

**SUBMISSION TO THE PRODUCTIVITY  
COMMISSION STUDY INTO  
PUBLIC SUPPORT FOR SCIENCE AND  
INNOVATION IN AUSTRALIA**

**MEDICINES AUSTRALIA  
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**Medicines Australia  
Submission to the Productivity Commission  
Review of Public Support for Science and Innovation**

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## Executive Summary

Medicines Australia proposed that there are a number of areas of focus that will assist to maximise the economic, social and environmental returns on public support for science and innovation in Australia. These are outlined below followed by a number of recommended actions and are discussed in detail in the submission.

Recommendations:

➤ **Stimulate sound science system (Section 2)**

- *Government to continue measures taken over recent funding cycles to increase GERD to internationally competitive levels.*
- *Government implement adequate incentives for universities and science training institutes to ensure increased numbers and scientific capacity of graduates adequate to meet future needs of publicly funded research, university science training and industry.*
- *Commonwealth and State Governments to collaborate to create an environment which encourages individual research development by clinicians and scientists in the public hospital system.*

➤ **Support for an innovative biopharmaceutical value chain (Section 3)**

- *Government ensure a vibrant private financial equity market for biotechnology and related sectors and address market failures in the current venture capital environment.*
- *Government develop and foster an investment culture appropriate for the long gestation periods required.*
- *Government to develop and implement policy settings that reflect the critical role of global pharmaceutical companies as the end customer of publicly and privately funded research.*
- *PBS policy settings stabilised to provide long term certainty for investors.*

➤ **Coherent, predictable and consistent innovation policies (Section 4)**

- *Government needs to ensure a mix of support programs to support continued investment along the biopharmaceutical value chain. The investment support should be of a scale and mix so as to engage global pharmaceutical companies – a key component of the value chain.*
- *Government to ensure investment policies that are consistent with the long lead times and to allow for variability in timing of spend on R&D programs inherent in the biopharmaceutical industry.*

- *Predictability in the policy environment through continuing to provide sector specific programs (such as a follow on to the P3 program and an R&D tax incentive program that can be accessed by global companies) to stimulate biopharmaceutical R&D investment.*
- *The need for a whole of government approach to policy development and implementation that ensures recognition of the links across the biopharmaceutical value chain and the resultant economic outcomes.*

➤ **Collaboration (Section 4.1.4)**

- *Government assist in creating partnerships and networks between global pharmaceutical companies and Australian biotechnology companies/research institutes so as to ensure a rate of return on Government's current investment in basic R&D. It may be timely to undertake a review of the existing collaborative research programs to ensure Government funding on the creation of these linkages is optimised.*
- *That a future DITR investment program for the biopharmaceutical industry rewards all collaborative projects across the value chain and can more effectively accommodate the creation of collaborations.*
- *Government to ensure that investment support is on a time and funding scale that allows projects to move up the value chain to a point where commercial uptake is optimised.*

➤ **Globally competitive public policy (Section 4.2)**

- *Government policy settings should recognise that the Australian biopharmaceutical sector functions in an intensively competitive international market for both investment in discovery R&D, clinical trials and infrastructure.*
- *Programs need to be easily understandable for effective communication to international headquarters*

➤ **Regulatory framework (Section 4.2.4)**

- *The new ANZTPA regulatory framework must produce timely clinical trials start-ups while ensuring adequate protections for patient safety through a rational evaluation of trial risk.*
- *That a nationally accepted Clinical Trials Agreement, Statement of Indemnity and Compensation Guidelines be developed so as to minimise delay in study start-up times.*
- *Recognition by Government of the link between reimbursement and investment activity and consideration to how the impacts can be minimised to support and encourage the development of innovative medicines in Australia.*
- *Implementation by Government of world's best practice in intellectual property.*

➤ **Technology Transfer (Section 3.2)**

- *Universities and research institutes institute programmes of education on intellectual property management and patent strategies as part of postgraduate and undergraduate science courses. This must ensure that academic promotion moves from a focus purely on number of publications to a recognition of the critical importance of IP protection over publications.*
- *University business offices function as enablers rather than barriers.*
- *Create a business environment where global pharmaceutical companies see value in a proactive local licensing initiative.*

## 1. Introduction

Medicines Australia welcomes the opportunity to contribute to the study by the Productivity Commission into the economic, social and environmental returns on public support for science and innovation in Australia. The study is timely and should support the case for more funding to ensure that pharmaceutical innovation continues to move forward at a rapid pace. It is important that the local environment stimulates and attracts innovation. There must also be recognition of the significant investment required to foster innovation and the long lead times required to realise the benefits.

### **Long-term rewards to Australia's economy and well-being through spending on pharmaceutical innovation:**

- **Productive and healthier population through advances in medicines - for every \$1 invested in medicines, there is a \$4.50 saving in more expensive and invasive medical interventions.**
- **Improved workforce productivity.**
- **Savings and reduced nursing and hospital care.**
- **More than \$500 million is spent every year by innovative medicine companies on research and development, much of it in clinical trials and support for areas like new biotech medicines and vaccines.**
- **\$3 billion in pharmaceutical exports - second largest exporter of manufactured products after the automotive industry.**
- **Increase of three weeks in longevity of life across the entire population through new medicines introduced over the past 30 years.**
- **Five year survival rates for cancer have increased by 25 percent since the 1970s.**
- **260 alliances with research centres around the country.**

Research Australia's 2005 Opinion Poll found Australians wanted more funding for health and medical research. 82% of those surveyed said it should be a high priority for Government over the next two or three years while 50% said they would prefer Budget surpluses to go to this area rather than tax cuts.

The pharmaceutical industry is one of the most knowledge-intensive and innovative industries forming an integral part of Australia's national innovation system.<sup>1 2</sup> It is strongly science based with new products emerging from research and developments in scientific

<sup>1</sup> Committee for Economic Development of Australia, 2004. *Innovating Australia*. Available: <http://ceda.com.au/public/publications/policy/index.html>.

<sup>2</sup> The pharmaceutical industry in Australia currently contributes some \$520 million annually to R&D, representing 48.8% of Australian gross domestic expenditure on R&D<sup>2</sup>. The industry is an important partner for institutional research organisations in Australia contributing an estimated 15% to the total research budget in this sector. Around 90% of pharmaceutical companies based in Australia are involved in R&D, collaborating in more than 260 alliances with research centres around the country. Department of Industry, Tourism and Resources, 2006. Available: <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?objectID=848F9330-F7BA-4D80-8578BCD96F96D993>

knowledge generating both economic impacts and knowledge spill overs. This has been recognised in the Commission's earlier work.<sup>3</sup>

There has also been recognition that governments must have a major role in shaping the national innovation system and that no single approach for government intervention can address all requirements. Supporting innovation through R&D must be based on robust policy with a combination of approaches such as:

1. creating and strengthening markets through intellectual property rights or facilitating collective industry research arrangements;
2. providing various forms of financial support to private firms conducting R&D; and
3. sponsoring and undertaking research within the public sector (universities, government departments and research agencies).<sup>4</sup>

These findings remain relevant today and the economic benefits and knowledge spill overs arising from innovation should be enjoyed by Australians well into the future. Given the critical influence of the national innovation system on longer-term growth prospects and outcomes, there is now a need for further policy frameworks and investment which foster and stimulate innovation. Government support of innovative industries must continue to be an important factor in the strength and success of the Australian innovation system.

Medicines Australia welcomes the opportunity provided by the Productivity Commission to make a formal submission to its review, *Public Support for Science and Innovation*. This submission will aim to:

1. demonstrate the quantum of investment made by the industry on public sector science and innovation and how this investment underpins the biopharmaceutical value chain.
2. provide evidence of the benefits to the economy of the ongoing support of the pharmaceutical industry to help Australia to commercialise public sector investment and support for small to medium enterprises (SMEs) through the biopharmaceutical value chain; and
3. and provide evidence of the benefits resulting from investment in the innovation system with particular emphasis on the pharmaceutical industry.

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<sup>3</sup> Industry Commission. *Report No. 44 Research and Development*. (1995) Australian Government Publishing Service, Canberra.

<sup>4</sup> Industry Commission. *Report No. 44 Research and Development*. (1995) Australian Government Publishing Service, Canberra.



**2. A vibrant Innovative Pharmaceutical Industry will ensure Australia's Public Investment in Science and Innovation returns a maximum benefit to the Australian economy and Society**

Federal and state governments have adopted policies aimed at establishing Australia as the site of a "knowledge economy". The rapid development of such economies in populous nations in our geographical region has added urgency to initiatives arising as a result. Australian subsidiaries of global pharmaceutical companies are important contributors to this movement by virtue of the science-based nature of their business and their interest in intellectual property (IP) arising from Australian research. Australian subsidiaries of global pharmaceutical companies are the principal customer for Australia's emerging biotechnology industry but their contribution is not confined to financial benefits that flow from licensing and other collaborative research agreements. Alliances between Australian companies and institutes bring significant learnings about research, development, manufacturing, commercialisation and marketing.

Virtually all biotechnology companies develop IP originating in universities and research institutes. Company officers frequently continue to hold senior academic positions. The path from publicly funded research to investment and economic success is thus quite short and the realisation of public investment in bioresearch depends largely on IP uptake by the Innovative Pharmaceutical Industry (IPI). Conversely and equally, the commercial attractiveness of Australian IP depends largely on effective government investment in basic research in many areas, at a stage well before commercial potential is apparent.

Significant challenges to the public, and therefore the industrial, research systems include the lower level of government investment in research relative to our major competitor nations in the North America, the EU and our near region and the prospect of a scientific workforce insufficient to meet the needs of rapidly expanding biotechnology and education sectors. The latter in turn reflects in part the poor uptake of science subjects at senior high school and university level.

A further barrier to sustaining medical relevance in bioresearch is the progressive withdrawing by state governments, in particular, of informal infrastructure support to clinicians in teaching hospitals. Providing educational courses and accreditation for researchers and industry will not only stimulate further improvement in clinical research standards and investigator sponsored research, but will help fill a significant knowledge gap currently being experienced across industry.

While they do not have the international profile of our major institutes, hospital-affiliated laboratories nevertheless provide an important route to research careers for our brightest clinicians and hospital based scientists as well as re-articulating medical challenges in the light of scientific advances.

**Recommendations:**

- ***Government to continue measures taken over recent funding cycles to increase GERD to internationally competitive levels.***
- ***Government implement adequate incentives for universities and science training institutes to ensure increased numbers and scientific capacity of graduates adequate to meet future needs of publicly funded research, university science training and industry.***
- ***Commonwealth and State Governments to collaborate to create an environment which encourages individual research development by clinicians and scientists in the public hospital system.***

### 3. Pharmaceutical Industry Value Chain – Innovative Global Pharmaceutical Companies are Essential Contributors to Commercialisation

In 2003 Australia had 250 biotech companies, half of which were in the health/biomedical sector. Australia has a well established research and medicines discovery (applied discovery research) capability. However, it lacks capabilities in medicines development, commercialisation and in manufacturing processes to support clinical trials and commercial production.

Innovative Global Pharmaceutical companies' investment in R&D in Australia takes a number of forms:

- Conduct of global and local clinical trials (through establishment of local clinical operations and in collaboration with public and private medical facilities).
  - Trial site notifications in Australia have grown from 400 in 1990/91 to 2300 in 2002/03. Of the trials conducted approximately 50% are estimated to be directly sponsored by pharmaceutical companies and the remainder are investigator initiated.
- Support for basic medical research (through provision of funds and/or pure substance/radio-labelled materials).
  - Pfizer is committed to spending \$184 million on R&D activities in Australia over 4 years (from 1 July 2005 to 30 June 2009). \$50 million of this is in discovery research. With over 60 qualified staff the Pfizer Australia Clinical Research Group has become the largest in the Southern Hemisphere and ranks in the top ten within Pfizer globally.
- Establishment of extended drug development capabilities beyond clinical operations or as Asia Pacific hub:
  - Eli Lilly's Clinical Outcomes Research Institute (CORI) was established as a regional centre of excellence in clinical research (*Evaluation of PIIP*, January 2003, Productivity Commission Research Report).
  - Bristol-Myers Squibb chose its Australian R&D arm as its Asia Pacific research hub for clinical R&D. BMS employs 25 specialists and invests \$5 million annually to R&D in Australia.<sup>5 6</sup>

These partnerships are complementary, with biotech companies and research institutes providing innovation in research and early stage development while global pharmaceutical companies provide finances, human resources, development experience and the ability to commercialise and market opportunities<sup>7</sup>.

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<sup>5</sup> Hill H. *Big pharma and investors eye Australian bio-innovation powerhouse*. Biopharm International, 2004. **17(6)**: 66-72.

<sup>6</sup> Bristol-Myers Squibb Australia. Available: <http://www.bmsa.com.au/about.html>.

<sup>7</sup> Burrill & Company, 2003. *Strategic Partnering Quarterly Newsletter*. Available: [http://www.burrillandco.com/pdfs/partneringNewsletter\\_0903.pdf](http://www.burrillandco.com/pdfs/partneringNewsletter_0903.pdf).

Historically, the greatest investment from global pharmaceutical companies has been in clinical development projects (that is a focus later in the pharmaceutical value chain - such as global clinical trials). In recent years, investment in Australian pre-clinical research projects (that is, moving back up the value chain to basic medical research and potential drug candidates) has increased.

As highlighted in the recent report of the House of Representatives, Standing Committee on Science and Innovation, collaboration between businesses is important in supporting and facilitating innovation. Evidence suggests that proximity matters, and that business collaborations can be encouraged through appropriate support for the development of industry clusters.”<sup>8</sup>

The pharmaceutical industry’s growth in R&D capability over the last decade in Australia (especially its sustained growth in clinical trials) has been a critical factor in creating linkages and business opportunities between the research headquarters within global pharmaceutical companies and Australian research institutions, local biotechnology and local pharmaceutical companies.

The importance of developing new linkages and improving existing partnerships between Australian subsidiaries of global pharmaceutical companies and the local biotech sector is clear, as evidenced by the increasing number of linkages between the pharmaceutical industry and research organisations<sup>9</sup>.

Partnerships between the two are necessary for Australian biotechnology companies and research institutions to complete product development and to ensure marketing and distribution strategies for their discoveries are maximised globally. The dependence of the biotech sector on a robust global pharmaceutical industry for investment via licence agreements, strategic alliances and contract research agreements is especially apparent during times when financial markets are less supportive of high risk investments in the biotech sector<sup>10</sup>. Indeed, AusBiotech has stated that “*Any action that causes contraction of the pharmaceutical sector or reduces its confidence in investing further in Australia will significantly undermine the biotechnology sector*”.<sup>11</sup>

Given the local Australian biotechnology sector’s reliance on the global pharmaceutical companies for funding to allow full development and commercialisation of drug candidates,

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<sup>8</sup> *Pathways to Technological Innovation*, House of Representatives Standing Committee on Science and Innovation, June 2006

<sup>9</sup> The Australian biotech industry has grown significantly (by about 50%) over the past 5 years and has become more robust and commercial. The number of ASX listed biotech companies has increased from 60 in 2001 to 11 at the end of 2005.

<sup>10</sup> AusBiotech, 2003. *AusBiotech Submission to the Review of Pharmaceutical Patent Extensions Policy and Springboarding Arrangements*. Available: <http://www.ausbiotech.org/pdf/review1.pdf>.

<sup>11</sup> AusBiotech, 2003. *AusBiotech Submission to the Review of Pharmaceutical Patent Extensions Policy and Springboarding Arrangements*. Available: <http://www.ausbiotech.org/pdf/review1.pdf>.

it is reasonable to assume that government support for pharmaceutical investment in R&D in Australia is beneficial to research organisations and the biotech sector as a whole.

The internationalisation of research and technology by global corporations complements their manufacturing and sales activities in major markets. “*For most countries there is a strong correlation between foreign affiliate shares of R & D expenditures and their domestic sales.*”<sup>12</sup> Thus, market access barriers relevant to primary and secondary production will also influence head office decisions on dispersion of global corporations’ research activities and investment. Barriers such as the taxation environment, pricing and regulatory procedures also impact decisions on location of R & D investment.

### **3.1 Support for an innovative biopharmaceutical value chain**

Gaps in the value chain include: pre-clinical testing (testing in animals, especially non-rodent models); scale up manufacturing capability for pre-clinical animal trials and to support clinical trials (testing in humans); shortage of highly trained people to design, build and operate manufacturing facilities, as well as process development scientists and engineers; limited capability for actives manufacturing; and very few laboratories and manufacturing facilities which meet international standards.

There are also funding barriers in the areas of medicines development funding and venture capital markets which appear not to be aware of the long lead times involved – 10 to 12 years compared with the 3 to 5 year times in which they expect to see a return on investment. The Australian capital market is not large enough to support an Australian biotechnology company in bringing a product to market. The product pipeline of Australian medicines discovery companies has been estimated to equate to 20 to 25 new drugs. The average capital raised by Australian biomedical companies has been in the range of \$5 to \$10 million. This is small by any measure in the light of the \$US800 million cost of developing a single successful medicine. While licensing their IP is the main exit strategy for Australian biotechnology companies, it appears that low investment quanta limit the resources needed to advance products through development. As a result, Australian companies are often obliged to look for licensing opportunities or public listing too early in their progress along the value chain to provide an investment return competitive with other sectors of the market.

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<sup>12</sup> Globalisation of Industrial R & D: Policy Issues, OECD 1999, p 16-17.

**Recommendations:**

- ***Government ensure a vibrant private financial equity market for biotechnology and related sectors and address market failures in the current venture capital environment.***
- ***Government develop and foster an investment culture appropriate for the long gestation periods required.***

In many instances these gaps force local biomedical companies to go overseas to undertake preclinical animal trials and to seek funding. Both Commonwealth and States Governments have made significant investments in the area of biotechnology. Returns on this investment will only be realised through the commercialisation of the research through partnerships with companies who have the resources to support the cost of development.

Alliances with locally based global pharmaceutical companies will provide Australian Biotechnology companies with access to overseas pre-clinical facilities; access to funding; access to technical expertise; and access to global commercialisation capability.

A central issue for global pharmaceutical companies looking for Australian opportunities in investment and alliances is the business environment and the principal element in pharmaceuticals is the Pharmaceutical Benefits Scheme. The industry supports the principles of the Scheme but its decisions have often been seen as overly focussed on the pharmacoeconomic aspects of its charter at the expense of the needs of patients or the expressed desire of successive governments to support an Australian biopharmaceutical industry. Large companies receive between 5,000 and 10,000 proposals for partnerships each year from all over the world. It is not surprising that the business environment in the country of origin bears on tie-breaking decisions between competing technology offerings.

**Recommendation:**

- ***Government to develop and implement policy settings that reflect the critical role of global pharmaceutical companies as the end customer of publicly and privately funded research.***
- ***PBS policy settings stabilised to provide long term certainty for investors.***

### Dynamic global competition for investment

In October 2003, Pfizer opened its US\$10.5 million Australian Biometrics Centre in Sydney to design and support clinical trials. The Centre managed up to 50 research studies and projects and employed 30 Australian biostatisticians, programmers and data managers.<sup>13</sup> Unfortunately, data management from this facility has now been moved to China to obtain reduced labour costs. Medical writing and statistics has been retained in Australia.

Quintiles, a global Contract Registration Organisation, established data management and statistics capabilities in Adelaide during the 1990s. In 2006 Quintiles has closed its Adelaide data management facility with work moving to India. The company had originally established the facility in Adelaide under a SA Government incentive program.

## 3.2 Technology Transfer

University and institute liaison with global pharmaceutical companies is almost invariably in the hands of technology transfer offices (TTOs). There are almost as many operating and business models as there are TTOs but in general they are charged with formulating and implementing institute policy on IP, negotiating on behalf of research groups and individuals and overseeing commercialisation. In some institutions, IP management is in the hands of a separate group from the commercialisation arm, especially where start up companies have been formed.

TTPs are intended to facilitate the licensing and commercialisation of publicly funded IP but this function is achieved to varying extents. TTOs have been found to act as barriers to the process in the US as well as Australia and the reasons are similar – overemphasis on a legal rather than an educational approach, lack of proactive policies to “mine” IP, poor adherence to timelines and medium understanding of the needs of prospective global pharmaceutical companies customers and the “fit” between research offerings and companies’ strategic priorities.

Licensing offices of larger global pharmaceutical companies have put in place systems of IP “scouting” in Australia, a role assigned to senior company executives, usually with strong science backgrounds. They make preliminary assessments, explain companies’ internal assessment systems and act as champions within their companies for Australian projects. These functions are recent and many Australian research groups who have pre-existing connections with corresponding company discipline groups approach them directly with IP. Such approaches are increasingly referred directly back to the local licensing person who is in a position to champion their work and communicate with the company science offices if direct communication breaks down.

<sup>13</sup> Hill H. *Big pharma and investors eye Australian bio-innovation powerhouse*. Biopharm International, 2004. **17(6)**: 66 -72.

**Recommendation:**

- ***Universities and research institutes institute programmes of education on intellectual property management and patent strategies as part of postgraduate and undergraduate science courses. This must ensure that academic promotion moves from a focus purely on number of publications to a recognition of the critical importance of IP protection over publications.***
- ***University business offices function as enablers rather than barriers.***
- ***Create a business environment where global pharmaceutical companies see value in a proactive local licensing initiative.***



#### 4. Consistent, Predictable and Long Term Innovation Policies

A recent OECD report entitled “*Innovation in Pharmaceutical Biotechnology: Comparing National Innovation Systems at the Sectoral Level*”<sup>14</sup>, used a case study approach across a number of countries to provide an interesting and relevant framework for analysing innovation policies in Australia.

The report proposes that there are first, second and third generation innovation policies for the biopharmaceutical sector.

*The focus of first and second generation policies was on the research and education system, the business system, framework conditions, infrastructure and intermediaries. The focus of third generation policies will be on government itself. An important function is to close the “co-ordination gap” within the government between separate departments that each deal with specific aspects of the innovation chain, but also between national, international and regional governments”.*<sup>15</sup>

It also proposes that effective innovation systems include a mix of policies.

#### 4.1 Australian Government: First and Second Generation Pharmaceutical Industry Policies

##### 4.1.1 Research and research infrastructure

Like many other governments around the world, the Australian Government has tended to focus on first and second generation policies. While GERD has been slipping compared with other like countries, the Government continues to see R&D investment as a key enabler within the industry. The innovative pharmaceutical industry applauds this approach.

The innovative pharmaceutical industry welcomed the 2006-07 budget announcements to increase funding for health and medical research. The investment of \$500 million over four years for the provision of additional grants through the National Health and Medical Research Council (NHMRC), and the \$170 million over nine years to establish a research fellowship scheme through the NHMRC, are positive initiatives to boost the level of medical research undertaken in Australia. Similarly, the National Collaborative Infrastructure Strategy and the \$235 million provided for the development of Australia’s physical R&D infrastructure will act as a further incentive for more researchers to become involved in

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<sup>14</sup> OECD., *Innovation in Pharmaceutical Biotechnology: Comparing National Innovation systems at the Sectoral Level.*, 2006.

<sup>15</sup>Ibid., 2006, page 12

R&D within Australia. It will provide the facilities and equipment necessary to develop the medical breakthroughs of tomorrow.

Our industry is also very supportive of the government's commitment to the Mammalian Cell facility – a facility integral to the continued development of the biopharmaceutical value chain.

#### **4.1.2 Investment Framework Policies: pharmaceutical programs and the R&D Tax Concession**

Most relevant to the innovative pharmaceutical industry has been the commitment of successive Federal Governments to improving the business and investment framework conditions. This is necessary given the path to market for Australian research is dominated by foreign owned global pharmaceutical companies. Hence there are issues of investment attraction and retention of foreign direct investment.

Since the late 1980s the Commonwealth Government has offered incentives for the pharmaceutical industry to undertake R&D or value-added manufacturing activity in Australia. These incentives were a trade-off designed to encourage industry investment despite the relatively poor pricing environment. Such programs are indicative of an early recognition of the need for third generation policies.

##### *Factor (f) Scheme*

Under the Factor (f) scheme, which ran from 1988 to 1999, participating companies were granted notional price increases for PBS listed products in return for increases in R&D or production activity. Expenditure on the Factor (f) scheme totalled approximately \$1 billion and was pivotal in retaining the innovative pharmaceutical industry in Australia. It secured new investment in the face of global rationalisation during the 1980s and 1990s.

Investment in the Factor (f) scheme generated benefits beyond those to the industry itself. As a result of Factor (f) pharmaceutical companies contributed: \$1.9 billion in export value added; \$1.9 billion in domestic value added; \$538 million on R&D expenditure; and \$604 million in investment expenditure over 8 years.<sup>16</sup>

Many of these Factor (f) achievements have had a lasting affect on the Australian pharmaceutical industry and led to many spill-over benefits including the strategic alliances between participant companies such as Pfizer and the Institute of Drug Technology to manufacture an active raw material and benefits outside the industry such as the passing on of skills and technology new to Australia. The following are examples of some of the key outcomes generated through the Factor (f) Scheme.

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<sup>16</sup> Industry Commission., *Report No. 51 The Pharmaceutical Industry.*, 1996., Australian Government.

### The Factor (f) Scheme – Key Outcomes

- 1992 Merck, Sharp & Dohme invested \$75 million on a dedicated plant for a major new product and to expand and upgrade existing facilities.
- 1990, Glaxo and Faulding announced a strategic alliance to develop a sustained release morphine analgesic for the management of severe pain. Faulding, using raw material supplied by Glaxo, manufactured the product.
- CSL announced that it would invest \$13 million in world-class manufacturing facilities and \$14 million in research into vaccines and biosynthetic hormones.
- Bristol-Myers Squibb committed to a \$9 million plant expansion and upgrade and to a \$17.5 million research program
- SmithKline Beecham invested \$26 million at its Dandenong site, doubled exports from \$8 million in 1987/88 to \$19 million in 1992 and increased eligible R&D expenditure from 0 to \$1.7 million in 1992. This created a further 60 skilled jobs at the Dandenong plant.
- Astra Zeneca increased exports from \$8 million in 1990 to \$65 million in 1995, pre-clinical research increased from a base of \$1.5 million in 1993 to \$4.4 million in 1995, created over 100 jobs, and formed a strategic and enduring alliance with Griffith University.
- Factor (f) created over 1000 new jobs.

### Pharmaceutical Industry Investment Program

A new program, the Pharmaceutical Industry Investment Program (PIIP) commenced on 1 July 1999 with \$300 million available over five years in return for commitments to increased investment, research and production value-added (PVA) activities. It aimed to stimulate investment in pharmaceutical activity and to develop Australia as a regional centre of excellence in R&D and manufacturing<sup>17</sup>

This smaller scheme attracted fewer participants – while 17 companies were involved in Factor (f) only nine were successful under PIIP. The limited scope of the PIIP was of concern to the innovative pharmaceutical industry. The companies that participated in PIIP

<sup>17</sup> Department of Industry, Tourism and Resources, 2006. Available: <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?ObjectID=FDBCC43B-898E-4433-AFCA84E5DF7D417D>.

generated around \$1.5 billion in additional activity and increased employment in the sector by 1,000. Under PIIP companies undertook activities worth \$6.2 billion for production value added and almost \$950 million in R&D<sup>18</sup>. In 2003, the Productivity Commission found in its evaluation of the PIIP that participating companies had increased the amount of Phase I and Phase II clinical trials undertaken as a proportion of total R&D, as well as the complexity of research undertaken<sup>19</sup>.

#### Outline of Remuneration and Commitments Under the PIIP

Company	PIIP Funding \$ (million)	Commitments
AMRAD	20	\$ 120m R&D spend; \$ 228m PVA
BMS	39	Double R&D spend; \$ 155m PVA
CSL	60	\$ 300m increase in R&D and PVA
Lilly	20	\$ 100m increase in R&D
F H Faulding	40	Unspecified increases in R&D and PVA
Glaxo Wellcome	27	\$ 137m increase in R&D and PVA
Janssen-Cilag	18	\$ 87m increase in R&D and PVA
Pfizer	39	\$ 194m increase in R&D and PVA
P&U	34	\$ 169m increase in R&D and PVA

Source: Department of Industry, Science and Resources.

#### Pharmaceuticals Partnership Program (P3)

The current scheme the Pharmaceutical Partnership Program (P3), which commenced in July 2004, provides \$150 million over five years with a \$10 million cap per applicant over the life of the program. While welcomed by the industry, the program was a significant reduction on incentives provided under previous program and it supported only a narrow range of activity.

A first year evaluation of the P3 was undertaken by the Centre for International Economics (CIE) for the DITR<sup>20</sup>. This report, while really too early to fully assess the benefits to the value chain and to the Australian economy given the long lead times involved in taking research to market, did find that the program:

- will result in an \$86 million increase in R&D investment
- is highly regarded by the industry and provides government with an avenue to engage with the industry;
- is likely to make a small positive net contribution to the Australian economy through promoting industry investment and associated spill overs – and that this is in addition to the private return to the firms receiving the grants under the program; and
- has promoted a small shift toward more novel R&D spending, generating spill overs that deliver a small net gain to the Australian economy.

<sup>18</sup> Department of Industry, Tourism and Resources, 2006. Available: <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?ObjectID=FDBCC43B-898E-4433-AFCA84E5DF7D417D>.

<sup>19</sup> Department of Industry, Tourism and Resources, 2006. Available: <http://www.industry.gov.au/content/itrinternet/cmscontent.cfm?ObjectID=FDBCC43B-898E-4433-AFCA84E5DF7D417D>.

<sup>20</sup> Centre for International Economics., Pharmaceuticals Partnerships Program: First year evaluation., 27 February 2006.

These results are indicative of a program focussed on improving investment frameworks.

This first year evaluation also noted some concerns with the design of the program, which echo the concerns of the innovative pharmaceutical industry. These can be summarised as follows:

- that the long lead times and the high risk nature of R&D in the biopharmaceutical industry can mean that projects are delayed. This can result in early under spends within a government program. The innovative pharmaceutical industry contends that this is normal and is not indicative of a failure on the behalf of any one participant or the government. It should also not result in a reallocation of funding;
- the incentives would need to be much greater than those under the P3 to have any significant impact on decisions by global pharmaceutical companies to establish an operation in Australia. Many innovative pharmaceutical firms have found that the maximum level of subsidy of \$10 million over 5 years is too small to justify applying for a grant and that the grants available are too small to leverage additional R&D investment from their head offices; and
- the program encourages firms to think about partnerships/collaborations but those that proceeded were largely in train. The industry supports, however, continued focus on collaborative activity across the value chain as this is the path to market for basic research undertaken in Australia but a future program needs to be more flexible to more effectively support new partnerships and collaborations.

The innovative pharmaceutical industry also contends that the five year duration of the program is not reflective of the long pharmaceutical development lead time. This impacts not only on the type of research proposed by participants but could impact on how far along the value chain the research is progressed.

In summary, targeted pharmaceutical industry programs are essential in:

- sending positive signals to global pharmaceutical companies head offices about the investment climate in Australia;
- stimulating partnerships between firms across the biopharmaceutical value chain;
- inducing additional R&D investment by the innovative pharmaceutical industry (as evidenced through evaluations of the Factor (f) scheme and the PIIP). Further evidence can also be drawn through an assessment of the results of programs in place in countries such as Canada, Singapore and Ireland;
- generating spill over benefits for the Australian economy. These include, for example, the transfer of skills backward and forward along the whole value chain.

Globally, most countries provide a mix of support for the biopharmaceutical industry. Most are concerned with a balance between horizontal or generic innovation policies that apply across industries or fields of technology, such as Australia's Commercial Ready program,

and measures cognisant of the sectoral or technological characteristics of biopharmaceutical innovation systems (e.g. P3)<sup>21</sup>.

Australia does currently have a mix although some schemes, such as the R&D Tax Concession, are not broadly available to the local affiliates of global pharmaceutical companies.

The R&D Tax Concession is the principal initiative to increase the amount of R&D undertaken in Australia. In the 2006-07 Budget, the scheme was estimated to provide \$414 million in tax concessions to Australian businesses for their R&D activities each year.<sup>22</sup> This incentive has low compliance costs and a demonstrable effect on increasing BERD within Australia. An R&D Tax Concession can also be more effective in facilitating R&D investment by allowing the companies to more flexibly decide on where to place investments, to scale up investments and to facilitate development of partnerships and networks.

Tax incentives are not unique to Australia but rather could be considered a minimum standard for an active R&D sector when compared to other international benchmarks. They are part of the mix of support needed to encourage innovation.

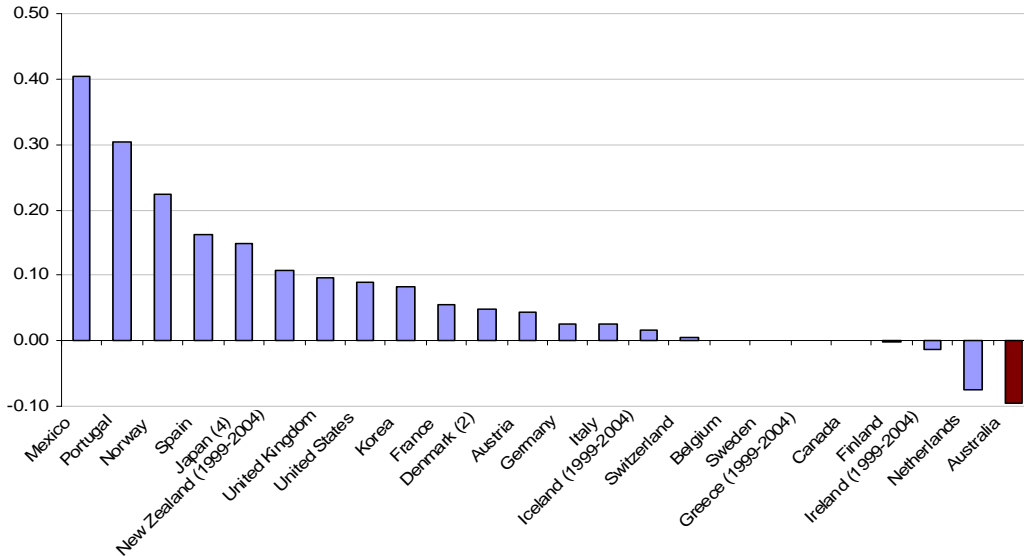
Many competitor nations now offer their own types of tax incentives (see following table) to stimulate both local and international investment in science and innovation. In fact, Australia is one of only three OECD nations that has been decreasing tax subsidies for large firms over the past decade.

<b>Canada</b>	Offers a permanent 20 per cent flat R&D tax credit. Many provincial governments also offer various incentives for research conducted in their provinces.
<b>China</b>	Offers foreign investment enterprises a 150 per cent deduction for R&D expenditures, provided that spending has increased by 10 per cent from the prior year.
<b>France</b>	Allows a 50 per cent R&D tax credit, including a 10 per cent flat credit and a 40 per cent credit for R&D expenditures in excess of average spending over the two previous years.
<b>India</b>	Allows companies a 100 per cent deduction for 10 years for scientific R&D.
<b>Ireland</b>	Offers a 20 per cent tax credit plus a full deduction, as well as a low 12.5 per cent corporate income tax rate.
<b>Japan</b>	Offers a flat 10 per cent R&D tax credit in addition to other incentives.
<b>United Kingdom</b>	Allows a 125 per cent deduction for R&D expenses, plus a 175 per cent deduction for expenditures exceeding a base amount.
<b>United States</b>	Allows a maximum 10 per cent incremental credit for qualified R&D expenditures in excess of a base amount, as well as an "Alternative Incremental Research Credit" formula.

<sup>21</sup> OECD., *Innovation in Pharmaceutical Biotechnology: Comparing National Innovation systems at the Sectoral Level.*, 2006, page 10.

<sup>22</sup> The Hon Ian MacFarlane MP, Media Release, 'R&D Tax Concession – A Winner for Business' 9 May 2006.

### Change in rate of tax subsidies for large firms for US\$1 of R&D, 1995-2004



Source: OECD Science, Technology and Industry Scoreboard 2005.

As noted above, the Australian innovative pharmaceutical industry is not eligible for the tax concession for R&D expenditure. Under the *Income Tax Assessment Act* and the *IR&D Act* the concession is limited to those entities that hold the intellectual property associated with the R&D domestically. This effectively prevents subsidiaries of multi-national entities, for which head office requires intellectual property to be held centrally, from accessing the benefit. For this reason, the concession has “strikingly low impact upon the fields of research associated with the medical and bio-science areas”<sup>23</sup> compared with other industries.

The Productivity Commission has previously considered the economic value of removing the beneficial ownership requirement for the pharmaceutical industry during the evaluation of PIIP. The Productivity Commission recommended that action be taken and this included another form of R&D industry assistance. The implementation of P3 could in part be described as Government’s response to that recommendation.

While lack of access to the concession is used by government to justify ongoing support to the innovative pharmaceutical industry through sector programs, the industry contends that it should be made available to ensure an adequate mix of support similar to other nations in addition to sector specific support programs. This type of support will stimulate additional investment by the pharmaceutical industry as it is cognisant of the long lead times inherent in taking a pharmaceutical product to market – and it is a predictable support mechanism.

<sup>23</sup> Howard Partners, ‘A study of government R&D expenditure by sector and technology’, Emerging Industries Occasional Paper #3, February 2000.

The innovative pharmaceutical industry contends that what is important for the Australian economy is the activity that is generated in not only creating a patentable invention, but in its development and subsequent path to market i.e. investment and job creation. It should not matter where the IP is held or where it is patented first. Access to the concession would have a positive effect on investment in R&D in Australia and would send positive investment signals to head office overseas.

**Recommendations:**

- ***Government needs to ensure a mix of support programs to support continued investment along the biopharmaceutical value chain. The investment support should be of a scale and mix so as to engage global pharmaceutical companies – a key component of the value chain.***
- ***Government to ensure investment policies that are consistent with the long lead times and to allow for variability in timing of spend on R&D programs inherent in the biopharmaceutical industry.***
- ***Predictability in the policy environment through continuing to provide sector specific programs (such as a follow on to the P3 program and an R&D tax incentive program that can be accessed by global companies) to stimulate biopharmaceutical R&D investment.***

#### **4.1.3 Third Generation Innovation Policies**

##### ***Whole of Government Approach – Strengthening the Value Chain***

There needs to be a whole of government approach specifically targeted to attract global innovative pharmaceutical industry R&D investment. The investment climate is currently intensely competitive.

Like many other countries, there are systemic market failures in parts of the biopharmaceutical value chain. Government has demonstrated its recognition of these failures through specific policies and programs. These policies and programs are developed and implemented across the public service.

For example, the Department of Education, Science and Training (and the Australian Research Council) and the NHMRC have responsibility for funding basic biopharmaceutical research. The Department of Industry, Tourism and Resources (DITR) is responsible for



ensuring the investment climate in Australia is conducive to continued private sector investment. The Government (and the Department of Health) are consumers of the end product and their buying power is also relevant in the biopharmaceutical policy environment.

It is important therefore that these departments work together to ensure a strong biopharmaceutical value chain that continues to take basic research up the value chain to realise a return on government investment.

**Recommendation:**

- ***The need for a whole of government approach to policy development and implementation that ensures recognition of the links across the biopharmaceutical value chain and the resultant economic outcomes.***

A whole of government approach with an emphasis on removing impediments to the biopharmaceutical value chain is necessary. One way to do this is to promote collaborative activity amongst the players in the value chain – from research to production. The innovative pharmaceutical industry believes that this is imperative in realising returns on government investment in basic research and in imbedding large manufacturers in Australia with the capacity to take products to market.

#### **4.1.4 Collaborative activity in the pharmaceutical industry**

The innovative pharmaceutical industry is one of the most global industries in terms of alliances and collaborative activities. The OECD in its 2006 study entitled: *Innovation in Pharmaceutical Biotechnology: Comparing National Innovation Systems at the Sectoral Level*; found through surveys of biotechnology firms that

*“a majority of these firms that were involved in collaborative arrangements with other firms had foreign partners...[but that] during the late 1990s there was a noticeable shift towards greater reliance on domestic knowledge sources. This could have been caused by the entry of many new dedicated biotechnology firms that were spun off from universities, firms etc”<sup>24</sup>*

This is certainly true in Australia where many large firms (global pharmaceutical companies) are forming partnerships with other parts of the value chain – both with research institutions and promising small biotechnology firms. Some examples are as follows.

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<sup>24</sup> *Ibid.*, page 11.

**AUSTRALIAN PHARMACEUTICAL COLLABORATION ACROSS THE INDUSTRY VALUE CHAIN**

- AstraZeneca has committed more than AU\$100 million to the Natural Product Discovery (NPD) program in collaboration with Griffith University, Queensland. AstraZeneca has confirmed its involvement through 2007.
- Several of AstraZeneca's 2004 patent applications were based on substances discovered through the NPD program.<sup>1</sup>
- In 2003, Monash University secured a Collaborative Research and Licensing Agreement with Schering AG to develop new potential therapies for prostate disease, male infertility and new contraceptive options.<sup>1</sup>
- Since 1995, the University of Queensland's Centre for Immunology and Cancer Research, CSL and Merck Sharp and Dohme (Australia) have been collaborating on the development of a vaccine for human papilloma virus (HPV). The University of Queensland's Professor Ian Frazer was awarded the '2006 Australian of the Year' for his pioneering work on this vaccine.<sup>1 1</sup>
- In 2003, Australian biotech company Prana announced a commercial collaboration with Schering AG to research new targets and development of diagnostics for Alzheimer's disease. The agreement provided for up to \$7.5 million in funding.<sup>1 1</sup>
- In 2003, Merck Sharp and Dohme (Australia) and Amrad announced an exclusive licensing and multi-year research collaboration agreement with a potential value of US\$112 million plus royalties. As at March 2004, Amrad had received AU\$11 million in milestone payments.<sup>1</sup>
- In 2006, Cytopia Ltd. and Novartis Institute for Biomedical Research Inc. (NIBR) entered into an agreement to develop an oral, small molecule for autoimmune diseases based on the JAK3 enzyme. The deal is worth AUD13 Million over 3 years and up to AUD274 Million for the deal period is successful. (Invest Australia, Inflow, Issue 12: 21 June 2006).
- Pfizer has invested over \$1.7M in the Peter MacCallum Cancer Centre supporting its capacity in Translational Research which included the development and purchase of the world's first Small Animal PET Scanner. This collaboration is seen as a pivotal collaboration for the development of Pfizer's oncology portfolio.

The Australian Government has put in a place a number of collaborative research programs to bring together industry and researchers. Most are generic programs supporting high quality research not just biomedical research.

There are programs administered by the Australian Research Council (linkage grants, centres of excellence and special centres of excellence), the NHMRC (Centres of Clinical Research Excellence and program grants for broadly based collaborative research), DEST

(CRC Program), AFFA (the Rural Research and Development Corporations), and CSIRO (the flagship program). The Australian Stem Cell Centre and the National Information and Communication Technology Centres of Excellence are also examples.

Collaborative research programs should return value to the Australian tax payer and all collaborating partners. For the innovative pharmaceutical industry, which is research-intensive, global and operates with extremely long lead times from discovery to commercialisation, collaborative programs must:

- be of a size and scale to attract international attention - this will serve to generate additional investment and attraction of skills;
- be of a size and scale to attract critical mass of researchers and industry funding;
- encourage the creation of research centres with capabilities that are truly globally competitive – conducting quality research that is world class;
- have funding that is long term i.e. ten years to ensure predictability and capacity to move basic research up the value chain;
- be commercially focussed and industry driven to ensure new products based on Australian ingenuity reach the market;
- limit the number of industry partners in each program to ensure exclusive access to research results; and
- have simple application and reporting requirements to ensure the funds available are spent on the research program.

Most of the collaborative programs listed above do not meet such criteria. The Australian Stem Cell Centre is a good example which is creating some critical mass in a defined area of medical research.

**Recommendations:**

- **Government assist in creating partnerships and networks between global pharmaceutical companies and Australian biotechnology companies/research institutes so as to ensure a rate of return on Government's current investment in basic R&D. It may be timely to undertake a review of the existing collaborative research programs to ensure Government funding on the creation of these linkages is optimised.**
- **That a future DITR investment program for the biopharmaceutical industry rewards all collaborative projects across the value chain and can more effectively accommodate the creation of collaborations.**
- **Government to ensure that investment support is on a time and funding scale that allows projects to move up the value chain to a point where commercial uptake is optimised.**

## 4.2 Globally competitive public policy

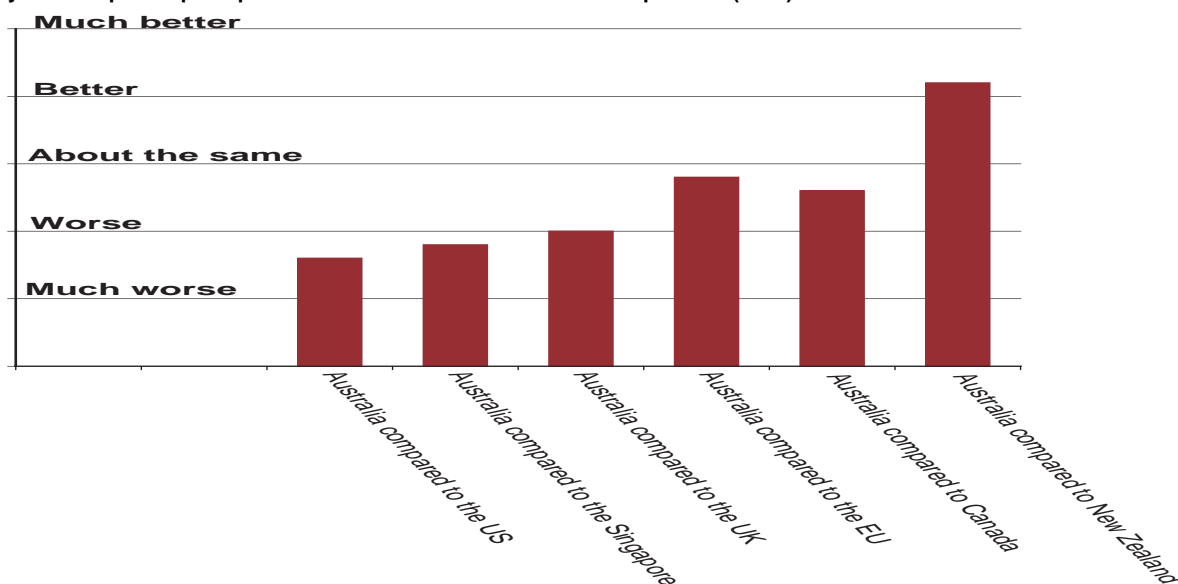
As identified by the OECD in its report Globalisation of Industrial R & D: Policy issues<sup>25</sup> the future for advanced countries lies in transforming themselves into knowledge-based economies, in which new knowledge and technologies are rapidly incorporated by industry to increase productivity and product quality and to reduce time to market. This common goal may pit the industrialised nations against one another in a competition to attract the research and development activities of global corporations (Global pharmaceutical companies).

Investment within the pharmaceutical industry bears out the OECD description of one nation competing with another to attract industrial R & D activity. With pharmaceutical industry investment in production and research activities being dispersed amongst developed and developing nations, Australian affiliates of multi-national corporations, including the Australian offices of Australian-owned companies, must compete with other affiliates to win a larger share of finite investment resources from the parent company.

A survey<sup>26</sup> in 2005 of innovative pharmaceutical companies headquarter perceptions of Australia as a location for R&D investment compared with other countries shows that Australia compared

- Less well with the EU and Canada (between “about the same” and “worse”)
- Much less well with the US, Singapore and the UK (between “worse” to “much worse”).

Survey of headquarter perceptions — Australia’s overall investment position (2005)



<sup>25</sup> OECD 1999, p 8

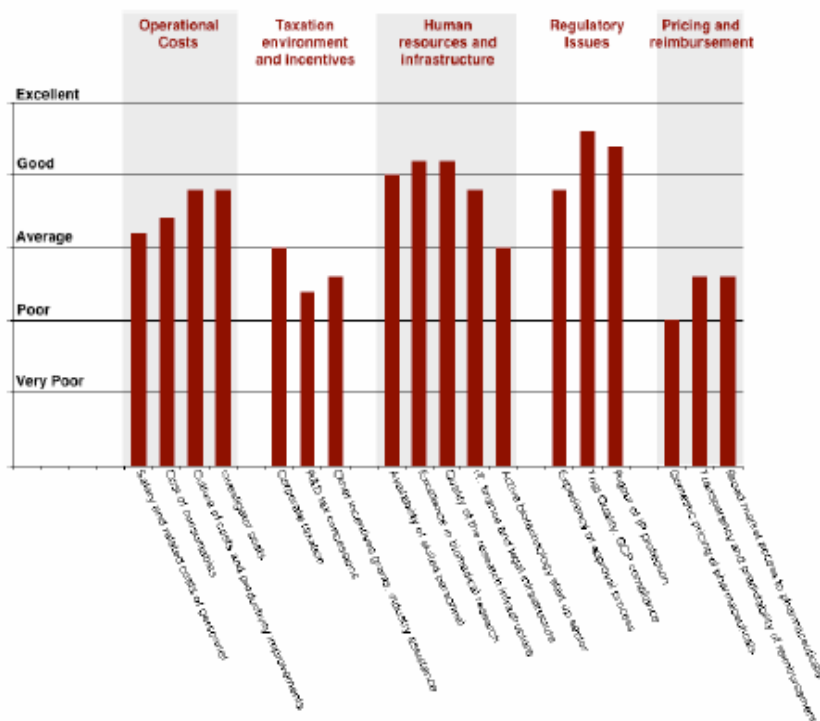
<sup>26</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, Figure 3.2: Survey of Headquarter Perceptions – Australia’s Overall Investment Position (2005), p40

### 4.2.1 Perception of the Australian Investment Climate for R&D

The same survey<sup>27</sup> in 2005 of innovative pharmaceutical companies headquarter perceptions of Australia as a location for R&D investment also highlights two key areas of weakness that negatively impact headquarter perceptions of the attractiveness of Australia for investment:

- Pricing and Reimbursement – market access, transparency and predictability of reimbursement and domestic pricing of pharmaceuticals<sup>28</sup> (which result in low drug prices by world standards - prices around 60 per cent less than US prices<sup>29</sup>)
- Taxation Environment and Incentives - lack of an attractive R&D tax concession and the other incentive programs provided having limited attractiveness<sup>30</sup>

Figure 3.3  
SURVEY OF HEADQUARTER PERCEPTIONS — AUSTRALIA'S R&D PROPOSITION (2005)



<sup>27</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, Figure 3.3: Survey of Headquarter Perceptions – Australia’s R&D Proposition (2005) p41

<sup>28</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, Figure 3.3: Survey of Headquarter Perceptions – Australia’s R&D Proposition (2005) p41

<sup>29</sup> The Productivity Commission, 2003, Evaluation of the PIIP, P3.10.

<sup>30</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, Figure 3.3: Survey of Headquarter Perceptions – Australia’s R&D Proposition (2005) p41

In the 2006 Allen Consulting Group Drivers of Pharmaceutical Investment report, it was asserted that these two key weaknesses in the Australian investment climate “are unlikely to be ‘the tipping factor’ in a large number of decisions, but generally reduce the overall attention paid to Australia and therefore limit its ability to achieve its ‘optimal’ performance in pharmaceutical investment attraction.”<sup>31</sup>

In 2006, further significant changes to the PBS (such as the automatic reduction of innovator pharmaceutical drug pricing at the introduction of generic drugs which has dramatically undermined the certainty of income for innovative drug companies in Australia) has further damaged the headquarters perception of market access, transparency and predictability of reimbursement and domestic pricing of pharmaceuticals in Australia.

Such changes to pricing and reimbursement will lead to reimbursement becoming a ‘tipping’ factor for headquarter decision makers, if it is not already for some companies. New Zealand is a clear example of the devastating outcome on investment in R&D that can result when reimbursement and pricing becomes a clear ‘tipping factor’ in the investment decision (see Case Study Two in Appendices).

#### **4.2.2 Securing innovative pharmaceutical company investment into the future**

To offset the negative impact of the reimbursement issue with headquarters’ decision makers, there is the need for an urgent, significant and radical overhaul of: the R&D Tax Concession and targeted pharmaceutical assistance programmes designed to boost R&D activities and infrastructure.

This should include allowing access for innovative pharmaceutical companies to the R&D Tax Concession without the limitations currently provided by the beneficial ownership test applied to Intellectual Property. There is also the need to develop targeted pharmaceutical industry assistance programmes (designed to boost R&D activities and infrastructure) that are globally competitive in character while also being simple for headquarters decision makers to understand.

Independently, The House of Representatives Standing Committee on Science and Innovation has made similar recommendations in their Report on Pathways to Technological Innovation (June 2006):

- “implement support mechanisms to specifically assist the progression of innovation through pathways other than the formation of start-up companies” (Recommendation 14).
- “assess the revenue implications and potential economic returns of extending the R&D tax concessions eligibility to include Australia based subsidiaries of global companies” (Recommendation 15).

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<sup>31</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, p46

There is clear evidence that the pharmaceutical industry responds to fiscal and economic drivers by investing in countries whose governments have instituted policies to address market access barriers. Australia under the Pharmaceutical Industry Development Program (Factor (f) Scheme (Phase I and II) and the Pharmaceutical Industry Investment Program (PIIP) are relevant examples; Canada, Singapore and Ireland provide international examples of where governments' explicit policies to competitively attract a larger proportion of pharmaceutical industry investment have been highly successful.

In this regard, Australia could consider Canada in more detail given that it also has a restrictive reimbursement system while having taken a very different approach to incentives for pharmaceutical R&D (see Case Study One in Appendices).

#### **4.2.3 India, China and Competitors from the Developing World**

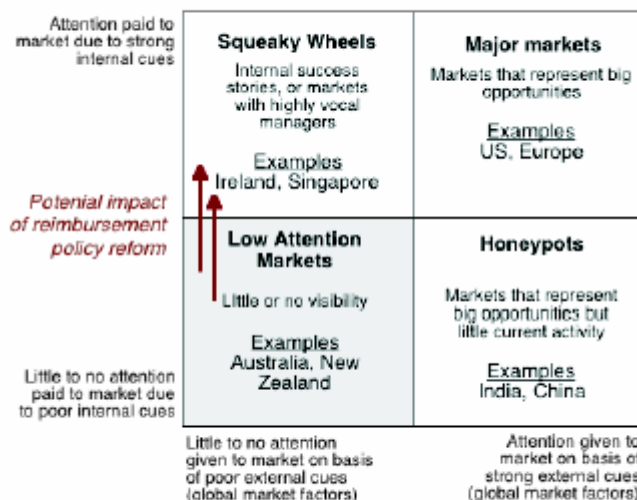
The global pharmaceutical environment is growing increasingly competitive. In particular, a number of countries from the developing world are becoming much greater competitors for clinical trials. These countries already have relative advantages in regards to costs and size of patient populations (for rapid patient recruitment and significant contributions to global clinical trial programmes). Their emergence as key competitors with Australia for investment in R&D is growing rapidly as their quality of biomedical research continues to improve, their quality of clinical trials improves, their regulatory timelines for trial approvals fall and with the very significant growth in their pharmaceutical markets and a huge market potential.

In the last 12 months, Australia has seen the loss of two global clinical trial data management facilities from Australia – the Pfizer capability to China and the Quintiles capability to India. These losses are indicative of the growing competition from China and India for Australia in clinical research.

**Australia needs to send a strong positive signal to global pharmaceutical companies.**

Figure 4.1

**MARKET CLASSIFICATIONS ACCORDING TO SOURCES OF GLOBAL ATTENTION**



Source: The Allen Consulting Group adaptation of London Business School's Sources of Global Attention framework, see, Birkinshaw, J., and C. Bouquet, 2005, *Getting the Attention You Need: Strategies for the Australian Subsidiary*, London Business School in association with CEO Forum.

If Australia is going to continue to maintain (or hopes to grow) international investment, it must provide a more favourable investment environment in order to positively differentiate itself in the global environment (see figure 4.1 Market Classifications according to sources of global attention<sup>32</sup>). The Government must implement appropriate policies to overcome the market access barriers to investment.

Without such a strong positive signal, then at best we will maintain the current level of investment for the short term and at worst will rapidly lose investment to India and China (as already seen with Pfizer and Quintiles data management centres in the last 12 months).

Medicines Australia hopes that the current Review of Public Support for Science and Innovation by the Productivity Commission will recommend policy solutions that will stimulate greater investment in research and development in Australia.

As well as creating policy settings that are globally competitive, it is critical that the policy settings are simple and easily understood. As discussed above in a world of intense global competition for R&D investment, small markets such as Australia often have a limited opportunity granted to gain headquarters' attention to R&D investment opportunities. It is therefore critical that the policies are simple and allow the attractiveness of R&D investment in Australia to be clear, unambiguous and clearly will be simple to administer for the company.

<sup>32</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, p 62



Consideration should be given to the development of a transparent Australian costing model to provide a reference point for the cost of investigations, study staff time, pathology costs and institutional overheads. Currently each institution charges independently and institutional overheads in particular are beginning to make research at individual sites prohibitive. An example of this is the University of NSW which is now charging 30% overhead.

**Recommendations:**

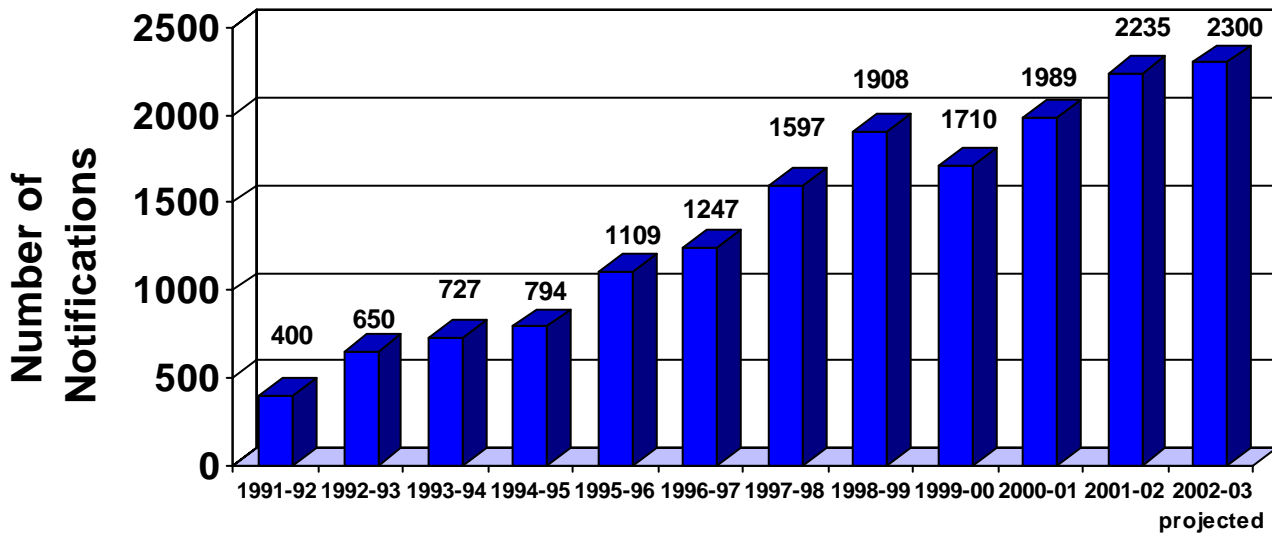
- ***Government policy settings should recognise that the Australian biopharmaceutical sector functions in an intensively competitive international market for both investment in discovery R&D, clinical trials and infrastructure.***
- ***Programs need to be easily understandable for effective communication to international headquarters***

#### **4.2.4 Globally Competitive Regulatory Framework**

For Australia to effectively compete for global investment in R&D, Australia needs to have a globally competitive regulatory environment.

The importance of this is highlighted by the very positive response from the innovative pharmaceutical companies to a more streamlined and timely regulatory environment for conducting clinical trials in Australia created following the Baume Report. Following changes to the regulation of the conduct of clinical trials in May 1991 and the introduction of the Clinical Trial Notification Scheme (CTN), the number of clinical trials conducted in Australia has dramatically increased. In this instance the government provided a response to the market access barrier of long delays in clinical trial regulatory “approval” and comparatively high regulatory costs under the Clinical Trial Exemption Scheme (CTX). The increase in clinical trial notifications since May 1991 is shown in figure below.

**Clinical Trial Notifications, per annum, 91-92 to 02-03**



There are significant activities currently underway to streamline the ethical review process for multicentre clinical trials in Australia that promise a great productivity boost and decrease in startup times for clinical trials in Australia.<sup>33</sup>

In parallel, there has been a report commissioned by NHMRC and TGA into Access to Unapproved Therapeutic Goods in Australia<sup>34</sup> in preparation for the formation of the Australian New Zealand Therapeutic Products Authority (ANZTPA). A formal Government response to this review is still awaited; however some legislation relating to clinical trial approval regulations has been released. This shows that there will be some clinical trials that will require mandated centralised regulatory review in addition to ethical review (details in regard to criteria for specifying these trials is at present not released). This is of concern to the industry as to-date the CTN scheme has been available for all trials in Australia and it has been used very responsibly by both sponsors and human research ethics committees. While industry supports the view that all clinical trials should have appropriate regulatory oversight to ensure patient safety, mandated centralised regulatory review in Australia should be very carefully defined to ensure that it only occurs when competent regulatory &/or scientific review is otherwise unavailable or has not been conducted on a (generally early phase) clinical trial.

<sup>33</sup> add DITR website URL here for the National Forum report from March 2006

<sup>34</sup> add reference here to Bansemer report

**Recommendation**

***The new ANZTPA regulatory framework must produce timely clinical trials start-ups while ensuring adequate protections for patient safety through a rational evaluation of trial risk.***

The Clinical Research Approval Environment is becoming increasingly legalistic resulting in significantly longer study start-up times. This is directly related to legal hurdles placed by Institutions' outsourced legal teams who are inexperienced in Clinical Research who are practising defensively. For example:

- Queensland Government drawn out process in accepting a Medicines Australia Clinical Trial Agreement and Indemnity Statement and Compensation Clause.
- The VMIA requirements are causing serious difficulties in Victoria due to their Insurance guidelines stipulating treatment in Government Hospitals and Doctors only as opposed to the standard Medicines Australia Compensation Guidelines.

**Recommendation**

***That a nationally accepted Clinical Trials Agreement, Statement of Indemnity and Compensation Guidelines be developed so as to minimise delay in study start-up times.***

There has been a discussion of the impact of the current reimbursement system in Australia on headquarter perceptions for investment in R&D elsewhere in this submission. As well as the impact of the policy setting on investment, the regulatory steps involved in gaining reimbursement and time to reimbursement also impact investment in R&D in Australia. For instance, in life threatening conditions many headquarters will agree to supply the new drug globally to trial patients through an extension study or compassionate use programme until the drug is marketed. In Australia, the fact that a drug is approved for marketing does not make the drug available for patient access.

Reimbursement of the drug is normally required for ethics committees to consider that patients truly have ready access to a new therapy after their involvement in a clinical trial. Australian affiliates of MNC therefore often have to go back and negotiate for supplies for Australian trials patients to be extended at least 1-2 years beyond the end of the trial with the knowledge that there is the possibility that the product will never be reimbursed and released in Australia. So quite aside from the impact of the reimbursement system in Australia in regard to global pricing, there are practical considerations that inhibit the conduct of clinical trials in Australia.

Furthermore, under the World Medical Association Declaration of Helsinki (the ethical underpinnings for all human experimentation) there is an ethical imperative not to conduct clinical trials in a country where there is no prospect that the drug will be marketed. When conducting clinical trials companies have no way of knowing the outcome of the trials and whether they will provide adequate data to ensure reimbursement in Australia.

In some therapeutic areas however, review of the development plan can predict with a high level of confidence that the trials being conducted will not provide data to support reimbursement in Australia at a globally acceptable level. For example, Novartis Pharmaceuticals Australia Pty Limited has stated they have declined involvement in significant global development trials with key new compounds in non-insulin dependent diabetes (vildagliptin) and in hypertension (aliskiren) – both first in class compounds and both due to concerns over reimbursement in the initially expected indications. This denies Australian patients and clinician access to and experience with first in class new therapies for key health concerns for Australia – type II diabetes and cardiovascular disease. Both these innovative compounds offer the theoretical potential for a major improvement in long term outcomes for patients, however this data will only come from long term trials (5 years) and Australia will not be involved in these trials.

**Recommendation**

***Recognition by Government of the link between reimbursement and investment activity and consideration to how the impacts can be minimised to support and encourage the development of innovative medicines in Australia.***

Australia's intellectual property regime is well constructed and well respected in the developing world. It is not however considered to be world's best practice and recent proposed amendments to allow earlier development of generic medicines before the expiry of the patent are not being counterbalanced by initiatives such as an increase in data exclusivity to 10 years.

**Recommendation**

***Implementation by Government of world's best practice in intellectual property.***

## **APPENDICIES**

Case Study One – Comparison between Incentives for Investment in Canada

Case Study Two – The New Zealand Warning

Case Study Three – Opportunities and challenges for attracting investment in R&D –  
clinical Trials

Medicines Australia - Background

## Case Study - Comparison to Incentives for Investment in Canada

To continue to maintain or especially to grow investment in research and development (R&D) in Australia by global pharmaceutical companies, there needs to be a whole of Government approach specifically targeted to attract global industry R&D investment. This approach is supported by Proposed action 4.3.1 of the Investment Review of Health and Medical Research (Grant Report) December 2004. Such a strategy can meet with success as evidenced by the Canadian experience.

The Canadian biopharmaceutical industry development experience is an excellent case study in that it supports the OECD contention that you need a mix of first, second and third generation policies and it is a good example to consider given its many similarities to Australia in respect of government structure, pharmaceutical reimbursements, size of local market, population size and corporate tax rate.

"Canada accounted for 10 percent of all global medicines discovered in 2001, despite its small population and sales figures, and reported an R&D intensity equivalent to the global average of 17.7 per cent."<sup>35</sup> Canada is a good example to consider as it has many similarities to Australia in regards to government structure, pharmaceutical reimbursement, size of local pharmaceutical market compared to the global market, population size and corporate tax rate.

The key differences are the proximity to the US market and the incentives provided to global pharmaceutical companies – which includes uncapped scientific research and experimental development credits of 20 per cent to large companies on all R&D and 35 per cent to Canadian corporations. A 1997 Evaluation Report<sup>36</sup> estimated a cost effectiveness of 1:38 (that is for each dollar of tax revenues foregone, there was an additional \$1.38 in spending). The report found this to be a cost-effective system.

More recently in a paper produced in 2004 by the Centre for Strategic Economic Studies<sup>37</sup> there was a comparison of the output from local biotech and pharmaceutical companies between Australia and Canada. It found that "Canada's biomedical innovation system has enjoyed a much higher level of commercial success than Australia's. Even based on the partial data we have, the number of drug candidates in Phase 3 is many times that in Australia."

It also goes on to observe that "Compared to Canada, Australia has significantly under-invested in private R&D in health and while the growth rates for the last decade have been about the same, the gap has remained large. Over this period the Commonwealth has significantly wound back its business innovation support schemes, in particular, the R&D tax concession arrangements, while Canada has made its more attractive."

It concludes that if "Australia's biomedical innovation system was to match the performance of Canada's, this analysis suggests that industry policy could usefully focus on three aspects:

- Public expenditure on health and biotech related R&D
- Funding to complement private financing of commercial development
- Policies designed to attract large pharmaceutical companies to partner biotechnology companies.

Medicines Australia contends that policies designed to attract large pharmaceutical companies to bring more research and development activities to Australia, will result in more likelihood of local biotechnology and pharmaceutical companies partnering with global pharmaceutical companies for mutual benefit.

<sup>35</sup> The Allen Consulting Group, Drivers of Pharmaceutical Industry Investment, September 2006, p 61

<sup>36</sup> Dept of Finance Canada and Revenue Canada, Dec 1997, The Federal System of Income Tax Incentives for Scientific research and Experimental Development: Evaluation report

<sup>37</sup> Bruce Rasmussen An Analysis of the Biomedical Sectors in Australia and Canada in a National Innovation Systems Context, Working paper No. 21

Linkages will result from proximity as highlighted in the recent House of Representatives Standing Committee report on Science and Innovation which states that “evidence suggests that proximity matters, and that business collaborations can be encouraged through appropriate support for the development of industry clusters”.

The report also recommends that the Australian Government:

- Implement support mechanisms to specifically assist the progression of innovation through pathways other than the formation of start-up companies (Recommendation 14).
- Assess the revenue implications and potential economic returns of extending the R&D Tax Concession eligibility to include Australian based subsidiaries of multinational companies (Recommendation 15).

Together these recommendations signal a move to support innovation through a decreased focus on only supporting SMEs and an increased support for global corporations as a means of boosting innovation.

**CASE  
STUDY  
TWO**

## **The New Zealand Warning**

A recent report on the impact of PHARMAC on pharmaceutical research and development in New Zealand highlights that “increasingly pharmaceutical companies are linking the placement of clinical research with the prospect of the product in clinical development being reimbursed in the country.”<sup>38</sup>

The 2006 report goes on to conclude, “In the last few years it has become increasingly clear that it is impossible to have PHARMAC in its present form and also have a robust biomedical environment from which to develop a sustainable local biotechnology industry.”<sup>39</sup>

Australian policy makers must not be under any delusions that the current positive perceptions of Australia’s:

- quality of biomedical research in Australia,
- the high quality of clinical trials in Australia,
- the low cost of clinical trials (relative to developed markets) or
- efficient regulatory processes

will not prevail should a very significant negative view of Australia be developed by headquarter decision makers on the basis of Australia’s policy towards market access, transparency and predictability of reimbursement of pharmaceuticals.

The withdrawal from research and development investment by innovative pharmaceutical companies in New Zealand must be seen as a concrete example of what Australia must avoid. New Zealand Government policy settings in regard to pricing and reimbursement have been to the severe detriment of biomedical research, conduct of clinical trials and the New Zealand biotechnology industry.

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<sup>38</sup> Dr Edward Watson, Nazadel Ltd, Pharmaceutical Research and Development in New Zealand on the Brink of the Abyss, May 2006, p 32.

<sup>39</sup> Dr Edward Watson, Nazadel Ltd, Pharmaceutical Research and Development in New Zealand on the Brink of the Abyss, May 2006, p 32.



**CASE  
STUDY  
THREE**
**Opportunities and challenges for attracting investment in R&D - clinical trials**

Clinical trials account for nearly half (42%) of all R&D spending in Australia which is significantly higher as a percentage of R&D spend than in the US (34%)<sup>40</sup>.

For some years Australia has enjoyed a relative competitive advantage over regional neighbours in terms of the quality of medical research, the cost of conducting clinical trials and the speed with which trials can be initiated (Clinical Trial Notification Scheme) and completed.

However, our competitive advantage is being eroded as other countries in the region have improved the quality of their own research capability, maintained low costs and are able to meet recruitment targets faster due to the availability of large population pools. In addition, both India and China provide the attraction of R&D investment in a rapidly growing and potentially very large pharmaceutical market.

There are a number of significant threats to maintaining or growing the current amount of activity in Australia in regards global clinical trials:

- Possible negative impact of the new ANZTPA trial approval processes on the current rapid clinical trial notification process :

The recently announced arrangements under the ANZTPA will require some clinical trials to go through a central ANZTPA review process. It is presently unclear which trials will require mandated centralised ANZTPA review, but the concern is that this review process will be significantly slower than the current CTN scheme and may render Australia globally uncompetitive in regards start-up timelines for clinical trials.

- Lower cost competitors with rapidly growing markets with large patient pools (China and India):

India and China have not historically contributed substantially to global clinical development programmes. However increasing quality, large patient populations, low cost, improving regulatory approval times for trials and their market potential are all driving investment into these countries.

- Reimbursement considerations leading to ethical objections to placing trials in Australia:

Aside from the negative image of Australia created through the distorted market for pharmaceuticals reimbursement in Australia; under the World Medical Association Declaration of Helsinki (the ethical underpinnings for all human experimentation) there is an ethical imperative not to conduct clinical trials in a country where there is no prospect that the drug will be marketed. For example, Novartis Pharmaceuticals Australia Pty Limited has stated they have declined involvement in significant global development trials with key new compounds in non-insulin dependent diabetes (vildagliptin) and in hypertension (aliskiren) – both first in class compounds and both due to concerns over reimbursement. This denies Australian patients and clinician access to and experience with first in class new therapies for key health concerns for Australia – type II diabetes and cardiovascular disease.

<sup>40</sup> The Allen Consulting Group, *Drivers of Pharmaceutical Industry Investment*, September 2006, p46

## **Medicines Australia - Background**

Medicines Australia is the national association representing the innovative medicines industry in Australia. Member companies represent more than 90 percent of the prescription market and are engaged in the research, development, manufacture, marketing and export of prescription medicines.

In partnership with key stakeholders Medicines Australia strives to drive the creation and development of a positive environment for the sustainable growth of the innovative and research-based prescription medicines industry. We are committed to enhancing the health of all Australians by providing timely and universal access to medicines of the highest quality, safety and efficacy.

A viable, diverse, research-based pharmaceutical industry operating in a competitive health care market is essential to achieving optimal patient health and wellbeing, while making a significant contribution to the Australian economy. As a prime example of a high technology, knowledge-intensive industry, it is a major contributor to employment growth and export expansion.

Medicines Australia promotes the interests of the industry by encouraging a favourable investment environment, working on behalf of its members in an advocacy and consultative capacity with government and non-government organisations in Australia and overseas.