AusBiotech Submission

to the

Productivity Commission Review of the

Pharmaceuticals Industry Investment Program (PIIP)

16 January, 2003

Executive Summary

The Australian biotechnology sector is developing at a significant pace as exemplified by growth in membership of AusBiotech Limited (Australia's biotechnology organisation) from approximately 350 members in mid 2001 to more than 1300 at the end of 2002. AusBiotech is the peak Australian biotechnology industry organisation representing a broad range of traditional and entrepreneurial biosciences such as, but not limited to, human and animal health, agriculture and food, diagnostics, medical and veterinary devices, bioinformatics, genomics, proteomics, nanotechnology, manufacturing, and environmental technologies.

Approximately 65% of products being developed by Australia's biotechnology companies relate to human health, including pharmaceuticals, medical diagnostics and medical devices. These products arise from research undertaken in Australian universities, CSIRO and private and public research institutes, Co-operative Research Centres (CRCs) and from within biotechnology companies themselves.

The Australian biotechnology sector is at a vulnerable stage of its growth and development cycle, with the confidence of investors currently waning. A continued growth of the human health related sector of the Australian biotechnology industry is likely to be facilitated by the presence of a robust, growing, local pharmaceutical sector, as has been the case elsewhere in the world.

Government intervention through the PIIP and its predecessor, the Factor (f) Scheme has been successful in creating growth of the Australian pharmaceutical industry in both *"Production Value Added*" and *"Research and Development"* areas. This has served to create a more favourable environment in which multinational pharmaceutical corporations can operate in Australia with a significant *"spillover effect"* into the biotechnology sector.

AusBiotech Limited supports a continuation of an industry development program along the lines proposed in the Pharmaceutical Industry Action Agenda, and as endorsed by the government in the latter part of 2002. Such a program will facilitate the growth of the pharmaceutical sector in Australia, which is vital for growth of a substantial part of the Australian biotechnology and associated sectors.

The Productivity Commission has been asked to undertake an evaluation of the Pharmaceutical Industry Investment Program (PIIP). As part of this evaluation, the Productivity Commission has advised AusBiotech that:

- The Terms of Reference ask that the Commission include the biomedical/bioscience sector in its definition of the pharmaceutical industry.
- The Commission notes that the pharmaceutical industry is engaging increasingly in collaborative R&D with biotech companies.
- The Commission would like information on the options for future industry development schemes and whether these should treat the biotechnology sector as part of the pharmaceutical industry

The Commission has requested a brief profile of the biotechnology sector to gain a better understanding of the industry.

In response to the Productivity Commission's advice to AusBiotech, representatives of AusBiotech have reviewed the Productivity Commission's draft Research Report, "Evaluation of the PIIP" and attended PIIP Evaluation Roundtable Discussions in Sydney (9/12/02) and Melbourne (11/12/02). AusBiotech's comments are outlined in this document.

2. Pharmaceutical Products from Australian Biotechnology

Biotechnology spans many industries including pharmaceuticals, medical diagnostics and devices, agriculture, veterinary medicine and diagnostics, food processing, bioinformatics, genomics, proteomics, nanotechnology and manufacturing, and environmental management. Biotechnology is used across the pharmaceutical *"value chain"* (below) either in research or by small or large companies, and can be the basis of the research being undertaken to develop new products, can be the new products or can be part of an industrial process that makes other products. A significant number of new developments in the pharmaceutical sector worldwide are currently sourced from biotechnology researchers.

The biotechnology sector is a high value added industry, with the potential to provide career development opportunities for Australian graduates, export income from product development, import replacement and of course, like the pharmaceutical industry, products and technologies that improve the human health and wellbeing.

Pharmaceutical Value Chain

Universities/Research Institutes	Small Start-Up Companies	Small-Medium Expansion Companies	Large MNC Pharmaceutical Companies
Discovery Research	Proof-of-Concept & Pre-Clinical Studies	Development and Clinical Trials (Phase I, IIA, etc.)	Completion of Product Development & Marketing

Moving from Left to Right in the Value Chain there is Increasing Value and Decreasing Risk

Australian scientists are regarded highly worldwide for their expertise in medical and clinical research. However, the track record for adding value to research and commercialising the outcomes of this research, is still poor. The primary routes for research commercialisation, that are discussed in more detail in 2.1 and 2.2, are:

- The product / technology can be developed to a point at which it will be attractive for licensing to larger companies, such as pharmaceutical companies, that have the capability to complete development and undertake the subsequent marketing activities.
- The product /technology can be licensed into a biotechnology company where further development can take place until it is ready for a pharmaceutical company.
- The product / technology can be developed by the originating scientists, for example, via a start-up company, if there exists the capability required to develop it to such a stage required for licensing, as above.

The choice of pathway will be determined by several factors, including the type of product / technology under development, the stage of development, and the requirements for commercialisation and thus who best can meet those needs.

The poor record in commercialisation in Australia is due to a number of factors (discussed more fully in the Pharmaceutical Industry Action Agenda). However, of pertinence in relation to this Submission, is the fact that Australia has a shortage of people with the skills, experience and qualifications required to assist with licensing and/or further development and clinical trialing of products. In addition, intellectual property (IP) management in research institutions and universities continues, in general, to be poor, and together with the lack of management skills, the transfer of technology to biotechnology and pharmaceutical companies is difficult, often complex and consequently slow. Fortunately, such skills are beginning to be accessed from the experienced pharmaceutical sector exemplifying, from the biotechnology perspective at least, the need to maintain the development of a vibrant pharmaceutical industry in Australia.

2.1 Licensing Technology to Pharmaceutical Companies

The cost of developing pharmaceutical products is high, the time to take technology from the bench to a product is lengthy and the risk of the product not getting to the market and providing a return, is very high.[1] [2] Therefore, a common route for commercialisation for a research project within a university/research institution is through partnerships with an interested strategic partner, such as a multinational pharmaceutical company (MNC). One major benefit of such a partnership, is that the university/research institution has access to, and can gain an understanding of, the commercially focussed approach and expertise that exists within the MNC. The knowledge that can be gained from an understanding of what makes a product marketable, and how a project must be conducted, in order to ensure the product becomes market-ready and market-acceptable, is very valuable.

Given a choice between an early, promising development and one that has demonstrated some proof of concept, MNCs will prefer to take the second option and license in technology that has progressed further down the development path, and so carries lower risk of failure.

Consequently, a vibrant, sustainable pharmaceutical industry in Australia is important, not only for the pharmaceutical industry itself and the benefits thus brought to the Australian economy, but also for the continued growth of Australia's fledgling biotechnology industry.

2.2 Development of Potential Pharmaceuticals from Biotechnology Companies

An alternate route for pharmaceutical product development to the building of strategic alliances with MNCs, as described above, is through alliances with smaller, more strategically focussed biotechnology companies. These are smaller companies, focussed on a particular area of development[3], funded by private investors or public capital markets such as the Australian Stock Exchange and generally created to develop a specific technology from discovery research.

The majority of Australia's more than 275 biotechnology companies are developing high value products from Australian research, especially pharmaceuticals, medical diagnostics and medical devices. Approximately 65% of products being developed by biotechnology companies relate to human health including pharmaceuticals[4]. These products arise predominantly from publicly funded research undertaken in Australian universities, CSIRO and private and public research institutes, Co-operative Research Centres (CRCs) as well as from within biotechnology companies.

Biotechnology companies depend on a number of key requirements for their successful start-up and growth, such as:

- The product being developed from research must address a well-defined market need in a large, growing, global market;
- The product must have a competitive advantage compared to other products in the market;
- The ownership of the intellectual property being developed must be clear and able to reside within the biotechnology company, or the company must have exclusive rights to the intellectual property. A large proportion of the value of a biotechnology company resides in the intellectual property owned by the company. It is critical for the survival and growth of

[1] The Ernst & Young Global Biotechnology Report 2002 notes that "from the point a drug candidate is identified in the lab, it takes an investment of up to 15 years and (US)$800 million to bring it to patients". In addition, Medicines Australia's latest figures indicate that only 1 in 5-10,000 compounds screened actually make it to market.

[2] The Ernst & Young Global Biotechnology Report 2002 states that "from the point a drug candidate is identified in the lab, it takes an investment of up to 15 years and (US)$800 million to bring it to patients."

[3] Note that not all products developed by biotechnology companies are based on biotechnology or biological substances. A number of Australian companies are developing products that are new chemical entities.

[4] Ernst & Young/Freehills Australian Biotechnology Report 2001

the companies that the intellectual property is able to be developed and subsequently traded (licensed or sold) at significant increases in value;

- The company must have experienced, commercial management and a strong research team with excellent scientific skills; and
- Biotechnology companies require substantial investment from private and public sector investors to develop the products in their portfolios. This high-risk investment generally comes from the venture capital community, private/angel investors, strategic investors and/or through the capital markets such as the Australian Stock Exchange. This can also include investment from MNCs.

Because of the cost of developing pharmaceutical products, partnerships with MNCs are necessary to complete product development and to ensure the marketing and distribution strategies for the biotechnology company's products are maximised globally. Partnerships can include, but are not limited to, licence agreements, strategic alliances, contract research agreements and joint ventures.

Further development of the product within biotechnology companies provides a number of benefits to the multinational pharmaceutical companies, such as:

- A biotechnology company can develop the product through the early stage, higher risk period, generally obtaining at least Phase I and early Phase II clinical trial data. This enables the MNC to obtain a licence to the product at a lower risk stage in development when the potential product is more advanced. (Consequently, the value is higher and is reflected in the licence arrangements);
- Biotechnology companies are generally more flexible in their decision-making than MNCs and can if necessary, make rapid decisions to change the direction of their work to obtain more fruitful outcomes. This can be very valuable to the MNC working as a strategic partner with the biotechnology company;
- The scientists working within Australian biotechnology companies or contracted to them are often world leaders in their particular fields of research. This is attractive to potential partners as the quality of the research the MNC has access to is therefore very high; and
- Both research and development can generally be undertaken at a lower cost in Australia than in the US and many parts of Europe.

The Australian biotechnology sector is at a critical and vulnerable stage in the development of its growth and expansion. Unlike the US and Europe, Australia does not have a large local pharmaceutical industry that can assist with product development. The importance of developing new linkages between biotechnology companies and local subsidiaries of multinational pharmaceutical companies, and improving the value of existing ones and has been highlighted in the Pharmaceuticals Industry Action Agenda.

During periods in which the financial markets are less supportive of high risk investments in the biotechnology sector, such as we are currently experiencing in Australia, the need for a robust, growing pharmaceuticals sector is even more critical. Any action that can increase the pharmaceutical sectors' confidence in investing further in Australia and that can prevent the contraction of the local pharmaceutical sector will significantly assist the growth of the biotechnology sector and further strengthen the commercialisation of research outputs.

3. A Ten Year Industry Development Package

One of the key recommendations in the Pharmaceuticals Industry Action Agenda is a proposal for an industry development program that will be the successor to the Pharmaceutical Industry Investment Program (PIIP) that expires in 2004. This new program is regarded as a cornerstone of a group of actions that will achieve the goals of the Action Agenda and drive substantial growth

of the pharmaceuticals sector with consequent and significant *"spillover"* effects into the biotechnology sector. Cabinet recently accepted the Pharmaceuticals Industry Action Agenda.

AusBiotech contributed to the Pharmaceuticals Industry Action Agenda and strongly supports the development of a new Program to replace PIIP for the reasons outlined above.

The Pharmaceuticals Industry Action Agenda acknowledged that the Australian pharmaceutical industry is at a watershed. The Australian industry has a strong platform from which to build a presence in the global pharmaceuticals industry including:

- A strong, internationally competitive basic science capability, which in certain fields is among the best in the world;
- Globally competitive cost structures for research and development;
- Intellectual property laws and regulation of therapeutic goods that are among the best in the world;
- Effective rules of law;
- An educated, highly skilled and English-speaking workforce; and
- A stable political system.

However, there are a number of factors that impede Australia's ability to build on the Nation's strengths and discourage international investment from financial markets and overseas-based MNCs. These factors include:

- Ineffective and few connections between the various parts of the value chain within Australia;
- Poor commercialisation of research outcomes;
- Diminishing returns on investment due to lower prices for products through the Pharmaceutical Benefits Scheme (PBS). Consequently, the current pricing of therapeutic products negatively impacts the ability of Australian subsidiaries of MNCs to obtain investment in Australia for additional R&D activities;
- Low interest by global companies to sustain and build their presence here because of negative perceptions of Australia's business and investment environment, especially in relation to the pharmaceutical sector;
- Low interest by global companies to sustain and build their presence here because of lack of recognition of Australia as a source of valuable drug discovery;
- The vulnerability of existing manufacturing plants to global rationalisation; and
- The absence of a pre-clinical infrastructure and a substantial primary manufacturing sector, an activity which has high value-add, and the ability to attract critical mass to the industry.

The need for increased links across the pharmaceuticals value chain has been identified through a number of activities and meetings including the AusBiotech 2002 National Conference, held in August 2002, and the Pharmaceuticals Industry Action Agenda initiatives. At AusBiotech 2002, investors from the United States and Europe commented on the difficulty Australia faces because of the lack of a vibrant, growing pharmaceutical industry in Australia. The consequence is the inability for Australian biotechnology companies to form linkages that enable transfer of skills, technology and intellectual property that will lead to commercialisation of products being developed. This has been crucial for development of the biotech sector internationally.

While Government funding has supported many parts of the value chain, a coordinated approach is required to stimulate value-adding linkages. Such links will stimulate development of products from basic research to manufactured product. An improved local operating environment that arises from a policy framework that supports the sector will provide managers of MNC subsidiaries in Australia with the ability to obtain for their local affiliates a greater ability to participate in investment activities related to research and development. The continued presence of multinational companies that have the capacity to provide the high levels of funding required to take a drug through to development is vital to the growth of the sector and critical to the viability of biotechnology companies.

The proposed industry development activities (provided in detail in the Pharmaceuticals Industry Action Agenda and summarised in the box below) will positively impact the growth of these companies. The consequent *"spillov*er" effects will be significant and will include increased investment in research and development, increased in-licensing and technology transfer from universities/research institutions and biotechnology companies, increased access to knowledge and research tools from the pharmaceutical companies to the universities/research institutions and biotechnology companies, increased local manufacture and export activity, and increased employment.

The major benefits of a renewed industry development program to replace the current PIIP Scheme are that:

- It will have benefits to all parts of the value chain, forging partnering between universities/research institutions, emerging biotechnology companies, expanding biotechnology companies, multinational pharmaceutical companies and generics manufacturers.
- It is designed to increase activity in existing Australian entities and to encourage the growth of new companies through the growth of the sector;
- It will increase the commercialisation of research and technology transfer between the entities in the value chain;
- MNCs will be able to capture unique products that will be developed in Australia over the next decade, and make these available worldwide for better treatment of diseases;
- It will increased the recognition of Australia's capabilities and strengths in world class research;
- It will ensure that the Australian industry adds value to the global pharmaceuticals market and can compete effectively internationally;
- It will facilitate the development of the critical mass needed in Australia in order to be able to compete globally in this sector;
- It will provide a mechanism to continue the benefits arising from the current and previous incentive schemes, which have been successful in creating some growth of the pharmaceuticals sector in Australia. The Industry Commission has reported that the Factor f Scheme, designed to partially compensate companies for the effects of low prices of pharmaceuticals under the PBS, was instrumental in bringing about $1.9 billion in export value added, $1.9 billion in domestic value added, $538 million in R&D expenditure and $604 million in investment.[5] The Government had committed approximately $1 billion in funding, representing a five-fold return on the taxpayer's investment in the scheme. This return on investment was based on the performance of a limited number of companies who participated in the Scheme; and
- It will send a clear message to the international community that the Australian Government is backing the development of this important industry and that Australia is a serious consideration for investment and MNC activities/initiatives. This point should not be underestimated, as international "perception" can be a deciding factor for investment if all other parameters are equal.

The Pharmaceuticals Industry Action Agenda, which was a significant and highly consultative process that AusBiotech contributed and participated in, outlines the principles for a new Industry Development Program and these are summarised in the box below.

[5] APMA, *Pharmaceuticals & Australia's knowledge Economy, Australia's pharmaceutical industry-a report,* volume 1, Australian Economic Analysis Pty Ltd, December 1998

AusBiotech supports the proposal in the Action Agenda for Government to target the development of pre-clinical infrastructure, and the development of primary (i.e actives) manufacturing in Australia, particularly bio-pharmaceuticals, as part of an industry development program. The need for multinational companies to establish new plants to satisfy demand for bio-pharmaceuticals provides an opportunity for Australia. It is recognised that an industry development program alone is not sufficient incentive for development of manufacturing plants; appropriate tax incentives would also be required. Pre-clinical infrastructure and primary manufacturing represent two gaps in Australia's value chain. In addition, there are funding/investment gaps in the technology/product development chain which could be targeted by the new incentive scheme and such initiatives would have a significant impact on the development of growth of Australia's biotechnology industry.

Principles of the new Industry Development Program
(From the Pharmaceuticals Industry Action Agenda)

1. An in principle commitment by the Government and Industry to a ten-year program beginning 1 July 2004, with firm commitments to the first five years of the program;
2. Being accessible for all parts of the value chain;
3. Building partnerships and collaborations among major companies, small companies and Australian research institutions;
4. Improving and increasing commercialisation of the outcomes of Australian research;
5. Addressing gaps in infrastructure;
6. Strengthening the investment by multinational pharmaceutical companies in Australia by encouraging the establishment of global hubs in R&D, manufacturing and services;
7. Encouraging high quality activities most likely to enhance the sustainability of the Australian industry and with most spin-off benefits for the Australian economy;
8. Having flexibility to support substantially more companies than have been supported under either the Factor (f) Scheme or the PIIP; and
9. Complying with WTO requirements.

4. Summary

The Australian biotechnology sector is at a vulnerable stage of its growth and development cycle, with the confidence of investors currently waning, despite Federal and State Governments' interest and investment to date, in the sector.

To prevent contraction, continuing private investment is needed in biotechnology companies and investment by pharmaceutical companies is required in emerging Australian biotechnology companies. Investment will only occur if there is confidence that the sector will develop and grow and continue to add value to investors. A critical part of this confidence is the presence of a vibrant, growing pharmaceutical sector that will ensure well-defined linkages can be created between biotechnology companies and MNCs enabling transfer of intellectual property, technology and people, thus providing real opportunities for locally developed products to be marketed globally.

It is critical that the stakeholders in the sector, including the Australian Government, focus on developing strong, long term, effective policies and programs that increase confidence in the sector and stimulate growth.

Consequently, the impact of a new incentive plan to replace the current PIIP Scheme on the Australian Pharmaceuticals Industry, and the flow-on (ie "*spillover*") effects to the Australian biotechnology and associated industries cannot be, and should not be, underestimated.