technologies. Subsidiaries of MNCs that have R&D functions in Australia facilitate the diffusion and absorption of knowledge generated outside of Australia.
Reduced duplication	The creation of networks between domestic and international researchers, as well as between firms and research institutions and organisations, can reduce the amount of duplicative work, increasing productive research.
Establishment of a specialised labour force	The establishment of a specialised labour force by industry clustering may increase beneficial linkages between firms (agglomeration benefits). Such benefits can include increased sharing of staff and lower coordination and cooperation costs.
Establishment of a critical mass of suppliers	Establishment of a critical mass of suppliers can lower input costs through economies of scale, lower transportation and communication costs and higher innovation amongst suppliers as there are greater returns to be captured.

Evidence of the presence of spillover benefits under P³

Responses to the survey are used to assess the presence of spillover benefits from expenditure on R&D under P³. Table 4.9 presents the responses to questions regarding spillover benefits. Respondents ranked the impact of P³ on a number of spillover benefits on a scale of zero (no impact) to five (significant impact) with 2.5 representing a middle of the range score. A mean of responses by Round 1 and 2 and Round 3 participants is presented.

Table 4.9: Spillover benefits resulting from P³

What spillovers have resulted from P ³ spending?	Rounds 1 and 2	Round 3
Skills transfer due to direct involvement in R&D	1.7	2.7
Improved networks among domestic researchers	1.8	2.8
Improved networks among international researchers	1.4	1.5
Improved reputation of Australian pharmaceuticals R&D	1.8	2.7
Increased demand for Australian based pharmaceuticals	1.3	1.2
Increased probability of discovery R&D productivity	1.4	1.8
Increased R&D efficiency	1.3	2.0
Increased access to common user R&D infrastructure	1.3	2.0

Source: Deloitte 2007 Pharmaceuticals Partnerships Program survey

From the survey responses it is clear that Round 3 participants saw greater spillovers than for Rounds 1 and 2, with a mean rating of 2.1 for Round 3 against an average score of 1.5 for Rounds 1 and 2. However, there is consistency between the two cohorts in terms of the spillovers that P³ has influenced the most:

- skills transfers due to direct involvement in R&D;
- improved networks among domestic researchers; and
- improved reputation of Australian pharmaceuticals R&D.

The higher level of reported spillovers for Round 3 could suggest that the higher incentive rate of Round 3 induced R&D that is associated with greater spillover benefits (R&D of higher quality or of a more novel nature) than the industry average.

From the results of the survey conducted as part of the CIE first year evaluation, spillover benefits were found to be present for Round 1 and 2 participants, but P³ had only a modest impact in changing the nature of R&D and hence spillovers.⁵⁵ Therefore, it seems consistent with the findings from the survey conducted as part of this evaluation that the spillovers for Round 3 have been higher than for Rounds 1 and 2.

It should be noted that the full market a non-market impact of spillovers that may be felt in the future due to P³ induced R&D are unlikely to captured using the assumptions that are in this evaluation and the surrounding literature.

The value of P³ spillover benefits

The value and the timing of spillover benefits from P³ will depend upon where expenditure from the program has been allocated along the pharmaceuticals value chain. Spillover benefits are largest when there are no barriers to third parties using the new knowledge – that is when innovation is non-excludable, which typically occurs at the basic research end of the innovation spectrum. In the pharmaceuticals industry the largest spillover benefits are

⁵⁵ Centre for International Economics, 2006, *Pharmaceuticals Partnerships Program: First Year Evaluation*, for Department of Industry, Tourism and Resources, p.36.

therefore most likely to result from discovery research.⁵⁶ However, the realisation of spillover benefits from discovery research will generally occur over a longer time horizon in keeping with the often long time horizons for private benefits captured from discovery R&D. A final assessment of the spillover benefits resulting from discovery R&D may not be possible for a decade or more after initial funding for such activity occurs. Therefore, in assessing the value of P³ spillover benefits, it is necessary to rely heavily on the literature surrounding the historically observed spillovers associated with different types of activity rather than on assessment of the actual spillover benefits delivered to date from P³ funded activities.

The Productivity Commission, in its PIIP evaluation, concluded that pre-clinical and early stage clinical trials may not produce many spillovers in their own right, but that they form part of the critical mass of the pharmaceuticals industry, playing an important role in enabling discovery research and the discovery and development of new pharmaceuticals.⁵⁷

However, in the context of the Australian pharmaceuticals industry, which undertakes relatively little discovery research and relatively more clinical trials (refer to Table 4.10 below), pre-clinical and early stage clinical trials can play an important role in the diffusion and adoption of new technologies and innovations developed overseas. Conducting clinical trials in Australia for a new technology developed overseas exposes Australian researchers to the new technology, thus diffusing the innovation in Australia.

Given the presence of multinational pharmaceuticals companies in the Australian pharmaceuticals industry, the pre-clinical and early stage clinical trials conducted by these firms are likely to be a source of significant spillover benefits in the Australian context. To the extent to which P³ has increased the number (and quality or novelty) of pre-clinical and early stage clinical trials being conducted in Australia by the multinational corporations, these clinical trials are likely to deliver direct spillover benefits above that of the enabling role.

Whilst late stage clinical trials may expose patients suffering from the targeted disease to a new drug earlier than would otherwise have been the case, the underlying need for the trial (the risk of unforeseen consequences) may mean that there is no net benefit from such earlier access to a new drug.⁵⁸ Late stage clinical trials are also likely to deliver spillover benefits associated with the diffusion and adoption of new technologies if early stage clinical trials were not conducted in the same location.

If the location at which pre-clinical and early-clinical trials are conducted is an important contributing factor in the decision about where to locate late-stage clinical trials, the spillover benefits from the diffusion of a new technology will be lower in the late stage clinical trials.

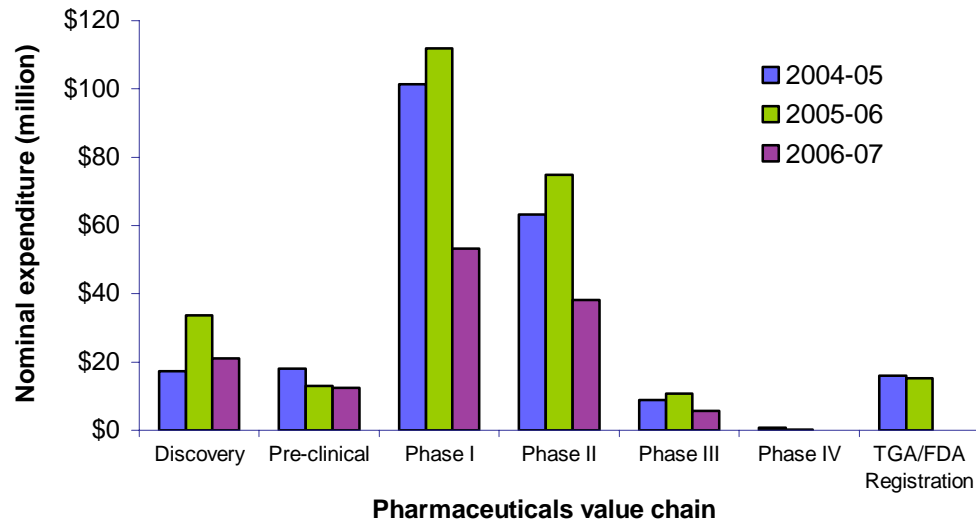
Information provided by AusIndustry from its GLAM database (which keeps records of the reporting by P³ participants) and from the P³ Annual Reports is analysed to determine the allocation of total P³ expenditure (i.e. baseline plus additional expenditure) by stage of development for Rounds 1 and 2 on individual projects. It is noted that there are some limitations to this dataset, such as the incomplete set of information for the financial year 2006-07, and some anomalies in data reported (for instance, one projected recorded negative expenditure). Notwithstanding these limitations, the data still provides a good general overview of the allocation of expenditure across the pharmaceuticals value chain, as illustrated in Figure 4.2 and Figure 4.3 for Rounds 1 and 2 respectively.

⁵⁶ Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, AusInfo, Canberra, p.4.7.

⁵⁷ Ibid, p.4.8.

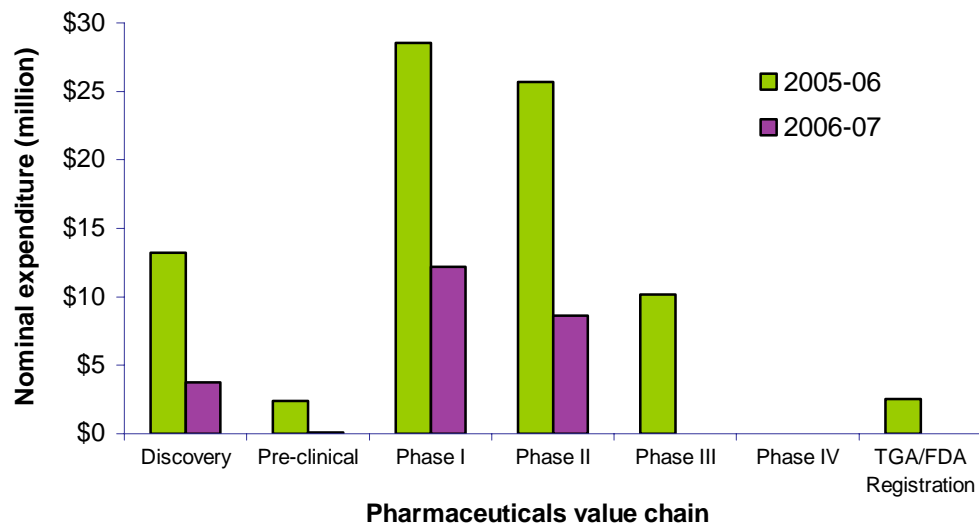
⁵⁸ Ibid, p.4.10.

Figure 4.2: Estimated allocation of P³ R&D expenditure for Round 1



Note: Data for three companies was not available for the 2006-07 financial year. Two companies withdrew from the program, but data is included where it had been provided when they were still participating in the program.

Figure 4.3: Estimated allocation of P³ R&D expenditure for Round 2



Note: Data for one company was not available for the 2006-07 financial year. Two companies withdrew from the program, but data is included where it had been provided when they were still participating in the program.

Table 4.10 shows the proportion of Round 1 and 2 expenditure under P³ allocated to each stage of development along the value chain. Given the incomplete information for the financial year 2006-07, the proportion is also calculated for only the first two years of P³, which provides a clearer indication of the allocation as it is not distorted by missing data points. Expenditure data by stage of development is published by Medicines Australia and PhRMA for the Australian and US industries respectively, and provide a benchmark against which to assess the allocation of expenditure under P³. While Medicines Australia's membership base does not include all potential P³ applicants, its members do perform a

significant portion of R&D expenditure for the pharmaceuticals industry⁵⁹ and is the best available proxy for sector R&D expenditure patterns across the R&D continuum.

Table 4.10: Proportion of P³ expenditure allocated across the pharmaceuticals value chain

Stage of development	Proportion of total expenditure	Proportion of total expenditure (excluding 2006-07 data)	Medicines Australia ⁽¹⁾	PhRMA Member expenditure ⁽²⁾
Discovery	12.3%	11.3%	9%	} 25.7%
Pre-clinical	6.2%	5.8%	7%	
Phase I	42.7%	42.9%	7%	5.8%
Phase II	29.3%	29.0%	14%	11.7%
Phase III	4.9%	5.3%	42%	25.5%
Phase IV	0.1%	0.2%	14%	13.3%
Registration	4.3%	5.5%	n/a	6.9%

Source: Analysis of information from the GLAM Database and PhRMA, 2007, *Pharmaceutical Industry Profile 2007*.

(1) Does not sum to 100% due to an 'other' category. Expenditure for 2005, approximate values only that have been interpreted from Medicines Australia, 2007, *Australian Pharmaceuticals Industry – Facts at a Glance*

(2) Expenditure for 2005, based upon responses from PhRMA Annual Member Survey 2007.

Expenditure on Phase I and II clinical trials has attracted the majority of expenditure under P³, representing a combined 72 per cent of expenditure. Both stages of development attracted significantly higher allocations of expenditure than the Australian (21 per cent) and US (17.5 per cent) benchmark expenditure profiles. Also, the Discovery and Pre-clinical stages of development attracted marginally higher expenditure than the Australian industry benchmark, but marginally lower than the US benchmark, whilst late stage clinical trials attracted significantly lower expenditure than the benchmarks.

This evidence suggests that P³ has been able to target R&D that is earlier in the product development stage, and which has higher spillover benefits. This presents a strong case that P³ has generated spillovers above the industry average. From the perspective of the community, this higher spillover R&D can be seen to be higher quality R&D as it generates greater community benefits than later stage R&D.

The high proportion of expenditure on Phase I and II clinical trials indicated by the data is supported by the messages received from companies through stakeholder consultations. In particular, MNCs said that Australia is highly competitive in attracting clinical trials, but less so for the earlier R&D stages, such as discovery research.

Whilst the evidence suggests that the R&D conducted under P³ has been in earlier stages of development than the benchmark for the Australian industry, the value of spillover benefits associated with P³ still needs to be determined.

⁵⁹ Medicines Australia, *Industry, Member Survey 2006-07*, Retrieved 21 January 2008 from <http://www.medicinesaustralia.com.au/pages/page4.asp>.

In its evaluation of the PIIP, the Productivity Commission used the range of estimates of spillover benefits range derived by the Industry Commission's 1995 report *Research and Development Review* of between 25 per cent and 90 per cent – that is for each dollar invested in R&D between 25 cents and 90 cents in spillover benefits are generated. The Productivity Commission adopted, somewhat arbitrarily, an average assumed spillover rate of 57.5 per cent for discovery and pre-clinical R&D and 25 per cent for clinical trials.⁶⁰

In arriving at these values the Productivity Commission noted the following:

- These are average spillover rates, not marginal spillover rates. To the extent that the most promising R&D activities are taken up first, the marginal rate of spillover benefits could be lower than the average.
- Spillover benefits are not likely to be higher in the pharmaceutical industry than other sectors because of the evidence that patents (and hence appropriability) are greater in the pharmaceuticals industry.
- The different stages of development may have different levels of R&D – clinical trials may have lower spillover rates given that the benefits will be greatest for the first of a set of trials rather than all trials, and that had the trials not been conducted in Australia they would have occurred elsewhere, leaving open the possibility for new technologies to diffuse from abroad.⁶¹

The evidence of spillover benefits from P³ presented above indicates that there is a higher proportion of expenditure occurring earlier in the pharmaceuticals value chain and that Round 3 had greater spillover benefits than Rounds 1 and 2. On the basis of this evidence it seems reasonable that the spillover benefits for Round 3 of P³ are greater than both Rounds 1 and 2 and the industry average and higher quality from the community's perspective.

With program participants having reported expenditure against individual projects, it is possible to refine the assumption regarding the estimate of spillover benefits associated with various stages of development along the pharmaceuticals value chain, and hence the spillover benefits attributable to P³.

The Productivity Commission, in its review of the PIIP, used an expected spillover benefit value of 57.5 per cent for discovery and pre-clinical R&D and 25 per cent for clinical and other R&D.⁶² However, in the context of the Australian industry, Phase I clinical trials play a critical function in linking the medical research sector to industry and can be expected to be much more like discovery and pre-clinical R&D in relation to their spillover profile. While this is a somewhat arbitrary distinction in the rates of spillovers for Phase I clinical trials, it is likely to better approximate the reality that these early stage clinical trials, given that they have a high 'research' component and play a critical role in the Australian context.

For the purpose of spillover valuation, we therefore assume that Phase II, III and IV clinical trials will result in spillover benefits of 25 per cent, whilst Phase I clinical trials will result in spillover benefits of 57.5 per cent. These spillover rates are adopted for Rounds 1 and 2 and, given the profile of R&D activities funded under P³, result in a weighted average spillover rate of 44.5 per cent for Rounds 1 and 2.

⁶⁰ Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, AusInfo, Canberra, p.11.

⁶¹ Ibid, p.10.

⁶² Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, AusInfo, Canberra, p.11.

The stakeholder responses shown in Table 4.9 suggest that the spillover benefits for Round 3 were higher than for Rounds 1 and 2 by, on average, 40 per cent. Therefore, as shown in Table 4.11 the spillover benefits assumed for Round 3 are 80.5 per cent for discovery, pre-clinical R&D and Phase I clinical trials (while this is a high spillover rate, it is still below the high end of spillover rate estimates produced by the Productivity Commission) and 35 per cent for Phase II, III and IV clinical trials. Given the balance of activities funded by P³, the overall weighted average spillover rate for Round 3 of P³ is therefore estimated at 62.3 per cent.

Using the information in Table 4.10, it is possible to allocate specific spillover benefits to the various stages along the pharmaceuticals value chain. Whilst some aggregation and averaging is still required, it does provide the ability to derive a more rigorous estimate of spillover benefits for the specific projects which were awarded P³ grants. These are summarised in Table 4.12, which suggests that the industry weighted average spillover benefit is 30.7 per cent, whilst that for Rounds 1 and 2 of P³ the spillover benefit would be 44.5 per cent, and the spillover benefit for Round 3 is 62.3 per cent. It also suggests that the spillover benefit associated with the change in the nature of R&D conducted as a result of P³ (through the selection of higher quality and more novel projects) is 13.8 per cent for Rounds 1 and 2 (44.5 per cent minus 30.7 per cent) and 31.6 per cent for Round 3 (62.3 per cent minus 30.7 per cent). These figures are used to present an alternative economic impact analysis in section 4.5.2.

Table 4.11: Spillover benefits of pharmaceuticals R&D

Stage of development	Proportion of total expenditure (excluding 2006-07 data)	Rounds 1 and 2 Spillover benefit ⁽¹⁾	Rounds 3 Spillover benefit ⁽¹⁾	Medicines Australia ⁽¹⁾	Industry Average Spillover benefit ⁽¹⁾
Discovery	11.3%			9%	
Pre-clinical	5.8%	57.5%	80.5%	7%	57.5%
Phase I	42.9%			7%	
Phase II	29%			14%	
Phase III	5.3%	25.0%	35%	42%	25%
Phase IV	0.2%			14%	
Registration	5.5%	n/a	n/a	n/a	n/a
Weighted spillover benefits		44.5%	62.3%		30.7%

Source: Analysis of AusIndustry data

(1) Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, AusInfo, Canberra

Not only does the R&D expenditure under P³ provide spillover benefits, but it also attracts additional foreign direct investment. The induced expenditure by MNCs would also result in a direct increase in economic activity in the Australian economy (the multiplier effect). For those Australian based companies which P³ induced an increase in R&D expenditure, this

multiplier effect would not occur, as it would have simply been a reallocation of Australian resources (rather than a net increase in Australian resources).

To the degree that the Pharmaceuticals Committee of Innovation Australia was able to select projects that were of a higher quality or of a more novel nature, this would result in the spillover benefits from the P³ expenditure having a higher than average rate of return and therefore being of higher quality from the community's perspective.

4.3.6 Summary of findings on effectiveness

The key findings from the evaluation of the effectiveness of P³ in achieving its stated objectives are:

Increase in pharmaceuticals R&D activity in Australia

There has been an increase in R&D expenditure amongst successful participants in the program. Evidence does suggest that firms awarded P³ grants have expanded their R&D expenditure as a result of the program. For instance, successful participants R&D spend has grown at a higher rate than the average for the sector as a whole. Stakeholders have also reported that the program has induced additional investment, including influencing the location of foreign direct investment to Australia. Round 3 appears to have had a higher inducement rate for attracting new R&D expenditure than Rounds 1 and 2.

The number of multinational firms with regional or global R&D operations in Australia

P³ does not appear to have resulted in MNCs establishing new regional or global R&D operations in Australia. However, it is possible that P³ has had a role in all MNCs with regional or global R&D operations in Australia retaining these operations in Australia over the past three years. P³ has positively influenced the level of R&D that MNCs with existing regional or global R&D operations in Australia have undertaken in Australia.

The number and quality of linkages and new collaborations

In relation to collaborations and partnerships, P³ is reported by stakeholders to have had a generally low to moderate impact. Strongest positive impacts were seen in relation to the development of partnerships with universities and medical research institutes. Participants in Round 3 tend to report higher positive impacts relating to collaborations and partnerships from P³ than do participants in Rounds 1 and 2, suggesting that these collaborations and partnerships are viewed as being of higher quality by participants.

The quality of R&D undertaken by participants

Projects awarded funding under P³ tend to be at an earlier stage of development in the pharmaceuticals value chain than the industry average. Therefore P³ has, on average, supported investment in projects that could be expected to deliver higher spillover benefits than the industry average. Feedback from participants in Round 3 suggests that Round 3 has had a 40 per cent greater impact on the level of spillover benefits than did Rounds 1 and 2. The shift towards earlier stage R&D is the best available proxy for the quality of R&D being undertaken.

The level of benefit to the Australian economy of P³

The net economic impact of P³ is discussed in detail separately below.

Encouraging the development of medicines for the global markets

In relation to developing medicines for global markets, stakeholders report P³ as having only a modest impact, with the strongest impact seen to be in assisting participants in gaining new intellectual property. Again, participants in Round 3 tend to report higher positive impacts from P³ relating to the development of medicines for the global market than do participants in Rounds 1 and 2.

Unsurprisingly, given the timeframes for medicines development and the fact that the majority of P³ funding has supported early stage R&D and clinical trials, the impact of the program in advancing the objective of developing medicines for global markets is not rated highly by participants. This is not a criticism of the program as such, but rather may suggest that the true impacts in this area may take several more years to emerge.

Overall summary of the effectiveness of P³

Leaving aside the question of the net economic impact of the program, which is discussed in detail in section 4.5, the program can be assessed as having made some positive contribution in relation to its objectives, with the strongest contribution being made to the attraction of new high quality R&D expenditure. It would also appear that the changes made to the program between the first two Rounds and Round 3 have increased the extent to which the program has made a positive contribution in relation to each of its key objectives.

Across the three rounds of the program, the number of applications has declined but the success rate of applications has increased. This reflects participants gaining progressively greater understanding of the requirement of the program and them better targeting applications to the program objectives. The higher success rate in Round 3 can therefore be interpreted as reflecting an increase in the average quality of application for that round when compared to earlier rounds.

The effectiveness of the program is also considered further in Section 4.5 below, in which an economic impact assessment of P³ is undertaken. The extent to which the program has delivered a net economic benefit or loss is an important factor in considering the overall performance of the program.

4.4 Efficiency of P³

4.4.1 Program administration

There are a number of elements to the administration of P³, including the establishment of the program application process and evaluation guidelines, selection of successful applicants and the ongoing management of the contracts with each of the successful firms.

The program was intended to distribute \$150 million in grants, while the total administration burden is forecast to be \$3.1 million, representing around two per cent of total grants initially expected. At this high level, given the relatively small size of the administration costs versus the total funding distributed (or to be distributed), administration of the project would be seen to be highly efficient and well below the benchmark administration costs of five per cent that were identified in the earlier CIE evaluation.⁶³

However, due to participant underspend and withdrawal, clawback due to funding under other R&D programs, and the redirection of \$10 million to the Mammalian Cell Production Facility⁶⁴, it is now expected that P³ will distribute around \$96.3 million of grants.⁶⁵ Taking

⁶³ CIE reported the following benchmark administrative costs: the R&D Start administration costs were 6 per cent of budget, the R&D Tax Concession estimates of costs range from 2.5 to 3.7 per cent, while the Export Market Development Grant administration costs were 4.3 per cent of the budget.

⁶⁴ DIISR, Mammalian Cell Production Facility, available at www.innovation.gov.au.

this into account, the administration costs are likely to actually represent around 3.2 per cent of funds available for distribution. This is still lower than benchmark administration costs.

The administration costs associated with the PIIP, however, were estimated to be less than one per cent of total program payments.⁶⁶ This suggests that the absolute administration costs of P³ are very similar to that of this past program (around \$3 million). The higher percentage of administration costs as a proportion of total intended disbursements under P³ is due to the lower total grant allocations under the program rather than to higher absolute administration costs. The PIIP distributed around 2.5 times the amount of grants as P³ is now expected to distribute. This highlights that there are certain fixed costs associated with establishing, managing and monitoring a large grant based program, and that economies of scale exist in managing a grants based program.

The Australian National Audit Office completed a performance audit of the management of P³, with the specific objectives of auditing how the department:

- promoted P³ and assessed the applications for funding;
- managed the funding agreements; and
- managed P³'s governance arrangements.

The ANAO report concluded that “overall the Program is being managed effectively by the Department”.⁶⁷ Two recommendations were made on ways in which to improve the administration of the program and these have been accepted by the Department.

Based upon the stakeholder consultations conducted in this evaluation, there is no evidence to suggest that the program has been managed in an inefficient manner. The findings from this evaluation are consistent with that of the ANAO.

The only area that companies felt that there was an inefficient program administration was in the process for substituting projects onto or off of the list of accepted projects eligible for P³ grant funding. The Pharmaceuticals Committee of Innovation Australia considers matters out of session throughout the year, however, the particular design of P³ causes financial constraints that can lead to delayed decisions. It was commented by a small number of firms that there were only a limited number of opportunities each year at which substitute projects were assessed and considered by the Pharmaceuticals Committee of Innovation Australia, and that there were opportunity costs associated with the time taken to approve new projects in some instances. This could be an area of the program which could be streamlined.

4.4.2 Program participants

The program efficiency also needs to be assessed from the point of view of those firms that apply for the grants and those who are successful in their applications and are required to meet ongoing reporting requirements.

⁶⁵ Calculation based upon the forecasts of R&D expenditure into the future as discussed in Section 4.5.1.

⁶⁶ Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, AusInfo, Canberra, p.6.16.

⁶⁷ Australian National Audit Office, 2007, *ANAO Audit Report No.46 2006-07: Management of the Pharmaceuticals Partnerships Program*, p.14.

Efficiency of application process

There is potentially some difference in the cost between small firms and larger firms. Larger firms, particularly MNCs, have to coordinate their responses with their head offices, including gaining an understanding of the firm's global portfolio of projects, and identifying projects which can be conducted in Australia. On the other hand, small Australian based companies will have a relatively simpler task to gather such information and identify future areas for R&D. The need to liaise with corporate headquarters increases the costs to the firm of preparing submissions.

The deadline for applications effectively places a cap on the cost of application. Round 3 survey respondents were not directly asked about the cost of application, however, stakeholder consultations sought to ascertain the effort required in preparing a submission. Most stakeholders felt that the application process was not overly burdensome. One MNC estimated that it took three to four weeks to prepare their application. At \$150 per hour this would equate to cost in the range of \$16,875 to \$22,500 to apply for Round 3.

On the other hand, non-MNCs suggested that the cost of application was quite low, particularly when compared to the amount of funding available, and the relative costs of applying for other R&D programs.

The CIE evaluation estimated total application costs of approximately \$420,000 for Round 1 and \$184,000 for Round 2. This results in a mean cost of approximately \$15,900 per applicant (including both successful and unsuccessful applicants). The Round 3 estimated costs are in line with the CIE estimated costs of Rounds 1 and 2.

Given that the program was trying to target particular R&D activities, detailed information is required in order to evaluate applicants and select successful firms in order to achieve the objectives of the program.

The average size of the P³ grant awarded was \$6.75 million across all three rounds. Therefore, the average cost of applying for P³ funding was less than one per cent of the average grant awarded. This suggests that the application process was efficient.

Another factor influencing the application efficiency of P³ has been the increase in application success rate across the three rounds. As noted in Chapter 3, in Round 1 the success rate was 42.3 per cent, in Round 2 it was 53.8 per cent and in Round 3 it was 75 per cent.

In conjunction with the increase in application success rate, the total number of applications declined significantly across the three rounds, from 26 in Round 1 to 13 in Round 2 to eight in Round 3. This has meant that the number of unsuccessful applications per round has fallen dramatically, from 15 in Round 1, to six in Round 2 and to two in Round 3. The extent of 'wasted' application expenditure can therefore be seen to have declined significantly across the three rounds of the program.

This reflects participants gaining a progressively greater understanding of the requirement of the program and better targeting applications to the program objectives. The higher success rate in Round 3 can therefore be interpreted as reflecting an increase in the average quality of application for that round when compared to earlier rounds.

Efficiency of ongoing compliance requirements

Successful firms are required to prepare quarterly reports, and an audited annual report providing information on their R&D expenditure and an update of progress on individual projects.

Whilst some stakeholders felt that the reporting requirements were overly onerous, it needs to be recognised that P³ was trying to target particular activities, so the reporting requirements needed to monitor these activities.

Most stakeholders were accepting of the reporting requirements and thought that it was a relatively straight forward process.

Only for the annual report, which required external audits of R&D expenditure, would there be any significant costs borne by applicants in meeting their compliance reports. Some firms commented that the systems had been established internally that meant that it essentially became a 'box ticking' exercise.

The survey aimed to capture information regarding the cost of preparing quarterly reports and other compliance requirements (from Round 3 applicants only as Round 1 and 2 applicants were captured as part of the CIE evaluation). Costs of preparing these compliance requirements for Round 3 varied widely, with a range from \$5,000 to \$25,000. However, given that only half of Round 3 participants responded to this question, the calculation of an average compliance cost is likely to be unreliable.

On the other hand, all Round 3 participants responded to the question regarding the number of hours spent on compliance each quarter, with some reporting only 10 to 20 hours, whilst others reported 100 hours per quarter. The average (mean) hours spent on meeting reporting requirements was 43 hours per quarter, which would equate to 172 per annum. This is in line with the CIE evaluation which found average hours spent on reporting amongst Round 1 and 2 participants was 143 per annum.

Whilst one MNC reported having to spend up to 100 hours per quarter on compliance, stakeholder comments from interviews suggested that most companies spent less than half of this amount of time. However, they noted that they did have to present audit information which added some additional cost over and above company hours. Compliance costs also depended upon the size of the grant received and the number of approved projects.

Overall, the compliance costs are likely to be in proportion to the number of individual projects which have received funding. Therefore, it would be expected that there is a correlation between compliance costs and the size of the grant – higher compliance costs would be associated with larger grants.

If labour is costed at \$150 per hour (in keeping with the CIE evaluation assumption), and total average annual compliance hours for Round 3 are 172 hours, average compliance costs would be \$25,800 per annum excluding provision of audit information. This is compared to the average compliance costs of \$22,000 reported for Rounds 1 and 2 by CIE.

It should be noted here that total compliance costs as a proportion of grants will be considerably lower for Round 3 when compared to Rounds 1 and 2 as the costs of compliance need to be born for two rather than five years. Hence, for an average grant of \$6.75 million, the compliance costs as a percentage of the grant would be 0.77 per cent for Round 3, but 1.63 per cent for Rounds 1 and 2 for a grant of the same size.

Whilst as a stand-alone program the administrative burden was relatively small on successful participants, one company suggested aligning the reporting format with that of the R&D Tax Concession reporting to reduce the duplication amongst the various programs companies can access. While this would contribute to an overall more efficient interface between government and private sector funding recipients, it may not be practical given the differences in definitions and processes between the programs.

4.4.3 Summary of findings on efficiency

The review team agrees with the ANAO's finding that P³ has been managed in an efficient manner. This holds in relation to both the efficiency of the application process and the efficiency of ongoing compliance processes.

Efficiency in relation to program administration costs, application costs and compliance costs all seem to be well within the acceptable performance range for Government programs of this type.

4.5 Net public and economic impact of P³

Before considering the net public and economic impact assessment conducted in this study, it is important to place in context what benefits from P³ are captured in this form of analysis and what potential benefits are not captured in the analysis. Pharmaceuticals research generates a range of impacts that can be clearly captured in the 'market' sphere – it can directly lead to productivity gains, increased production, exports and employment. Not all of these benefits in the market sphere will be captured by the private entity undertaking the research, with some 'spilling over' to deliver a wider economic benefit of the community. The economic impact analysis of P³ in this study is focused only on capturing these 'market' sector privately and publicly captured economic benefits resulting from P³.

It must be openly acknowledged that this represents only a partial accounting of the total beneficial impacts that may be associated with the pharmaceutical research supported by P³. Research, in addition to generating impacts in the market sector over the short to medium term, can also generate a range of longer term beneficial impacts to society. For instance, if pharmaceuticals research leads to better treatment of illness ten or fifteen years from now, this would confer significant economic and non-economic benefits to the community. Better health outcomes will increase labour force participation and productivity, things that fall within the 'market' sphere, but will also have a profound 'non-market' value, namely, the value we place on living longer and healthier lives. While there are attempts now being made in economic theory, such as through contingent choice valuation methodologies, to place an 'economic' value on profoundly non-market goods such as the personal value we place on life and health, such approaches are beyond the scope of this study.

The public and economic impact assessment of P³ in this study should therefore be viewed for what it is, an attempt to capture the costs and benefits of P³ over a limited time horizon where only impacts clearly within the 'market' sphere are factored into the calculations. As such, it is necessarily only a partial accounting for the potential long terms societal costs and benefits that may result from P³.

Methodologies applied in assessing the economic impact of P³

To inform an overall assessment of the appropriateness, effectiveness and efficiency of P³, it is important to develop an estimation of the economic impact of the program on the Australian economy.

In order to provide results that are comparable to those of the CIE 2006 evaluation of P³, the same approach to estimating aggregate impacts on the economy is then taken, incorporating the findings from Round 3 (as presented in preceding sections) of the program where necessary.

An alternative analysis is then conducted that utilises updated information and additional analysis to refine assumptions made within the CIE analysis. A nominal discount rate of five per cent per annum is used to discount all values back to June 2004 values (so that they are directly comparable to the estimates in the CIE 2006 evaluation).

Finally, to provide a further level of analysis and comparison, the methodology used by the Productivity Commission in its 2003 assessment of the R&D component of the PIIP is applied to P³ performance data.

4.5.1 Economic impact when using CIE assumptions

Projections of expenditure

Projections of the future R&D expenditure by successful firms are forecast in order to determine the overall economic impact of P³. The projections use the actual audited R&D expenditure over the first three years of P³ (2004-05 through to the end of 2006-07 financial year). The final two years of expenditure information is forecast using the following assumptions:

- Forecast expenditure for firms successful in Rounds 1 and 2 is based upon individual companies' past performance. For instance, if a company has shown a record of an underspend of 10 per cent, then it is assumed that it will continue to underspend by 10 per cent over the final two years of the program.
- For firms successful in Round 3, the observed total underspend relative to initial forecasts of firms successful in Rounds 1 and 2 adjusting for withdrawals (6.6 per cent underspend) is adopted.
- Actual expenditure for years 2004-05, 2005-06 and 2006-07 is used.

Table 4.12: Induced R&D expenditure associated with P³ (\$ million)

Year	Baseline R&D expenditure	Additional R&D expenditure	Induced R&D expenditure from Foreign Direct Investment	Total Induced R&D expenditure
2003-04				
2004-05	161.9	16.8	0.8	6.7
2005-06	209.8	59.8	2.9	23.9
2006-07	154.3	56.3	2.7	22.5
2007-08	207.1	92.7	4.5	37.1
2008-09	207.1	90.0	4.3	36.0
NPV	810.4	265.6	12.8	106.3

Source: Deloitte analysis using CIE assumptions

Quantified benefits of P³

Quantified benefits to the Australian economy as a result of P³ are:

- multiplier benefits from increased foreign direct investment; and
- spillover benefits associated with:
 - attraction of foreign direct investment;

- investment of Australian funds that would otherwise not have been invested in R&D; and
- additional R&D under P³ that attracts spillovers at a higher rate than the industry average.

Attraction of funds from overseas that, in the absence of P³, would not have been invested in Australian based R&D, has direct expenditure effects in the Australian economy. The additional R&D expenditure, as it flows through the economy, results in a multiplier effect, that is the total impact on the economy, and is typically measured as a multiple of the level of additional expenditure. The CIE evaluation used a multiplier effect of 1.3 as its expected value, with a lower and upper bound of 1.0 and 1.5 respectively. CIE estimated that an expected 12 per cent of total induced expenditure was from foreign direct investment.

The CIE evaluation assumed that the expected value of the spillover benefits associated with the induced expenditure were equal to 61 per cent. The full spillover benefit rate is applied to the R&D associated with the inducement of foreign direct investment that otherwise would not have come to Australia.

Expenditure that has been induced from within Australia that would not have otherwise been invested in R&D also receives the full spillover benefit rate of 61 per cent.

Based on its analysis of induced expenditure, the CIE evaluation assumed that of the total additional R&D expenditure above the baseline, that an expected 40 per cent of this total had been induced by P³.

The competitive process of selecting and awarding grants is able to select projects that are either of a higher quality or more novel. Therefore, expenditure that would have been invested in R&D in the absence of P³, results in a higher level of spillover benefits as expenditure in pharmaceuticals R&D under P³. The CIE evaluation assumed that spillover benefits associated with the change in the nature of R&D were valued at 10 per cent.

Table 4.13: Benefits associated with P³ (\$ million)

Year	Multiplier benefit	Spillovers from induced R&D	Spillovers from change in R&D nature	Total Public Benefit
2003-04				
2004-05	1.0	4.1	1.0	6.2
2005-06	3.7	14.6	3.6	21.9
2006-07	3.5	13.7	3.4	20.6
2007-08	5.8	22.6	5.6	34.0
2008-09	5.6	22.0	5.4	33.0
NPV total	16.6	64.8	15.9	97.3

Source: Deloitte analysis using CIE assumptions

Quantified costs of P³

Costs associated with P³ are incurred by both the Government (public costs) and the private sector firms (private costs). Public costs associated with P³ are:

- cost of program administration;
- P³ grant payments; and
- deadweight loss associated with raising funds (through taxation).

Costs of program administration were provided by AusIndustry to CIE as part of the first P³ evaluation. The actual grant payments made through P³ to firms is based upon the assumption that due to the presence of other Government R&D programs, such as the R&D Tax Concessions, some clawback provisions occur. CIE assumed that the actual P³ payments are 3 percentage points lower than the grant rate (i.e. there is an effective taxable grant payment of 27 per cent for Rounds 1 and 2. Round 3 would have a taxable grant payment rate of 47 per cent).

In order to make the grant payments, there is a need for government to collect tax from the public – taxes are higher with P³ than without. However, through taxation there are reductions in Gross Domestic Product and consumption levels – a deadweight loss is generated. Some of the reasons for this deadweight loss are that:

- raising of taxation acts to reduce incentives for private sector investment;
- the transfer of private consumption to public consumption acts overall to reduce the capital intensity of Australia's industry structure;
- increasing taxation reduces the level of disposable income, some of which would have been saved. A reduction in the savings rate leads to a decrease in the current account balance via a decline in the trade account balance; and
- collecting and spending taxation revenue carries non-productive transaction costs.

The CIE evaluation assumed that the deadweight loss from the taxation required to raise the funds for P³ was equal to 30 per cent of the total costs of the program (including administration and grant payments).

The cost associated with actually increasing R&D expenditure is equivalent to the induced R&D expenditure, i.e. it is net of the increase that would have occurred without P³.

Table 4.14: Costs associated with P³ (\$ million)

Year	P ³ Grants	Administration Cost	Taxation Deadweight Loss	Total Public Cost
2003-04		0.7	0.2	0.9
2004-05	5.1	0.4	1.7	7.2
2005-06	11.9	0.5	3.7	16.1
2006-07	21.1	0.7	6.5	28.3
2007-08	28.6	0.4	8.7	37.7
2008-09	29.6	0.4	9.0	39.0
NPV total	80.6	2.8	25.0	108.4

Source: Deloitte analysis using CIE assumptions

The private cost associated with P³ involves the costs of program application and ongoing compliance costs.

Expected economic impact

Based upon the midpoint CIE assumptions outlined above, the expected returns from P³ to the public sector are shown in Table 4.15. Using the assumptions of the CIE evaluation, and incorporating the additional information for Round 3 firms, the expected public benefit from P³ would be \$97.3 million (in 2003-04 net present value terms). This benefit is associated with the multiplier and spillover benefits associated with the additional R&D expenditure under P³. However, the public costs of program administration, raising funds (taxation deadweight loss) and the grant payments total \$108.4 million and result in an expected net public loss of \$11.1 million. However, as is highlighted later by a sensitivity analysis of this result, this figure should be interpreted as indicating that P³ is likely to have been close to neutral in terms of public costs and benefits.

Table 4.15: Expected public return associated with P³ (\$ million)

Year	Total public benefit	Total public cost	Net public benefit
2003-04		0.9	-0.9
2004-05	6.2	7.2	-1.0
2005-06	21.9	16.1	5.8
2006-07	20.6	28.3	-7.7
2007-08	34.0	37.7	-3.7
2008-09	33.0	39.0	-6.0
NPV total	97.3	108.4	-11.1

Source: Deloitte analysis using CIE assumptions

Within the CIE 2006 evaluation, it was concluded that P³ was expected to result in a small net public benefit. When the same assumptions are used, and Round 3 is incorporated into the analysis (as shown in Table 4.15), P³ is expected to result in a small net public loss. The incorporation of Round 3 into the analysis results in a net program loss because of the higher grant rate available under Round 3. Instead of each company returning a small net public benefit from P³ funding on average, as found in the CIE analysis, the higher grant rate is essentially assumed to induce additional R&D expenditure at the same rate per dollar of additional R&D expenditure, but it comes at a higher cost because of the increase in the grant rate from 30 cents to 50 cents. This dynamic means that the additional cost results in a net public loss from the program. However, as has been discussed in this report, it is not in fact likely that the inducement rate or spillover rate for Round 3 would be the same as was estimated by CIE for Rounds 1 and 2.

Table 4.16 presents the separate public benefits and costs calculated for Rounds 1 and 2 and for Round 3 using the CIE assumptions.

Table 4.16: Expected public return associated with P³ (\$ million)

Year	Total public benefit		Total public cost		Net public benefit	
	Rounds 1 and 2	Round 3	Rounds 1 and 2	Round 3	Rounds 1 and 2	Round 3
2003-04	0	0	0.9	0	-0.9	0
2004-05	6.2	0	7.2	0	-1.0	0
2005-06	21.9	0	16.1	0	5.8	0
2006-07	20.6	0	28.3	0	-7.7	0
2007-08	27.4	6.5	26.8	10.9	0.6	-4.4
2008-09	23.3	9.7	22.9	16.1	0.5	-6.4
NPV total	84.4	12.9	86.8	21.6	-2.5	-8.6

Source: Deloitte analysis using CIE assumptions

Expected private benefit

The additional R&D expenditure under P³ is expected to result in companies developing new products, and earning a return on their investments. Based upon survey responses, the CIE assumed a direct private return on R&D of 20 per cent (note that in practice only a small number of total projects funded under P³ would be expected to actually result in a return on investment but these successful projects would typically deliver very high individual returns). Given the time taken for a new product to be developed, it is assumed that there is a ten year lag between the R&D expenditure and the return on investment.

The costs of application and compliance and the net additional investment in R&D all form part of the assessment of private benefits. CIE assumed a cost of compliance of nine per cent. This estimate is higher than the range we have estimated based on feedback from stakeholders consulted in this review.

Using these assumptions, CIE calculated that the net private benefits would be an expected net present value of approximately \$113 million. It was not clear from the CIE evaluation report how the private benefits were calculated, which meant that the analysis could not be replicated.

Although P³ delivered a marginal public benefit, there are clear private benefits flowing from participation in the program. However, approximately 36 per cent of the awarded grants were offered to international firms.⁶⁸ Of those firms that remain in the program, 44 per cent of offered grants fall under foreign owned companies. This indicates that approximately half to two-thirds of the net private benefits would be expected to flow back into the Australian economy through shareholders.

⁶⁸ Note that in calculating this figure, Mayne Pharma (Australian owned) received an offer, which has been included in the Australian total, but was subsequently taken over by Hospira (American owned).

Sensitivity analysis

As noted throughout the analysis there is considerable uncertainty associated with some of the parameters in the economic analysis. Therefore, a sensitivity analysis is conducted using lower and upper bounds for various parameters. These, along with the expected values used above, are summarised in Table 4.17.

Table 4.17: Upper and lower bound assumptions used in conducting a sensitivity analysis

Parameter	ROUNDS 1 and 2			ROUND 3		
	Lower bound	Expected value	Upper bound	Lower bound	Expected value	Upper bound
Inducement	25%	40%	54%	25%	40%	54%
Net additional FDI	7%	12%	16%	7%	12%	16%
Multiplier effect	1	1.3	1.5	1	1.3	1.5
Spillover benefits	25%	61%	90%	25%	61%	90%
Spillover benefits from change in nature	0%	10%	20%	0%	10%	20%
Share of funding increase covered by P ³		27%			47%	
Deadweight loss	20%	30%	40%	20%	30%	40%
Cost compliance		9%			9%	
Discount rate		5%			5%	

Source: Deloitte analysis using CIE assumptions

Based on the CIE modelling approach, the expected value of the program, based on parameters near the mid-point of the parameter ranges, is for a net public loss of \$11.1 million. However, using the upper and lower bound estimates for the assumptions underlying the economic model, the sensitivity analysis shows that, based upon the CIE modelling approach, P³ could potentially result in a net public loss of \$95.5 million, but could also deliver a net public benefit of up to \$87.9 million. However, it is unlikely that either of the extremes would eventuate, as it would require all parameters (a number of which are not connected) to be at the same end of the plausible range for these parameters.

Table 4.18: Sensitivity analysis (\$ million)

	Lower bound	Expected value	Upper bound
Multiplier effects	4.6	16.6	34.4
Spillovers – additional R&D	16.6	64.8	129.1
Spillovers – change in nature	0.0	15.9	24.4
TOTAL PUBLIC BENEFIT	21.3	97.3	188.0
Grant payments	80.6	80.6	80.6
Administration	2.8	2.8	2.8
Deadweight loss from taxation	33.4	25.0	16.7
TOTAL PUBLIC COST	116.7	108.4	100.1
NET PUBLIC BENEFIT	-95.5	-11.1	87.9
BENEFIT COST RATIO	0.18	0.90	1.88

Source: Deloitte analysis using CIE assumptions

Given the wide range of potential results across the lower to upper bound estimates, the expected value result, when using the CIE assumptions, should be interpreted as essentially pointing to P³ being approximately neutral from a public cost/public benefit perspective.

4.5.2 Alternative modelling scenario with alterations to CIE assumptions

There is comparatively more information available about P³ now than when the CIE evaluation was completed in 2006. Therefore, it is timely to revisit some of the assumptions that were used in the 2006 economic impact assessment (and used in the previous sub-section to estimate the economic impact of incorporating Round 3 into the analysis).

As discussed in Section 4.3.4, some changes to the inducement rates associated with Rounds 1, 2 and 3 may be warranted. While inducement rates are very difficult to determine with accuracy, we believe a more reasonable set of lower, expected and upper bound inducement rates are 13, 28 and 43 per cent for Rounds 1 and 2 and 21, 47 and 72 per cent for Round 3.

As discussed in Section 4.3.5, some changes to the estimation of spillover benefits associated with Rounds 1, 2 and 3 may also be warranted. Using the information in Table 4.10, it is possible to allocate specific spillover benefits to the various stages along the pharmaceuticals value chain. The analysis suggested that the industry average spillover benefit is 30.7 per cent, whilst for Rounds 1 and 2 of P³ the expected spillover benefit would be 44.5 per cent, and the expected spillover benefit for Round 3 is 62.3 per cent. It also suggests that the spillover benefit associated with the change in the nature of R&D conducted as a result of P³ (through the selection of higher quality and more novel projects) is 13.8 per cent for Rounds 1 and 2 and 31.6 per cent for Round 3.

A final change made to the CIE assumptions is in relation to the extent of dead weight loss associated with taxation. Based upon the results from a broad range of general equilibrium modelling that the project team is familiar with and on recent commentary on this issue by senior Productivity Commission staff⁶⁹, we believe that 30 per cent dead weight loss rather than 40 per cent should be used as the upper bound and 25 per cent rather than 30 per cent should be used as the expected level of dead weight loss.

Table 4.19: Upper and lower bound assumptions used in conducting a sensitivity analysis

Parameter	ROUNDS 1 and 2			ROUND 3		
	Lower bound	Expected value	Upper bound	Lower bound	Expected value	Upper bound
Inducement	13%	28%	43%	21%	47%	72%
Net additional FDI	7%	12%	16%	7%	12%	16%
Multiplier effect	1	1.3	1.5	1	1.3	1.5
Spillover benefits	25%	44.5%	75%	25%	62.3%	75%
Spillover benefits from change in nature	0%	14%	44%	0%	32%	44%
Share of funding increase covered by P ³		27%			47%	
Deadweight loss	30%	25%	20%	30%	25%	20%
Cost compliance		5%			2%	
Discount rate		5%			5%	

Source: Deloitte analysis

Tables 4.20 to 4.23 set out for the alternative modelling scenario the expected:

- induced R&D expenditure associated with P³;
- benefits associated with P³;
- costs associated with P³; and
- expected public return associated with P³

⁶⁹ Dr Ralph Lattimore, Assistant Commissioner, Productivity Commission, *Presentation to CCST Group*, Canberra, 14th March 2007. In this presentation a 20 per cent dead weight loss was pointed to as a reasonable ‘rule of thumb’ when assessing the ‘cost’ of funding government programs.

Table 4.20: Induced R&D expenditure associated with P³ (\$ million)

Year	Baseline R&D expenditure	Additional R&D expenditure	Induced R&D expenditure from Foreign Direct Investment	Total Induced R&D expenditure
2003-04				
2004-05	161.9	16.8	0.6	4.7
2005-06	209.8	59.8	2.0	16.7
2006-07	154.3	56.3	1.9	15.8
2007-08	207.1	92.7	3.5	29.3
2008-09	207.1	90.0	3.6	30.1
NPV	810.4	265.6	9.7	80.9

Source: Deloitte analysis using alternative case assumptions

Table 4.21: Benefits associated with P³ (\$ million)

Year	Multiplier benefit	Spillovers from induced R&D	Spillovers from change in R&D nature	Total Public Benefit
2003-04				
2004-05	0.7	2.1	1.7	4.5
2005-06	2.6	7.4	5.9	16.0
2006-07	2.5	7.0	5.6	15.1
2007-08	4.6	14.5	10.5	29.5
2008-09	4.7	15.6	10.8	31.0
NPV total	12.6	38.9	28.9	80.4

Source: Deloitte analysis using alternative case assumptions

Table 4.22: Costs associated with P³ (\$ million)

Year	P ³ Grants	Administration Cost	Taxation Deadweight Loss	Total Public Cost
2003-04		0.7	0.2	0.9
2004-05	5.1	0.4	1.4	6.9
2005-06	11.9	0.5	3.1	15.5
2006-07	21.1	0.7	5.5	27.3
2007-08	28.6	0.4	7.3	36.3
2008-09	29.6	0.4	7.5	37.5
NPV total	80.6	2.8	20.8	104.2

Source: Deloitte analysis using alternative case assumptions

Table 4.23: Expected public return associated with P³ (\$ million)

Year	Total public benefit	Total public cost	Net public benefit
2003-04		0.9	-0.9
2004-05	4.5	6.9	-2.4
2005-06	16.0	15.5	0.5
2006-07	15.1	27.3	-12.2
2007-08	29.5	36.3	-5.7
2008-09	31.0	37.5	-4.9
NPV total	80.4	104.2	-23.8

Source: Deloitte analysis using alternative case assumptions

Table 4.24 summarises the expected economic impacts of P³, including upper and lower bound estimates based on the sensitivity testing ranges set out in Table 4.19.

Table 4.24: Alternative economic impact assessment (\$ million)

	Lower bound	Expected value	Upper bound
Multiplier effects	2.6	12.6	29.9
Spillovers – additional R&D	9.3	38.9	93.4
Spillovers – change in nature	0.0	28.9	62.5
TOTAL PUBLIC BENEFIT	12.0	80.4	185.8
Grant payments	80.6	80.6	80.6
Administration	2.8	2.8	2.8
Deadweight loss from taxation	25.0	20.8	16.7
TOTAL PUBLIC COST	108.4	104.2	100.1
NET PUBLIC BENEFIT	-96.4	-23.8	85.7
BENEFIT COST RATIO	0.11	0.77	1.86

Source: Deloitte analysis

When the above changes are made to the CIE assumptions, and more recent data relating to participant performance is used, the estimated economic impact of P³ ranges from a net public loss of \$96.4 million, to a net public benefit of \$85.7 million. The expected value derived is a net public loss of \$23.8 million.

This range of results again highlights that there is significant uncertainty around the actual impact that P³ is expected to have on the economy and that it cannot be definitively determined whether P³ will result in a net public cost or benefit. However, given the results, and when only quantifiable economic impacts are considered, under this methodology the result suggests P³ is more likely that P³ will result in an overall public cost than that it has generated a net public benefit.

It is important to note that when Rounds 1 and 2 are considered separately to Round 3, the economic impact analysis suggests that the changes made to the program for Round 3 have improved its economic impact profile.

It should also be stressed that the economic benefits able to be captured in this study are limited to clearly ‘market’ sphere benefits that are expected to be delivered over the short to medium term.

Table 4.25 presents the separate public benefits and costs calculated for Rounds 1 and 2 and for Round 3 using the revised assumptions.

Table 4.25: Expected public return associated with P³ (\$ million)

Year	Total public benefit		Total public cost		Net public benefit	
	Rounds 1 and 2	Round 3	Rounds 1 and 2	Round 3	Rounds 1 and 2	Round 3
2003-04	0	0	0.9	0	-0.9	0
2004-05	4.5	0	6.9	0	-2.4	0
2005-06	16.0	0	15.5	0	0.5	0
2006-07	15.1	0	27.3	0	-12.2	0
2007-08	20.0	9.5	25.8	10.5	-5.7	-1.0
2008-09	17.0	14.0	22.0	15.5	-4.9	-1.5
NPV total	61.6	18.8	83.5	20.8	-21.8	-2.0

Source: Deloitte analysis using alternative assumptions

As Table 4.25 indicates, the increase in inducement rates and spillover rates for Round 3 have been sufficient to improve the net economic impact profile of Round 3 when compared to earlier rounds. These improvements have more than offset the higher relative cost of Round 3 (due to the higher grant rate). Under the alternative modelling scenario, the benefit cost ratio of P³ is shown to have improved from 0.74 for Rounds 1 and 2 to 0.90 for Round 3.

Expected Private Benefit

The CIE analysis assumed a cost of compliance equal to nine per cent of the grant received. Based upon the stakeholder consultations, most firms felt that the quarterly and annual reporting requirements were neither overly onerous nor costly. It is considered that the 9 per cent assumption, which would equate to a cost of \$180,000 per annum for firms that received a \$10 million grant over five years (and even higher annual costs for firms in Round 2 and Round 3), is an overly high estimate.

Based on analysis of stakeholder feedback, more appropriate estimates for compliance costs would be in the order of five per cent for Rounds 1 and 2 and two per cent for Round 3.

This change in assumption around compliance costs would result in a slight increase in the private benefits when compared to the \$113 million estimated by CIE. However, as we are unable to replicate the CIE calculations in relation to private benefits we can not provide a point estimate for private benefits.

4.5.3 Alternative modelling scenario based on Productivity Commission approach to the PIIP evaluation

In its 2003 review of the PIIP, the Productivity Commission undertook an economic cost-benefit assessment of the PIIP. The approach that the Commission used was to calculate the net benefit of the PIIP using the following formula:

Net Benefit = Margin + Health + Spillover - Leak - Financing – Admin – Compliance + Other

Where,

MARGIN is the difference, if any, between the private post PIIP rate of return on induced activity compared with alternative uses of those resources. It has been calculated as $m \cdot (IVA + IRD)$ where m represents any difference in the rates of return, IVA is induced value added and IRD is induced R&D expenditure.

HEALTH is the incremental health benefit from any drugs listed only because the PIIP subsidy allows the notional price to meet a company's global floor price.

SPILOVERS are benefits from pharmaceutical activity accruing to third parties (such as R&D collaborators, suppliers and other pharmaceutical firms) that do not pay for these.

LEAK is any pure transfer of PIIP payments to foreign shareholders. To the extent that some PIIP payments to foreign owned firms do not induce activity there is a loss to Australia. LEAK can be calculated as $PIIPF \cdot (1 - \tau_f) \cdot (1 - i)$ where PIIPF is the actual payments to foreign owned firms, τ_f is the rate of Australian company tax for foreign owned firms, and i is the inducement rate by foreign owned firms.

FINANCING is the adverse efficiency effect arising from the distortionary impacts of raising funds for the PIIP. Since PIIP payments are assessable income, the net amount of public funds needed is less than the notional budget of the program. FINANCING is calculated as $m_{eb} \cdot [PIIPF(1 - \tau_f) + PIIPD(1 - \tau_d)]$ where m_{eb} is the marginal excess burden per dollar of public revenue, PIIPD is the actual payments to domestic owned firms, and τ_d is the effective tax rate for domestic owned firms.

ADMIN is the government administrative cost of the program, covering both the one-off costs of establishing the scheme (such as the selection process) and the ongoing costs of monitoring, payment and management of the program.

COMPLIANCE measures the business compliance costs, covering both the one-off application costs for both successful and unsuccessful applicants and the ongoing reporting costs for participants.

OTHER represents other benefits and costs not identified above. One such potential benefit is any inducement effect of the PIIP on expenditures such as health education programs and sponsorship, as part of Broad Activity Commitments.

Source: Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, AusInfo, Canberra, p.6.5

The Commission then assessed that in the case of PIIP, values for Margin benefit were in fact zero for the purposes of evaluating the PIIP, thereby simplifying the formula to:

Net Benefit = Health + Spillover + Other – Leak – Financing – Admin – Compliance

The Productivity Commission then made the following conclusions regarding the appropriate treatment of the drivers of each variable in this formula:⁷⁰

⁷⁰ Productivity Commission, 2003, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, AusInfo, Canberra, p.6.20

- In relation to Health, they found that the incremental health benefit of drugs listed only because of PIIP subsidy was \$7.5 million. PIIP funds were predominantly provided on the basis of production value added activity rather than R&D activity, with only 20 per cent of PIIP payments driven by R&D activity.⁷¹ It may therefore be reasonable to assume that the Health benefits attributable to the R&D component of the PIIP under the Commission's methodology would be in the order of \$1.5 million, which equates to approximately \$56,000 per \$ million of R&D related payments made under the PIIP.
- The Commission used an assumed inducement rate for R&D of 60 per cent under the PIIP.
- The Commission applied in their calculations a spillover social rate of return on induced basic and pre-clinical R&D of 57.5 per cent and a spillover social rate of return on induced clinical and process R&D of 25 per cent.
- The effective company tax rate (domestic) was specified as 20 per cent and the company tax rate (foreign) was specified as 30 per cent.
- The marginal social cost assumed per dollar of public funds distributed under the PIIP was assumed to be 27.5 per cent.
- In relation to Other benefits, induced commitments for health education programs and sponsorship of \$1.75 million were estimated. Again, as with Health benefits, if this is attributed to the R&D component of the PIIP in the same ratio of R&D funding to total PIIP funding, the Other benefits attributable to the R&D component of the PIIP would be approximately \$350,000, which equates to \$13,000 per \$million of R&D driven funding provided under the PIIP.
- Administration and compliance costs (one off and recurrent) were calculated based on consideration of the specific situation observed for the PIIP.

The above calculation methodology and key assumptions can be applied to the specific details of P³ to allow for a comparative estimation of the net benefit of P³.

For P³, the calculation of each element of the Net Benefits formula (in nominal rather than constant dollar terms as per the Productivity Commission's approach in the PIIP evaluation and using the Productivity Commission's methodology and assumptions surrounding inducement rates, spillover rates and financing costs) is set out in Table 4.26.

The application of the methodology (and its assumptions regarding inducement rates, spillover rates and financing costs) used by the Productivity Commission in its review of the PIIP to the specifics of the P³ results in an estimated Net Benefit for P³ of positive \$9.8 million.

⁷¹ This is the ratio identified by the Productivity Commission based on the first three years of the program. See *Ibid*, p.6.20. However at the conclusion of the program, the proportion of total PIIP payments for R&D activity was 25.8 per cent.

Table 4.26: Calculation for P³ of each element of the Productivity Commission net benefit formula

Formula element	Assumptions	P3 specific data	Calculation
Health	\$56,000 of benefits per \$million of P ³ grant payments	Total P ³ net grant payments of \$96.3 million	Health benefits = 96.3 x \$56,000 = \$5.4m
Spillover	Inducement rate of 60% Spillover rate of 57.5% for pre-clinical R&D and 25% for all clinical and other R&D	Total additional R&D activity of \$265.6million.	Spillover benefits = [\$45.2m x 0.6 x 0.575] + [\$220.4m x 0.6 x 0.25] = \$48.6m
		Total additional discovery and pre-clinical R&D of \$45.2 million Total additional clinical and other R&D of \$220.4 million	
Other	\$13,000 per \$million of P ³ grant payments	Total P ³ net grant payments of \$96.3 million	Other benefits = 96.3 x \$13,000 = \$1.3m
Leak	Inducement rate of 60% Taxation rate for foreign firms of 30%	Total P ³ net grant payments to foreign owned firms of \$39.9 million	Leak costs = \$39.9m x 0.7 x 0.4 = \$11.2m
Financing	Financing costs for grants are equal to 27.5% of grant payments	Total P ³ net grant payments and administration costs of \$99.4 million	Financing costs = \$99.4m x 0.275 = \$27.3m
Admin	Actual program data is appropriate	Total P ³ administration costs \$3.1 million	Admin costs = \$3.1m
Compliance	Actual program data is appropriate	Total P ³ compliance costs of \$3.9 million	Compliance costs = \$3.9m
Net Benefit			Net Benefit = \$5.4m + \$48.6m + \$1.3m - \$11.2m - \$27.3m - \$3.1m - \$3.9m = + \$9.8m

Source: Deloitte analysis applying Productivity Commission PIIP evaluation assumptions to P³ data

If the methodology of the Productivity Commission is matched to the CIE assumptions regarding inducement rates, spillover rates and financing costs, an estimated Net Benefit for P³ is negative \$21.0 million (Table 4.27).

Table 4.27: Calculation for P³ of each element of the Productivity Commission net benefit formula

Formula element	Assumptions	P3 specific data	Calculation
Health	\$56,000 of benefits per \$million of P ³ grant payments	Total P ³ net grant payments of \$96.3 million	Health benefits = 96.3 x \$56,000 = \$5.4m
Spillover	Inducement rate of 40% Spillover rate of 61% for all R&D	Total additional R&D activity of \$265.6 million. Total additional R&D of \$106.2 million	Spillover benefits = [\$106.2m x 0.4 x 0.61] = \$25.9m
Other	\$13,000 per \$million of P ³ grant payments	Total P ³ net grant payments of \$96.3 million	Other benefits = 96.3 x \$13,000 = \$1.3m
Leak	Inducement rate of 40% Taxation rate for foreign firms of 30%	Total P ³ net grant payments to foreign owned firms of \$39.9 million	Leak costs = \$39.9m x 0.7 x 0.6 = \$16.8m
Financing	Financing costs for grants are equal to 30% of grant payments	Total P ³ net grant payments and administration costs of \$99.4 million	Financing costs = \$99.4m x 0.3 = \$29.8m
Admin	Actual program data is appropriate	Total P ³ administration costs \$3.1 million	Admin costs = \$3.1m
Compliance	Actual program data is appropriate	Total P ³ compliance costs of \$3.9 million	Compliance costs = \$3.9m
Net Benefit			Net Benefit = \$5.4m + \$25.9m + \$1.3m - \$16.8m - \$29.8m - \$3.1m - \$3.9m = - \$21.0m

Source: Deloitte analysis applying Productivity Commission PIIP evaluation methodology to P³ data using CIE assumptions

If the methodology of the Productivity Commission is matched to the ‘alternative’ Deloitte assumptions regarding inducement rates, spillover rates and financing costs an estimated Net Benefit for P³ of negative \$4.7 million (Table 4.28).

Table 4.28: Calculation for P³ of each element of the Productivity Commission net benefit formula

Formula element	Assumptions	P3 specific data	Calculation
Health	\$56,000 of benefits per \$million of P ³ grant payments	Total P ³ net grant payments of \$96.3 million	Health benefits = 96.3 x \$56,000 = \$5.4m
Spillover	Inducement rate of 28% for Rounds 1 & 2 and 47% for Round 3 Average spillover rate of 45% for for Rounds 1 & 2 and 62% for Round 3	Total additional R&D activity of \$265.6 million. Total additional R&D of \$64.5 million for Rounds 1&2 and \$16.6 million for Round 3	Spillover benefits = [\$64.5m x 0.45] + [\$16.6m x 0.62] = \$39.3m
Other	\$13,000 per \$million of P ³ grant payments	Total P ³ net grant payments of \$96.3 million	Other benefits = 96.3 x \$13,000 = \$1.3m
Leak	Inducement rate of rate of 28% for Rounds 1 & 2 and 47% for Round 3 Taxation rate for foreign firms of 30%	Total P ³ net grant payments to foreign owned firms of \$30.2 million for Rounds 1&2 and \$9.7 million for Round 3	Leak costs = [\$30.2m x 0.7 x 0.72] + [\$9.7m x 0.7 x 0.53] = \$18.8m
Financing	Financing costs for grants are equal to 25% of grant payments	Total P ³ net grant payments and administration costs of \$99.4 million	Financing costs = \$99.4m x 0.25 = \$24.9m
Admin	Actual program data is appropriate	Total P ³ administration costs \$3.1 million	Admin costs = \$3.1m
Compliance	Actual program data is appropriate	Total P ³ compliance costs of \$3.9 million	Compliance costs = \$3.9m
Net Benefit			Net Benefit = \$5.4m + \$39.3m + \$1.3m - \$18.8m - \$24.9m - \$3.1m - \$3.9m = - \$4.7m

Source: Deloitte analysis applying Productivity Commission PIIP evaluation methodology to P³ data using Deloitte assumptions

4.5.4 Summary of findings on net public and economic impact

Based on the three different modes of impact analysis (detailed in Sections 4.5.1, 4.5.2 and 4.5.3), a diversity of results are produced:

- When the assumptions used by CIE are maintained and net public impacts calculated using current available performance data, the net public cost/benefit of P³ is calculated to be between minus \$95.9 million and positive \$87.9 million. The ‘expected’ result is minus \$11.1 million. Given the scale of the program and the uncertainties surrounding the assumptions, this should be interpreted as suggesting

that the expected public cost/benefit of P³ is close to neutral when the CIE assumptions are used.

- When some of the assumptions used by CIE are altered to reflect more recently available information and net economic impacts are calculated using currently available performance data, the net public cost/benefit of P³ is calculated to be between minus \$96.4 million and positive \$85.7 million. The ‘expected’ result is minus \$23.8 million. Given the scale of the program and the uncertainties surrounding the assumptions, this should be interpreted as suggesting that under this methodology the expected public cost/benefit of P³ is likely but not certain to be moderately negative.
- The application of the methodology (and assumptions regarding inducement rates, spillover rates and financing costs) used by the Productivity Commission in its 2003 review of the PIIP to the specifics of P³ results in an estimated net economic benefit for P³ of positive \$9.8 million. If the methodology of the Productivity Commission is matched to the CIE assumptions regarding inducement rates, spillover rates and financing costs, the estimated net economic benefit for P³ is negative \$21.0 million. If the methodology of the Productivity Commission is matched to the ‘alternative’ Deloitte assumptions regarding inducement rates, spillover rates and financing costs the estimated net economic benefit for P³ is negative \$4.7 million. Given the scale of the program and the uncertainties surrounding the assumptions, this range of results when applying the Productivity Commission methodology should be interpreted as suggesting that the expected public cost/benefit of P³ is close to neutral.

Given the variation in results that flow from the different methodologies and assumption approaches (and the inherent uncertainty around the selection of these assumptions), with mid-point impact estimates ranging from of -\$23.8 million to +\$9.8 million, we believe that the most appropriate overall conclusion to draw in relation to the quantifiable public and economic impact of P³ is that, while the balance of probability is towards a small negative impact, the actual overall public economic impact of P³ is likely very close to neutral. Reading more into the results than this would be falling into the trap of attributing ‘false precision’ to the mid-point impact estimates.

While the public costs and public benefits of P³ are of primary interest for the purposes of the program review, it should be noted that a private net benefit exceeding \$100 million is expected to be generated by the program, with between half and two thirds of this benefit expected to accrue to Australian owned firms.

It should also be stressed that the public and economic benefits able to be captured in this study are limited to clearly ‘market’ sphere benefits that are expected to be delivered over the short to medium term. As such, the analysis represents only a partial accounting of the potential total long term benefits from P³.

5 Options for the future

This chapter considers the merit of a successor program to P³. Options for future action are then assessed in terms of whether a clear need for the action exists; a clear rationale exists for the Government action (e.g. presence of an unaddressed market failure); and the option for action is likely to be both effective and efficient in achieving its objective(s).

5.1 Context for a future program

One of the challenges for this review, and especially the question of possible options for a future program, is that there is considerable uncertainty about the future mix of Commonwealth programs to support innovation.

The Commonwealth Government has launched the *Review of the National Innovation System*. The review will, amongst other things, be looking at ways of reducing the number of innovation programs which currently exist at both the Commonwealth and State/Territory levels. The review guidelines and terms of reference note that there are now 169 Commonwealth and State innovation programs. The nature and level of R&D taxation concessions to be applied in the future is also a key agenda item for the *Review of the National Innovation System*.

As discussed in Chapter 3, P³ needs to be seen in the context of general measures designed to support innovation and the R&D taxation concessions in particular.

Against this background, it is difficult to make concrete recommendations about a future program for pharmaceuticals/biotechnology. We have therefore primarily focused on identifying a number of options for consideration by policy makers. However, three specific recommendations are then provided in relation to the development of a post P³ program.

5.2 Beyond P³

A key question in relation to post P³ intervention in the pharmaceuticals R&D market is whether the original rationale for intervention in relation to the pharmaceuticals/biotechnology sector retains validity and, if so, what, if any, special support program should replace P³.

As discussed in Chapter 4, the underlying rationale for P³ seems to depend on the proposition that there are significant spillovers associated with pharmaceuticals R&D and that for a variety of reasons it is likely that the market left to its own devices (and, indeed, enhanced by the presence of a range of generally available instruments designed to support business R&D) will under invest in pharmaceuticals/biotechnology R&D.

There seem to be three main sources of market failure that may provide a rationale for a post P³ program:

- The first is the one identified by the Productivity Commission, namely, that because of the rules around the beneficial ownership of IP, multinational companies which hold ownership of IP outside Australia are excluded from the benefits of the R&D tax concession. While it is true this distortion has been partially addressed – the beneficial ownership rules for IP in terms of accessing the 175 per cent Premium R&D Tax Concession have been changed to allow access by MNCs – the exclusion of MNCs from the 125 per cent R&D Tax Concession remains in force.

- The second, which presumably underlies the access of smaller Australian pharmaceuticals/biotechnology companies to P³, concerns market failure in the provision of risk capital for smaller companies in the sector which means such companies are unlikely to be able to grow to their full potential.
- The third, which seems to underlie the emphasis on partnerships in P³, concerns a market failure associated with the development of strong and sustained partnerships between multinational companies and Australian emerging companies and researchers.

In the face of these market failures, there is a reasonable expectation that it ought to be possible to design a new program for the pharmaceuticals/biotechnology industry that deals with these sources of market failure and results in the achievement of net benefits when account is taken of the costs of funding the program.

The design of a new program would need to take into account the lessons learned from experience with P³ and the likely context in which any new program will need to operate.

Consultations with the pharmaceuticals/biotechnology sector have thrown up a number of issues which the discussants believe are also relevant to the case for a successor program to P³ and the design of such a program. Major themes/viewpoints to emerge were:

- The multinational companies tend to argue that there is a need for some type of successor program to P³ which sends a message to decision makers in their headquarters that the Australian government is interested in the development of the pharmaceuticals industry and is prepared to have a special program for it.
- Some multinationals also argue that given the highly competitive nature of global competition to attract pharmaceuticals R&D that additional action is warranted to support the investments that already exist in Australia – P³ reduces the cost differential between undertaking R&D in Australia and overseas.
- Funding for the ‘base’ rather than for incremental increases in R&D spend was suggested by a number of stakeholders – some of these stakeholders did however acknowledge that there could be questions about the ‘additionality’ of such an approach. The response was that stopping a reduction in spend is in fact similar in concept to prompting an increase in spend, arguing that in both cases Government funding leads to R&D spend being higher than it would otherwise have been.
- One multinational company also highlighted the importance of a program like P³ in the facilitation of partnerships between multinationals and smaller Australian based biotechnology companies and research institutions. They suggest that it is through these partnerships undertaking fundamental innovative research that Australia is able to have a seat at the table in the global pharmaceuticals industry – the survival of the Australian biotechnology sector is seen as important to the MNC.
- There is general concern that the funding cap of \$10 million is too low to call forth step change investments in R&D that are needed to lift the industry’s capability and performance to a higher level. Indeed some companies suggested that in its current form (and given the changes to the tax concession) there would be little merit to extending the current program into the future. Some large company stakeholders suggested that given the total budget of P³, better bang for buck would be achieved if that level of funding was distributed as just a small number (less than five) of large grants to support major (\$100 million plus) investments in the sector in terms of both R&D and R&D infrastructure. This would involve targeting step change large scale new investments in R&D rather than incremental additional spend over current levels.

- Some other companies identified the need for a focus on attracting ‘footloose’ R&D expenditure in order to overcome the requirement of P³ funding to be expended on specific projects and the process of substituting projects into or out of the program. It was also noted that pharmaceuticals R&D funding in some other countries is directed at funding an outcome rather than a specific project (which is typically associated with large allocations of funds, i.e. \$20 million or more).
- Smaller Australian companies tended to support an ongoing program that addresses the special problems they face in accessing risk capital for investments that are high risk and have long pay-offs. They argue that the value that will accrue to Australia from ideas being taken further along the development chain before IP is sold to multinational companies is likely to be much greater than that delivered by supporting incremental increases in R&D by MNCs.
- As well as arguing strongly that dedicated funding for them was needed, smaller companies/their industry association also argued for funding to be easier to access and more flexible.
- Other stakeholders commented that especially in light of changes to the 175 per cent Premium R&D Tax Concession there are now few incentives to keep intellectual property in Australia, and that a future program should reward companies for retaining their intellectual property in Australia.
- A number of MNC stakeholders noted that a grant scheme that adds revenue to the top line carries more weight in discussions with head-office than an R&D tax concession does. Even if the percentage support is similar, top line influencing grants would be preferable to a tax concession – provided of course that the grant is not much harder to access or that compliance costs are not higher than under the tax concession.

5.3 Overview of post P³ options

There are five core options set out below for the Government to consider in relation to what, if any, sector specific policy should succeed P³. Government may wish to consider:

1. not replacing P³ with any new industry specific program, but rather relying upon general measures to provide incentives for industry R&D activity;
2. continuing with P³ in its current form;
3. refining the design of P³ to increase the inducement rate of the program and drive step change additional R&D investment by large pharmaceutical companies; or
4. refining the design of P³ to implement a smaller scheme focused only on Australian emerging pharmaceuticals/biotechnology companies. The R&D tax concession would under this approach be relied upon as the primary mechanism to encourage investment by larger companies; or
5. introducing a new scheme whose purpose is to facilitate only ‘partnership’ investments in pharmaceuticals related multi-party access infrastructure where the partnerships involve pharmaceuticals companies and public research sector.

It is important to note here that these options are not intended to represent a collection of different proposals put forward by stakeholders. The options are based on the review team’s consideration of the views of stakeholders, analysis of P³ performance and consideration of the principles of good program design that have been set out by the Productivity Commission.

5.3.1 Option 1: No successor program to P³

The default position for the Government to consider is to allow P³ to run to its conclusion and to not introduce any successor program. Under this option, R&D incentives for the industry would default to the general R&D incentives available to all industries. These general measures include a range of tax and grant based incentives.

This approach has the benefit of not introducing inter-sectoral distortions and would avoid the administrative costs associated with setting up and operating a new industry specific R&D incentive program.

As the Productivity Commission noted in its 2003 evaluation of PIIP:

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

- the costs of increased complexity in managing a diverse set of policies, both to government and to firms (which might be eligible for assistance in multiple industry programs);
- the costs of lobbying and rent seeking on the part of firms who stand to benefit;
- the costs of resisting regulatory capture on the part of government; and
- the distorting effects arising from the unequal treatment of different industries.

Because of these problems, it is often better to develop generic assistance programs that target the underlying market, firm or government failures, without regard to sectoral boundaries.”

Productivity Commission, 2003, Evaluation of the PIIP, p.4.2.

In its 2003 evaluation of the PIIP, the Productivity Commission also concluded that:

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

Productivity Commission, 2003, Evaluation of the PIIP, p.4.6.

It should be noted that in its submission to the Productivity Commission on the draft report of the PIIP evaluation, that the former DITR expressed that it was “concerned that the report understates the spillovers from the pharmaceuticals industry in Australia” and that “the analysis is not conclusive” on this issue. However, it would seem reasonable that in the absence of conclusive evidence on this issue, that the first preference should be to use general rather than sector specific policy instruments to encourage R&D investment. The burden of proof should, in effect, lie with those advocating a sector specific initiative.

The Productivity Commission also found that the justification for a sector specific successor to PIIP that focused on R&D was that the pharmaceutical sector was particularly impacted by the beneficial ownership requirements that then existed in relation to the R&D tax concession. This no longer holds due to the changes made to the beneficial ownership rules relating to the 175 per cent Premium R&D Tax Concession.

The extent to which general incentives for R&D address the general market failures surrounding R&D is an issue beyond the scope of this review. However, if general incentives are deemed sufficient to address general market failures for R&D – by large subsidiaries of MNCs, large domestic companies and SMEs – it is not clear that any additional specific program for the pharmaceuticals/biotechnology sector would be justified.⁷²

The negative of this option would be that it would effectively represent a decrease in the incentives currently available to the pharmaceutical/biotechnology industry to undertake R&D in Australia. The 175 per cent Premium R&D Tax Concession is somewhat mimics the incentives provided by P³, but at a lower incentive rate (22.5 cents in the dollar via the concession versus 35 cents in the dollar after tax via P³) than the incentive offered in Round 3. A direct comparison of the 175 per cent Premium R&D Tax Concession and P³ is set out in Appendix A.

A reduction in support available for pharmaceuticals R&D would be expected to lead to somewhat lower levels of R&D activity being undertaken. However, if general support for R&D is increased as a result of the recommendations from the recently commenced *Review of the National Innovation System*, this concern may be avoided.

5.3.2 Option 2: Continue with P³ in its current form

While, the changes to P³ between Rounds 2 and 3 have increased its effectiveness in advancing its objectives, it would still appear to be a marginal program from a net economic impact perspective. Based on the analysis set out in Chapter 4, the overall public costs of the program appear likely to match or marginally outweigh the public benefits of the program.

Stakeholder consultations also showed that the ability for the program to drive additional high quality R&D activity depended to a very large extent on the location of the company within the business cycle. In a number of cases industry stakeholders indicated that P³ subsidised activity that would have occurred anyway, while on the other hand, due to design features such as the spending cap and limited mechanisms for redistributing monies, some additional activity that might have been realised was not.

This evaluation suggests that based on the first three years of the program and its estimated cost effectiveness, notwithstanding the recent improvements to the program, that there is not a compelling case for P³ to be continued past 2009 in its current form. This conclusion is further confirmed when account is taken of the relative merits of the use of sector specific rather than general policy instruments to encourage R&D.

5.3.3 Option 3: Redesign P³ to focus on inducement of larger scale additional R&D investment

One future option would be to build on the lessons learned through the three rounds of P³ to improve the design of a competitive, incremental R&D scheme and in doing so, drive greater levels of additional, high quality R&D investment. Design refinements would include:

⁷² In the UK, the Pharmaceutical Industry Competitiveness Task Force (PICT), in its 2001 review *Value of the Pharmaceutical Industry to the UK Economy*, notes when considering the value of spillovers from pharmaceuticals R&D that “similar spillover benefits might be produced if the resources were diverted to R&D investment in any other industry”. This study also suggests that of the 37% spillover benefits it finds in relation to Pharmaceuticals R&D, 26% is captured by other pharmaceutical companies and 11% by other industry sectors. It is notable that in its broader report on the industry, the PICT makes no claim that R&D spillovers in the sector are higher than for R&D in other industry sectors.

- *Removal of the \$10 million cap per company* — The survey and stakeholder consultations showed that the higher rate of incentive over the shorter time frame for grants in Round 3 made a difference for a number of companies to attract R&D activity to Australia that would not have otherwise occurred. However, a number of companies indicated that the \$10 million cap was too low and that potentially large R&D activities were being missed. It may still be the case that the program would provide grants in the range of \$5 million to \$10 million on average, however, the Pharmaceuticals Committee would have the option to fund a larger project or portfolio if it were judged to merit Government support.
- *Allow for improved re-distribution of monies from underperforming companies to companies that expect to over-perform relative to their application amount* — P³ sought to provide a flexible program through multiple entry rounds. However variability in R&D project success means that expenditure is difficult to forecast, and even with the multiple entry points funding was underspent by a number of companies and this was not easily transferable to companies that saw their R&D spending capacities exceed initial expectations.
- *Only allow funding to be provided to support basic research or phase one clinical trial projects* — as has been noted by the Productivity Commission and others, spillovers are likely greatest in relation to basic research and early stage clinical trials (which involve significant research elements) rather than in later stage clinical trials.

Some analysis has previously suggested that an uncapped program would risk subsidising a single company's profits without providing for benefits to the community, or would also potentially risk a significant proportion of the program's expenditure going unspent as a result of the major project 'falling over'. With regard to the former point, the ability for Government to evaluate the quality and additionality of a project should not be expenditure dependent. Similar to P³ and other investment attraction schemes, the proponent would still be required to show that the activity or project would not occur but for the incentive. With regard to the latter point, the risk of monies being tied up in a single company would be reduced with the design refinement to allow more frequent re-distribution of monies among successful applicants.

The program would remain competitive-entry, which would require applications to be assessed for the extent to which additional, high quality R&D would be undertaken. In this way this program would be expected to result in higher levels of additionality and novelty in the R&D being undertaken than an entitlement program such as the 175 per cent Premium R&D Tax Concession.

As a competitive entry program, however, there would not be any reduction in the compliance and administrative costs of the program. There may be slightly higher costs, too, for proponents of larger projects, should the Government introduce additional evidence standards for these investments.

In relation to the expected net economic benefit of this option, increasing the inducement rate to levels higher than Round 3 and focusing only on supporting basic research and early stage clinical trial projects would be expected to improve the net benefit of the program when compared to P³. It would be anticipated that the net impact of the program would move closer to the high end impact estimate for P³ rather than the mid-point estimate set out in the alternative economic impact assessment in Section 4.5.2.

For this option to be justified, a case would need to be established that this sector specific initiative would be expected to yield higher economic returns than would a similarly designed initiative open to project submissions from all industry sectors. It is not clear that such a case currently exists.

5.3.4 Option 4: Redesign P³ to focus on smaller Australian companies

This option is based on the continuing perceived market failure facing innovative SMEs in terms of accessing the risk capital these companies need to allow them to take their IP further than otherwise would be the case, and thereby avoid the need for sale of IP at a too early stage.

The elements of the scheme would be similar to the Round 3 rules for P³ but access would only be available to small to medium sized Australian pharmaceuticals/biotechnology companies and funding would only be for basic research and early stage clinical trial projects.

The overall level of funding for the program would be at a significantly lower level than that of P³ given the narrower range of eligible companies accessing the scheme.

In relation to the net economic benefit of such a program, the focus on small to medium sized Australian companies doing early stage R&D would preclude capture of any benefits associated with inducement of FDI. However, the focus on early stage R&D only would result in higher spillover rates for funded activity than the average for P³.

As with option 3, for this option to be justified, a case would need to be established that this sector specific initiative would be expected to yield higher economic returns than would a similarly designed initiative open to project submissions from all industry sectors. It is not clear that such a case currently exists.

5.3.5 Option 5: A scheme to support significant 'partnerships' investments in R&D infrastructure

As the name of P³ suggests, supporting the development of partnerships between the leading pharmaceuticals companies, emerging Australian companies and Australian researchers and research entities was seen as one of the objectives of the scheme reflecting the view that there would be underinvestment in this activity without incentives being provided.

A recent example of the kind of partnership project that could be considered is the Biopharmaceutical Formulation Centre located at CSL which was opened in October 2007. The Centre, which will be used to formulate quantities of experimental biotechnology medicines under GMP for use in clinical trials, was partly funded by the Victorian Government and CSL. The facilities will be used for CSL for their own development purposes, a key partner Swinburne University and to provide a service to small biotechnology companies needing assistance in formulating their own products for testing.

Also indicative of such partnership infrastructure is the \$10 million grant that was provided in the 2006-07 Commonwealth budget for the establishment of a small-scale Mammalian Cell production facility in Australia. The lack of such a facility had previously resulted in R&D work being moved offshore.

Key features of a program targeted at supporting major partnerships to develop multi-party access infrastructure could be the following:

- *Competitive-entry* — proponents would need to show that the project would not occur but for the incentive, that the program would yield high social and economic benefits (including significant spillovers), and that the project would build long term partnerships between pharmaceuticals companies, smaller biotechnology companies and Australian researchers and research entities;
- *Individual projects uncapped* — proponents would need to show that the project would not occur in Australia but for the incentive and the level of support required by Government.

The net economic benefit of such a program may potentially be higher than P³ as it could achieve higher levels of inducement and also higher spillover benefits through providing long term infrastructure that would benefit multiple parties over a prolonged period of time.

As with options 3 and 4, for this option to be justified, a case would need to be established that this sector specific initiative would be expected to yield higher economic returns than would a similarly designed initiative open to project submissions from all industry sectors. It is not clear that such a case currently exists.

5.4 Findings

Noting the current *Review of the National Innovation System* and its potentially significant impact on a range of Government policies impacting the business R&D environment, we make the following three findings regarding the development of a post P³ program:

- **Finding 1:** P³ should not be renewed in its current form when it ends in June 2009.
- **Finding 2:** Work should not commence on development of a successor program until after the release of both the Green Paper from the *Review of the National Innovation System* review panel and the subsequent release of a White Paper response from the Government.
- **Finding 3:** As a precondition to development of any sector specific program to support pharmaceutical sector R&D, compelling evidence should be presented to demonstrate why such a program should be developed in preference to a generally available program.

Appendix A

Other R&D incentives in Australia

Introduction

The purpose of this Appendix is to examine the generally available programs designed to support R&D and innovation and to compare them to the support available under P³.

The Appendix seeks to put into context the range of R&D incentives and how they impact across the pharmaceuticals development spectrum.

Finally, the Appendix also presents a detailed comparison between P³ and the 175 per cent Premium R&D Tax Concession.

125 per cent R&D Tax Concession

The 125 per cent R&D Tax Concession is a broad based scheme designed to increase the level of R&D across all sectors. The concession is available to companies incorporated in Australia which are undertaking R&D. Companies are required to register with the Innovation Australia Board before claiming the concession. The concession allows eligible companies to claim up to 125 per cent of expenditure incurred on R&D activities from assessable income when completing their annual income.⁷³ Expenditure which can be claimed through the 125 per cent R&D Tax Concession includes:

- salaries and wages;
- contracted expenditure;
- other direct expenses;
- net cost of materials used in trials; and
- depreciation on plant and equipment to the extent it is used in R&D.

Expenditure cannot be claimed if it is incurred on behalf of another person or organisation, or if the expenditure is not at risk, e.g. it will be reimbursed by another person or organisation. There is no cap on the amount that can be claimed.

175 per cent Standard Premium R&D Tax Concession

The 175 per cent 'Standard' Premium R&D Tax Concession provides a 50 per cent premium to the 125 per cent tax concession for those companies that increase their level of eligible R&D above a rolling three year average. The 50 per cent premium allows companies conducting Australian owned R&D to claim up to 175 per cent of expenditure incurred on R&D activities from assessable income when completing their annual income assessment, and can only be claimed on the expenditure that is greater than the three year average.

The increase and average R&D expenditure are determined on a group basis and there is an allocation of the premium amount to the group members which have increased their R&D spend over the average. Eligible expenditure includes:

- salaries and wages;
- contracted expenditure;

⁷³ Australian Taxation Office, *Research and development tax concession: Overview*. Retrieved from <http://www.ato.gov.au/randd>.

- other direct expenses (excluding lease/hire of plant and equipment and contracts for service which are in substance for the hire of plant and equipment); and
- net cost of materials used in trials.

While there is no cap on the amount of eligible expenditure that can be claimed, if there is no increase in spending over the three year rolling average, no deductions at 175 per cent will arise (though they may still be eligible for the 125 per cent Tax Concession).

175 per cent International Premium R&D Tax Concession

On 1 July 2007 amended legislation came into effect that enables foreign owned R&D to claim the 175 per cent deduction, in certain circumstances (the 175 per cent 'International' Premium R&D Tax Concession). The deductions apply to expenditure incurred on Australian-centred research and development activities, i.e. those R&D activities undertaken in Australia, or else directly related to core R&D activities undertaken in Australia. The R&D activities must be undertaken by an Australian-based company on behalf of a grouped foreign company that resides in a country with which Australia has a double tax treaty, pursuant to a written agreement between the two companies. The base rate of the deduction is 100 per cent with scope to claim 175 per cent as a premium deduction.

The written agreement must be between the foreign company and the eligible company and no other party. The activities can be undertaken by the eligible company or be sub-contracted to another entity. As with the Australian owned R&D 175 per cent Premium R&D Tax Concession, the additional deduction applies to the increase over the average of the previous three years. The rolling three year average is determined by one of the following:

- Where no expenditure has been incurred in the prior three years, all eligible expenditure can be claimed at 175 per cent. In order to qualify, the eligible company and any other company with which it is grouped for R&D purposes could not have existed in Australia in the preceding ten years. The foreign company could also not have been a primary or secondary group member of any R&D group during the preceding ten years.
- Where expenditure has not been incurred in the prior three years, transitional measures apply whereby the previous three years are deemed to be 90 per cent, 80 per cent and 70 per cent of the immediate year's expenditure.

In order for the foreign owned R&D deduction to operate, section 73B(9) of the *Income Tax Assessment Act 1936* will not apply, i.e. the condition that the R&D is not to be on behalf of another does not apply. Also not applying to this new program is section 73(CA), which would otherwise deny deductions, as it applies to funding/reimbursement of costs by the foreign company of any R&D undertaken in Australia.

Subsection 73B(1) of the *Income Tax Assessment Act 1936* states that:

In this section, unless the contrary intention appears:

Research and development activities means:

- a) systematic, investigative and experimental activities that involve innovation or high levels of technical risk and are carried on for the purpose of:
 - i) acquiring new knowledge (whether or not that knowledge will have a specific practical application);
 - ii) creating new or improved materials, products, devices, processes or services; or

- b) other activities that are carried out on for a purpose directly related to the carrying on of activities of the kind referred to in paragraph (a)

The definition refers to two types of R&D activities: core activities in (a) and supporting activities in (b). The two types of activities are brought into the IRDA 1986 definition of R&D activities because of subsection 39A(2) of the IRDA, which states:

Subject to subsection (1), expressions used in this Part that are defined by section 73B of the *Income Tax Assessment Act 1936* have in this Part, unless the contrary intention appears, the same meanings as in that section.

With regard to the international premium, the Innovation Australia Board will be able to certify if the activities are Australian-centred R&D activities. The Board will determine if directly related activities have the dominant purpose of supporting systematic, investigative and experimental R&D activities conducted in Australia.

R&D Tax Offset

The R&D Tax Concession allows eligible Australian companies undertaking defined R&D activities to claim a tax deduction of 125 per cent, and in some cases 175 per cent, of eligible expenditure when lodging their annual tax returns.

The Government has enhanced the R&D Tax Concession by providing small companies with an R&D Tax Offset (i.e. a refundable tax offset), equivalent to the value of the deduction under the R&D Tax Concession provisions. The Government recognises the importance of providing innovative small companies, particularly those in tax loss who cannot gain immediate benefit from the R&D Tax Concession, an opportunity to increase their cash flow when they most need it during their initial growth phase.

The R&D Tax Offset is available to eligible Australian companies with an annual group turnover of less than \$5 million and R&D group expenditure of up to \$1 million. Smaller companies in tax loss, that would otherwise carry forward R&D related tax losses, can realise these losses as a cash equivalent payment when their tax return for the relevant year is processed. This provides assistance to these smaller firms at the time they need it most, in their growth stages.⁷⁴

COMET

The \$140 million Commercialising Emerging Technologies (COMET) program was established in 1999. The COMET program is a competitive grants program targeted at early stage growth companies and spin-off companies to facilitate the commercialisation of innovative products, processes and services.

The program was intended to address perceived market failures which hindered the commercialisation of innovation. The problem identified was that many early stage firms did not possess the management expertise and/or resources to bring their ideas to market; this has shaped the form and scale of assistance provided through the COMET program.

To be eligible for COMET assistance companies must meet a range of eligibility and merit criteria including that the innovation has commercial potential, turnover of applicant companies must total less than \$8 million over the last two years or not exceed \$5 million in either year. Applicants must be less than five years old and companies must have ownership or beneficial use of any IP necessary to commercialise the innovation.

COMET provides business assistance through:

1. Services provided by to private sector Business Advisers, and

⁷⁴ Further information can be obtained from the AusIndustry website www.ausindustry.gov.au or the *Innovation Australia Annual Report 2006-07*.

2. Financial assistance to support the engagement of specialist third-party service providers.

COMET financial assistance is available in two tiers:

- Tier 1 grants provide assistance at a rate of 80 per cent of eligible expenditure, up to \$64,000 (exclusive of GST); and
- Tier 2 grants provide assistance at 50 per cent of eligible expenditure up to \$56,000 (exclusive of GST).

These grants are capped at \$120,000 per customer for up to two years, and a maximum of \$5,000 for individuals.

In 2004, the COMET program was extended to 2011 through *Backing Australia's Ability*, with slight modifications to the awarding and provision of assistance; the program is currently being evaluated by ACIL Tasman.

Pre-seed Fund

The Pre-Seed Fund (PSF) program aims to increase the role of private sector investors in funding and managing the commercialisation of research from Australian universities, Cooperative Research Centres and Australian Government research agencies.

The PSF program involved the establishment of venture capital funds, managed by private sector fund managers, which would invest in projects or spin out companies. The maximum investment in any project or company is \$1 million. In total, the Australian Government has provided over \$72.7 million to the funds, which has been matched by contributions from the private sector to bring the total capitalisation to \$104.1 million. Investments can be made into projects or companies established to commercialise research.

Eligibility for PSF support requires that, at the same time of initial investment by a licensed fund, a company must:

- be undertaking pre-seed stage R&D activities;
- be incorporated in Australia;
- if not controlled by some or all of the qualifying researchers actually carrying on those R&D activities within the company is controlled by either an eligible institution or a qualifying researcher(s), or both; or
- utilise in its R&D activities intellectual property at least 50% of which is owned by an eligible institution or qualifying researchers;
- have no sales revenue;
- have a majority of the personnel carrying on its R&D activities (by number) and assets (by value) inside Australia;
- use all the proceeds from the fund's initial investment in Australia;
- meet such other requirements as the Board thinks fit; and
- whose purpose it is at all times to commercialise the outcomes of those R&D activities and not solely or primarily research studies.

An eligible project is a project which, at the time of initial investment by a fund:

- involves pre-seed stage R&D activities being carried out either within or derived from an eligible institution;

- has at least 50% of the background IP being applied in it and at least 50% of the Project IP attributable to it owned by either or both of the eligible institution in or by which the project is being carried on, and qualifying researchers;
- is controlled or supervised by an eligible institution and be undertaken in Australia;
- has not generated any sales revenue;
- has a majority of the personnel engaged in it inside Australia;
- will use all of the licensed fund's initial investment in Australia;
- meets such other requirements as the Board thinks fit; and
- which is carried on at all times for the purpose of commercialising the results of those R&D activities and not solely or primarily for research studies.

Companies and projects that have already received funding from other Government programs for activities similar to those proposed to be funded out of the proceeds of an investment by a licensed fund are not eligible companies or eligible projects unless those activities have been completed or are different to those proposed to be funded. Eligible companies or eligible projects are however eligible to subsequently seek funding through other Commonwealth programs, subject to the terms of those programs.

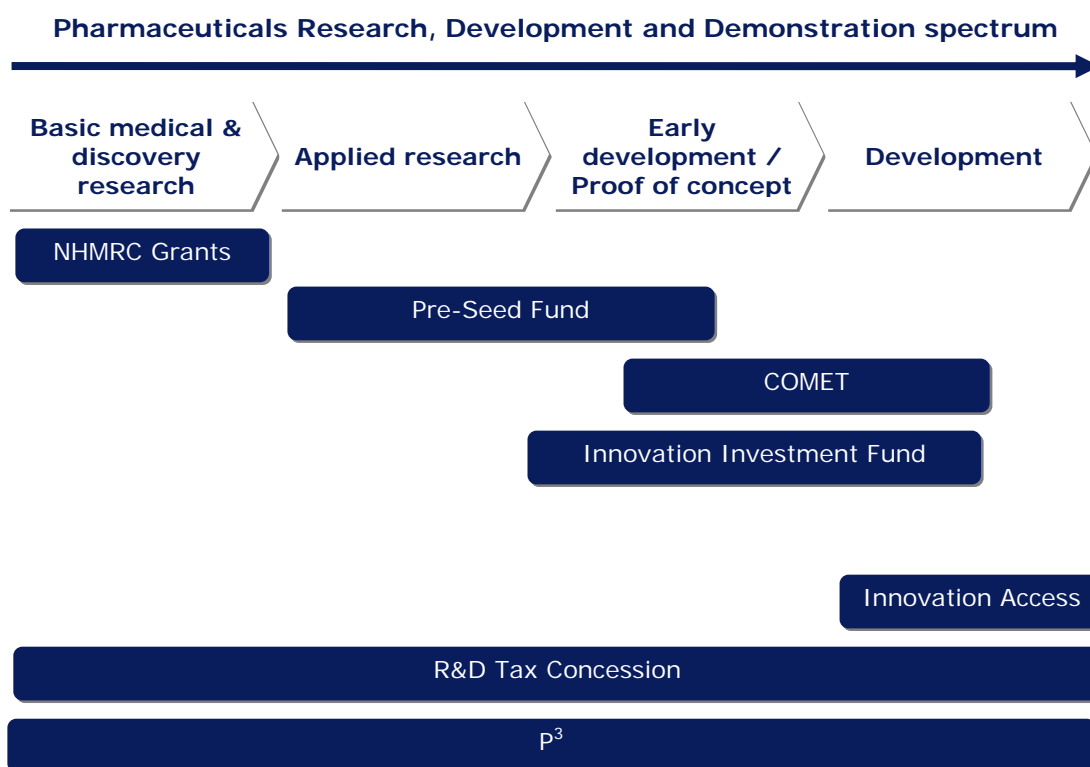
Types of R&D funding covered under different programs

Development of new pharmaceuticals typically involves a chain of activities from laboratory based research to the development of a new product. The different stages along this value chain can be described as:

- *Basic medical and research discovery* – R&D focused on the development of novel approaches to treating diseases, through the development of drugs that are generally either molecules or biologicals.
- *Applied research* – R&D focused on testing and developing the drug in a laboratory, prior to any trials on humans.
- *Early development/proof of concept* – R&D focused on testing on healthy human volunteers (Phase I), involving small scale testing on patients (Phase II) and large scale testing on patients (Phase III). This stage is also known as Clinical Trials R&D.
- *Product development* – Only when the product has been through the Clinical Trials and product approval processes will commercial scale product development occur.

A number of Commonwealth funding programs have been established to provide support to R&D activities across the pharmaceuticals development spectrum. These are outlined in Figure A.1.

Figure A.1: Commonwealth funding support along the pharmaceuticals development spectrum



Source: Adopted from presentation by former DITR, *Pharmaceuticals Partnerships Program (P³) – Overview and Update*

The high cost and lengthy product development timeframes associated with pharmaceuticals means that a number of the programs outlined above simply can not provide the scale of funding required to drive the industry investment in R&D that Government is aiming to stimulate with P³. For instance, the COMET and Pre-seed Fund have caps on the level of funding any individual company can receive.

The R&D Tax Concession is the only other program, in addition to P³, that covers the full spectrum of activities associated with pharmaceutical development. It provides for the deduction of eligible R&D expenditure against assessable income, without a cap, in any industrial sector. The 175 per cent Premium R&D Tax Concession provides even greater incentives for increasing R&D activity.

Furthermore, the changes to the beneficial ownership test have meant that foreign companies are able to claim for their Australian R&D activities even if the intellectual property is held offshore (subject to certain criteria). This amendment may alter the need for P³.

Eligible activities for which claims can be made under both P³ and the 175 per cent Premium R&D Tax Concession must be systematic, investigative and experimental. Eligible expenditure under the two programs includes:

- salary and associated on-costs;
- contracted expenditure;
- R&D consumables;
- expenditure associated with administrative support for the R&D activities;

- overheads associated with the R&D section; and
- net cost of trials.

In addition, P³ also allows expenditure associated with technology transfer and intellectual property through licensing and protection, something not covered by the Tax Concession.

Both P³ and the 175 per cent Premium R&D Tax Concession require that the eligible R&D expenditure must have increased relative to the average of the eligible expenditure over the previous three years. P³ makes payments on the actual increase over the agreed base level of expenditure through a quarterly reporting and payment process, whereas the 175 per cent Premium R&D Tax Concession is claimed through deductions in the annual income tax return.

The proportion of R&D expenditure that is not an increase over the three year average is eligible for the 125 per cent Tax Concession under both P³ and the 175 per cent Premium R&D Tax Concession, except for foreign owned R&D under the 175 per cent, which is not eligible for the 125 per cent Tax Concession. However, the 175 per cent Premium R&D Tax Concession allows eligible expenditure relating to foreign owned R&D to receive the same total benefit as Australian owned R&D under the 125 per cent and 175 per cent Premium R&D Tax Concessions.

A total benefit payment to any company is capped at \$10 million per round under P³, whereas there is no cap under the 175 per cent Premium R&D Tax Concession.

Perhaps the biggest difference between P³ and the 175 per cent Premium R&D Tax Concession is the application process. P³ requires companies to lodge formal applications and forecast eligible R&D expenditure. They are then ranked and selected on the basis of four merit criteria: track record and capability; scope and nature of partnerships and collaborations, technical merit of proposed activities; and, the level of benefit to the Australian economy. Under the 175 per cent Premium R&D Tax Concession, companies need to register their R&D activities with the Innovation Australia Board, and have a three year registration listing with AusIndustry for the R&D Tax Concession.⁷⁵

A comprehensive comparison of the difference between P³ and the 175 per cent Premium R&D Tax Concession are summarised in Table A.1.

NOTE: The information in this document is general in nature and is not to be read as professional advice. The information concerning the income tax consequences is not binding in any way on the Commissioner of Taxation.

For information relating to registration or the eligibility of activities, please call AusIndustry on 132846. Alternatively, email RDTAXCON@innovation.gov.au or visit the website at www.ausindustry.gov.au.

For information on expenditure issues please contact the Australian Taxation Office on 132866. Alternatively visit the website at www.ato.gov.au/randd

⁷⁵ A three year R&D history can be achieved by claiming R&D at 125% for three years and registering for the R&D Tax Concession; or being grouped (for R&D purposes) with a company which satisfies the history requirement.

TableA.1: Comparison of P³ (Round 3) and 175 per cent Premium R&D Tax Concession

Incremental Tax Concession (175 per cent Premium)	P³ – Pharmaceuticals Partnerships Program (Round 3)
<p>Background</p> <p>To encourage a sustained business investment across all industry sectors in R&D on a long-term basis.</p> <p>R&D Tax Concession is part of Income Tax Assessment Act and is based on self-assessment, i.e. the tax payer makes the determination as to the eligibility. This is later subject to audits.</p> <p>The 175 per cent deduction, (as discussed above) is divided into:</p> <ul style="list-style-type: none"> - Australian owned R&D - Australian centred, foreign owned R&D (this applies for years of income post 1 July 2007). 	<p>Background</p> <p>Competitive grant program aimed at increasing high quality pharmaceuticals R&D in Australia by all companies at all stages of the pharmaceutical development process.</p> <p>Grants are awarded via a competitive process to the applicants that best meet the merit criteria.</p> <p>Third Round – closed 20 Nov 2006. It provides grants from 1 July 2007-30 June 2009</p>
<p>Program administration</p> <p>Jointly administered by Innovation Australia Board assisted by AusIndustry and the Australian Taxation Office</p>	<p>Program administration</p> <p>Program Delegate – General Manager of Innovation & Collaboration - AusIndustry</p> <p>Pharmaceuticals Committee of the Innovation Australia Board</p>
<p>Eligibility criteria</p> <ol style="list-style-type: none"> 1. The applicant must be an eligible company, namely a body corporate incorporated under a law of the Commonwealth or of a State or Territory and must be incorporated in Australia 2. Applicant company can be from any industrial sector 3. The applicant must have continuous 3 year registration listing with AusIndustry for the R&D tax concession. A three year R&D history achieved by claiming R&D at 125 per cent for 3 years and registering for R&D tax concession; or receiving grants for projects; or being 	<p>Eligibility criteria</p> <ol style="list-style-type: none"> 1. The applicant must be a company incorporated under the Corporations Act 2001 (Cth) and must be the only company from its group of related bodies corporate that is applying for this round. 2. The applicant must be part of the pharmaceutical industry. 3. The applicant must have undertaken R&D activities for at least three years prior to the start date of this round. 4. The applicant must propose to increase (above a base level) expenditure on eligible Australian Pharmaceuticals R&D activities for each year in

Incremental Tax Concession (175 per cent Premium)	P³ – Pharmaceuticals Partnerships Program (Round 3)
<p>grouped (for R&D purposes) with a company which satisfies the history requirement.</p> <ol style="list-style-type: none"> 4. The applicant must have increased its R&D spend for the year above a base level determined by their average R&D expenditure over the previous three years. 5. For the International Premium, applicants must conduct R&D in Australia on behalf of a grouped foreign company that resides in a country with which Australia has a double tax agreement. 6. Where the Australian company or any of its grouped companies have had a previous presence in Australia, the relevant 3 year R&D history for the 175 per cent International Premium is the foreign owned R&D expenditure. Special transitional arrangements exist for the 2007-08 financial year that allow companies to take advantage of a deemed R&D history. 7. Where foreign grouped companies have not established a presence in Australia prior to the commencement of this measure, they will be deemed to have a nil R&D expenditure history. Eligible companies can claim the first year R&D expenditure at the 175 per cent rate. 8. Calculations of an eligible company's entitlement to the additional 75 per cent deduction are performed on a group basis, and will take account of any decreases in relevant expenditure on 'Australian owned' R&D activities. 	<p>order to participate in the Program.</p> <p>Applications are then ranked according to four merit criteria:</p> <ol style="list-style-type: none"> 1. The Track Record and Capabilities of the Applicant 2. Scope and Nature of Partnership and Collaborations 3. Technical Merit of the Proposed Activities 4. Level of Benefit to the Australian Economy
<p>Application process</p> <p>Access to R&D Tax Concession is a two-stage process:</p> <ol style="list-style-type: none"> 1. Registering the companies R&D activities with the Innovation 	<p>Application process</p> <p>Must lodge applications in accordance with the directives put in the approved application form.</p>

Incremental Tax Concession (175 per cent Premium)	P³ – Pharmaceuticals Partnerships Program (Round 3)
<p>Australia Board by registration deadline (10 months after company Year end of income)</p> <p>2. Claiming the additional tax deductions in the company annual Income Tax Return.</p>	
<p>Calculation of deduction</p> <p>175 per cent Premium = (Amt of deduction on Aus-owned R&D x 50%) + (Amt of deduction on Foreign-owned R&D x 75%)</p> <p>N.B. Refer to s73RA & s73RB – method statements for the calculation of increase in expenditure on Australian vs. Foreign owned R&D by the eligible company</p> <p>-No cap amount exists, however, if there is no increase over the average, no access to 175%.</p>	<p>Calculation of payments</p> <p>Max. Annual Payment = (Forecast – Base) x 50% (Round 3)</p> <p>N.B. Base value = Rolling average of previous three years incremental R&D expenditure (pharmaceutical) from 04-05 to 06-07</p> <p>-Total benefit payable to any company is capped at \$10 million.</p> <p>-Participating companies report actual R&D expenditure quarterly.</p> <p>-Grants are paid quarterly in arrears based on eligible expenditure throughout the financial year to date.</p> <p>Under/Over-performance relative to the Forecast expenditure may be carried over from year to year.</p>
<p>Eligible Activities and Expenditure</p> <p>Eligible Activities must be Systematic, Investigative and Experimental (SIE), involving high levels of technical risk and activities can be directly related to the carrying out of one or more SIE activity.</p> <p>For the Australian centred R&D in regard to directly related activities to SIE activities there is an <u>additional test</u>, i.e.</p> <p><i>‘the activities are carried on for a purpose directly related...; the purpose is the sole or dominant purpose for which the activities are carried on’</i></p> <p>Eligible Expenditure (Australian and Foreign-owned) includes:</p>	<p>Eligible Activities and Expenditure</p> <p>Eligible Activities = Systematic, Investigative and Experimental Activities and those directly relating to these.</p> <p>Eligible Expenditure is expenditure incurred in Australia in undertaking eligible Australian pharmaceuticals R&D activities.</p> <p>This includes expenditure incurred in Australia only directly by or on own behalf of the applicant or related body corporate.</p> <p>Eligible expenditure for P³ includes those categories mentioned for the Incremental Tax Concession Program.</p>

Incremental Tax Concession (175 per cent Premium)	P³ – Pharmaceuticals Partnerships Program (Round 3)
<ul style="list-style-type: none"> -Salary & On-costs -Contract Expenditure -R&D Consumables -Administrative Support Expenditure -R&D Section Overhead - Net cost of trials 	<p>In addition the following are also able to be claimed:</p> <ul style="list-style-type: none"> -Technology transfer -Intellectual Property – In-licensing -Intellectual Property – Protection* <p>*Companies can claim IP Protection despite their activities not fulfilling the definition of eligible pharmaceuticals R&D.</p> <p>\$200,000 cap/yr of eligible IP expenditure may be counted for any year of the base.</p>
<p>Other Eligibility</p> <p>Minimum expenditure of \$20,000 p.a. per claimant applies except when an RRA is contracted. Computer software R&D must satisfy an additional multiple sale requirement.</p> <p><i>For Australian-owned R&D</i></p> <ol style="list-style-type: none"> 1. On own behalf – claimant must bear financial risk, control of activities and be the beneficial owner of the results of the R&D 2. R&D activity results must be for the benefit of the Australian economy 3. Must be done on behalf of the overseas parent/related entity 4. Whether activities are undertaken on behalf of a grouped foreign company is determined by reference to a written agreement between 	<p>Other Eligibility</p> <p>Not applicable for P³</p> <p>This applies to P³</p> <p>This applies to P³</p> <p>Expenditure relating to activities carried out overseas will need to be excluded from the forecasts of R&D Expenditure and from the base calculations.</p> <p>Expenditure on activities undertaken by Australian-employed staff outside Australia is not eligible expenditure.</p> <p>Expenditure on R&D activities in Australia that are funded by a related</p>

Incremental Tax Concession (175 per cent Premium)	P³ – Pharmaceuticals Partnerships Program (Round 3)
<p>the Australian company and the foreign company.</p> <p><i>For Foreign-owned R&D</i></p> <ol style="list-style-type: none"> 1. Foreign company must be an eligible company, i.e. incorporated under a law of foreign country with which Australia has a double taxation agreement 2. R&D must be done on behalf of the overseas parent/related entity by a grouped company incorporated in Australia. 3. Whether activities are undertaken on behalf of a grouped foreign company is determined by reference to a written agreement between the Australian company and the foreign company. 4. The fact that the expenditure is not at risk does not prevent a claim being made. 	<p>body corporate outside Australia is eligible</p> <p>Interaction with R&D Tax Concession</p> <p>Companies that participate in P³ are not precluded from accessing the R&D Tax Concession. However, the R&D Tax Concession clawback provisions apply.</p>

Appendix B

Stakeholder consultations and survey respondents

The list below sets out the organisations and the interviewees that were consulted with as part of the P³ evaluation.

Amgen	Katherine Grigg, Mark Tennyson
AusBiotech	Anna Lavelle
AusIndustry	Judy Zielke
ChemGenex	James Campbell
CSL	Rachel David
Generic Medicines Industry Association	Di Ford
GlaxoSmithKline	Ashley Bates
Janssen-Cilag	Judy Bell
Medicines Australia	Ian Chalmers, Deb Monk
Merck Sharp & Dohme	Sara Pantzer
Novartis	Martin Cross
Peptech (now Arana Therapeutics)	Niall Henderson, Wendy Oliver
	Mr Paul Bell, Board member, Biota Holdings
	Professor John Funder AO, Professor Department of Medicine, Monash University
Pharmaceuticals Committee of Innovation Australia	Dr Suzanne Lipe, Chief Operating Officer, Norwood Immunology Ltd
	Dr George Moore, Director GENKIMED Pty Ltd
	Dr Ian Pitman, Consultant
	Professor Susan Tett, Professor, School of Pharmacy, University of QLD

	Martin Cross - Novartis
	David Edmonds - Peptech Animal Health
	Deborah Monk - Medicines Australia
	Sara Pantzer - Merck Sharp and Dohme
Pharmaceuticals Industry Council's Industry Development Taskforce	David Pullar - Sanofi-Aventis
	Dieter Torheiden - Solvay
	Sue MacLeman - Benitec
	Mike Kabos - Bristol-Myers Squibb
	Gail Morgan - GlaxoSmithKline
Roche	David Kingston
Sanofi-Aventis	David Pullar
Servier	Gary Harman
Starpharma	Nigel Baade
Tissue Therapies	Nigel Johnson
Wyeth	Vanessa Stevens
iNova Pharmaceuticals	Tony Martin

The list below presents the successful firms that completed or did not complete the survey, as well as other firms who either did not apply or were unsuccessful.

COMPLETED SURVEY

DID NOT COMPLETE SURVEY

FIRMS AWARDED P³ GRANTS UNDER ROUND 1

Acrux	Zenyth (withdrawn, now part of CSL)
ChemGenex	CSL responded on behalf of Zenyth
CSL	
Eli Lilly (withdrawn)	
Janssen-Cilag	
Hospira (formerly Mayne Pharma)	
Merck Sharp & Dohme	
Novogen	
Pharmaxis	
Servier Laboratories (withdrawn)	

FIRMS AWARDED P³ GRANTS UNDER ROUND 2

CBio	Alchemia (withdrawn)
Peplin	Alphapharm (withdrawn)
Pfizer	Prana Biotechnology (declined)
Starpharma	

FIRMS AWARDED P³ GRANTS UNDER ROUND 3

Arana Therapeutics (formerly Peptech)
Janssen-Cilag
Progen Pharmaceuticals Limited
Tissue Therapies
GlaxoSmithKline
Vital Health Sciences

COMPLETED SURVEY

DID NOT COMPLETE SURVEY

FIRMS UNSUCCESSFUL OR DID NOT APPLY FOR P³

Roche Products

Wyeth Australia

Amgen Australia

ICON Clinical Research

Probiotec

Metabolic Pharmaceuticals

Sanofi-Aventis

Genzyme Australasia

Allergan Australia

Novartis

Source: Analysis of Deloitte survey

Appendix C

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