30 April 2008

Secretariat to the Expert Panel
Review of the National Innovation System
Department of Innovation, Industry, Science, and Research
GPO Box 9839
CANBERRA ACT 2601

Review of the National Innovation System
Submission by the Pharmaceuticals Industry Council

Declaration of Interest

The Pharmaceuticals Industry Council (the Council) is pleased to have the opportunity to respond to the Expert Panel as part of the Review of the National Innovation System.

The Council is a unique forum for providing expert advice to the Australian Government. It brings together senior executives from companies and industry associations [AusBiotech, the Generic Medicines Industry Association and Medicines Australia] from three industry sectors, including the research-based and generic medicines sectors, and the biotechnology sector.

Our priorities include a commitment to working with the Government: to increase investment in research and development; to create an environment that will attract investment in clinical research; to establish flexible regulatory, reimbursement, and tax regimes, which are globally competitive; and to increase Australia's share of the global market for biomedical and pharmaceutical products.

The constituent bodies of the Pharmaceuticals Industry Council will make individual submissions to the Review of the National Innovation System. The Council hopes that these separate submissions, and the proposals they make, will inform the Review Panel's deliberations on how best to achieve innovative results for the Australian biomedical and pharmaceutical industry, as well as for the Australian community. Above all, the Council hopes and looks forward to a productive engagement with the Australian Government, the Department of Innovation, Industry, Science, and Research, and, importantly with the Review Panel.

Yours Sincerely

Will Delaat
Chair, Pharmaceuticals Industry Council

Executive Summary

Knowledge-intensive industries are key drivers of economic growth. They improve productivity, support the growth of real wages and high-value exports, and enhance competitive advantage. The biomedical and pharmaceutical industry – which encompasses the research-based and generic medicines sectors and the biotechnology sector – is an excellent example of a knowledge-intensive industry.

The Australian biomedical and pharmaceutical industry is at a crossroad. During the 1990s, two Federal assistance programs, the Factor F scheme and the Pharmaceuticals Industry Investment Program, provided a powerful impetus for growth, and helped the industry invest hundreds of millions of dollars to create what is today a significant contributor to the socio-economic health of Australia.

However, more recent declining investment may indicate the end of an investment cycle in Australia, following higher investment levels in 1990s. This demonstrates that over the next few years, if major investment is not encouraged and facilitated, the industry will again face an environment of disinvestment, as foreign direct investment is diverted to nations that are actively and aggressively competing for investment in this industry.

Government support for the biomedical and pharmaceutical industry is critical in order to improve its international competitiveness, stimulate investment, and develop Australia as a regional centre for research and development (R&D), manufacturing and export.

The Pharmaceuticals Industry Council believes that Government support for this industry, in which research, development and manufacturing sit at the very core of a viable business model, should be guided by the following principles:

- A focus on maintaining and increasing net investment in research, development, and manufacturing through a well-designed (and thus cost-effective) investment attraction program.
- Support for partnerships and alliances across the value chain, and between global and local companies, especially to facilitate the growth of small firms [such as biotechnology startups] conducting outcome-oriented research and development. This is particularly important for Government in gaining a return on its investment in medical research and in assisting small biotechnology firms to grow.
- A focus on developing an internationally competitive environment and incentives to maintain and grow R&D and manufacturing infrastructure with the ultimate aim of facilitating the development, manufacture, and distribution of innovative products that improve health outcomes of Australians and, through exports, people around the world.

Submission

What are the goals and priorities of the Pharmaceuticals Industry Council?

The Pharmaceuticals Industry Council (the Council) is a forum for providing expert advice to the Australian Government. It brings together senior executives from companies and industry associations [AusBiotech, Generic Medicines Industry Association and Medicines Australia] from three industry sectors, including the research-based and generic medicines sectors, and the biotechnology sector, or, collectively, the Australian biomedical and pharmaceutical industry. The Council's priorities include a commitment to working with the Government: to increase investment in research and development; to create an environment that will attract investment in clinical research; to establish flexible regulatory, reimbursement, and tax regimes, which are globally competitive; and to increase Australia's share of the global market for biomedical and pharmaceutical products.

In its latest publication, *Trade and Assistance Review 2006-2007*, the Productivity Commission confirms that "there are significant market failures surrounding research and development and that a number of existing R&D assistance measures, while amenable to improvement, are likely to yield net benefits for the Australian community as a whole."[1]

Australia has enjoyed a strong global reputation for world class science and a world class medical system. These have been key drivers in increasing foreign and domestic biomedical and pharmaceutical R&D investment in Australia. However, these advantages are under strong and growing threat from countries such as India and China, which are rapidly increasing their scientific and medical capabilities.[2]

Given these challenges, the Council believes that any Government support for the biomedical and pharmaceutical industry, in which research and development sit at the very core of a viable business model, should be guided by the following principles:

- A focus on maintaining and increasing net investment in research and development through a well-designed (and, thus, cost-effective) investment attraction program.
- Support for partnerships and alliances across the value chain, and between global and local companies, especially to facilitate the growth of small firms [such as biotechnology startups] conducting outcome-oriented research and development. This is particularly important for Government in gaining a return on its investment in medical research and in assisting small biotechnology firms to grow].
- A focus on developing an internationally competitive environment and incentives to maintain and grow R&D and manufacturing infrastructure with the ultimate aim of facilitating

[1] Productivity Commission, *Trade and Assistance Review 2006-07*, Annual Report Series, 2008, sec 3

[2] In a survey of senior industry clinical research directors attending the Council's 2008 Research & Development Taskforce Forum on 2,3 April 2008, 41% (n=16) predict that their companies are likely to diminish the amount of activity over the next 5 years and 23% (n=9) predict that the amount of activity will be static with current environment for clinical research in Australia. Attendees reported that this was due to increased competition from India, China and the rest of Asia for investment and resources within their companies.

the development, manufacture, and distribution of innovative products that improve health outcomes of Australians and, through exports, people around the world.

Growth in the biomedical and pharmaceutical industry is inextricably linked to constant innovation; indeed without innovation, growth in this industry would be impossible. Very importantly, the industry's research and development activities within Australia have a very significant flow on effect in promoting innovation within public hospitals and research facilities, through the training, research and development experience and other technical capabilities/equipment created through industry funded R&D activities. The Council, therefore, offers its fullest support to the Australian Government as it attempts to find ways to create an effective and long-term environment of innovation and creative vitality.

What does the biomedical and pharmaceutical industry need from the Government?

Innovative industries such as the biomedical and pharmaceutical industry rely on a highly skilled labour force, on strong intellectual property laws, on equitable access to domestic and foreign markets, on a transparent and efficient regulatory environment, and, above all, on favourable Government policies, such as a globally competitive tax regime and strategic assistance, that help to maintain and enhance a nation's competitive advantages. Australia can rightfully boast of its many achievements in these areas. Certainly, over the last twenty years, Australia has been a rewarding base for the biomedical and pharmaceutical industry - and it still is. The question is: can Australia continue to attract investment in innovation?

Given the changing dynamics of global trade, and the increasing competition Australia will face as an investment destination in the future, the Government must ensure that this country can at least retain (and continue to attract) foreign and domestic investment in innovative and knowledge-intensive industries. Australia does not necessarily offer an economic advantage, (and thus a competitive real return on investment), particularly not when compared to several emerging economies such as Brazil, India, and China, and this is unlikely to change.

Therefore, in order to successfully compete with these countries in attracting biomedical and pharmaceutical investment the Australian Government should develop and implement policies that specifically target our sustainable competitive advantages in conducting high quality research and development [particularly in the areas of product and process development and clinical trials; access to both a highly-skilled workforce and also world-class universities and public research institutions; and in the manufacture and export of products of exemplary quality and safety.]

Reform of the tax regime, including the *R&D Tax Concession* program, will be important to this process. If tax incentives and changes to Australia's broader corporate tax regime are to be one of the cornerstones of Australia's innovation policy, then they must be competitive with those countries that are our direct competitors. The Pharmaceuticals Industry Council welcomed the introduction of the 175% *R&D Tax Concession* [International Premium] in 2007 because it partially addressed the market failure relating to overseas ownership of intellectual property.

But even so, Australia's tax provisions remain uncompetitive; and they will not affect a change in corporate behaviour in the global market place. For example, although Australia's statutory corporate income tax rate (30%) is at par with the OECD average, this just means it is at par with statutory income tax rates in the U.S., Japan, Germany, Italy, Canada, France, and the United Kingdom (excluding the Republic of Ireland). These G7 countries and several other OECD nations are not Australia's direct competitors, especially in terms of aggregate R&D expenditures or levels of access to large 'domestic' markets.

However, these countries do offer what the OECD calls "intangible benefits," such as relative proximity to the global headquarters of multinational firms, historical continuity of expertise, and local know-how. According to the OECD, such intangibles allow most North American and European OECD members (or the overwhelming majority of OECD's constituents) to tax corporate incomes at relatively high levels without discouraging overall investment. Lacking these and several other "intangibles," and lacking also a fundamental strength gained by virtue of having immediate access to large "domestic" markets, Australia, should not continue to benchmark its tax competitiveness (or competitiveness in general) to OECD averages.[3]

The Australian Industry Group has suggested a phased reduction of the statutory corporate tax rate to 25% from the current 30% over a five year period. However, for tax policy to be effective, the Council recommends that the Australian Government should identify exactly which countries Australia is likely to compete with over the next ten to twenty years. In the biomedical and pharmaceutical industry, our direct competitors are Ireland, Singapore, Canada, South Korea, Philippines, and increasingly the United Arab Emirates, China, and India. The average effective corporation tax rate in these countries is between 15% to 20%; in Australia, the effective tax rate, taking into account existing concessions when applicable, is between 28% and 30%.

A competitive tax regime, with respect to a list of relevant competitors, is vitally important as a significant driver of innovation in Australia. Indeed, studies examining cross-border flows suggest that, on average, investment only increases when there is a substantial decrease in average effective tax rates.[4] In order to achieve this, tax incentives must apply to a broad range of activities, and not just research and development, which, for the biomedical and pharmaceutical industry, as for many others, forms but one part of a much bigger value chain. The resulting net increase in domestic income from utilisation of tax incentives can then be shared with the Government through personal income tax (additional employment), sales tax (additional sales), and property tax (additional facilities).

However, the Australian Government is strongly encouraged to recognise that tax incentives and corporate tax treatments in general are but one of the determinants of investment, especially foreign direct investment. According to a recent OECD report, "Foreign direct investment is attracted to countries offering: access to markets and profitable opportunities; a

[3] OECD, *Tax Effects on Foreign Direct Investment*, Policy Brief, 2008, p. 2, 3-5
[4] See: ESRC, *Multijurisdictional Economies: Trade and Tax/Amenity Competition*, 2007; Rudd de Mooij and Sjef Ederveen, *Taxation and Foreign Direct Investment: A Synthesis of Empirical Research*, International Tax and Public Finance, 10:6, 2003

predictable and non-discriminatory legal and regulatory framework; macroeconomic stability; skilled and responsive labour markets; and a well developed infrastructure. All of these factors will influence the long-term profitability of commercial projects, which will ultimately determine whether investment, particularly foreign direct investment, is made or not."[5] In other words, tax incentives can only complement strategic Government interventions and not replace them.

Therefore strategic industry support becomes vital to maintain investment in critical industries.

In 1988, when the pharmaceutical industry was facing massive disinvestment and loss of manufacturing capacity due to trade liberalisation and a difficult domestic operating environment, and Australia was facing an escalating deficit in the pharmaceutical balance of trade, the (then) Labor Government introduced the Factor F scheme, which ran from 1988 to 1999. Under Factor F (and nearly $1 billion in Federal support), the industry's core capacity to conduct research and development and manufacture high-value therapeutic products for domestic and export markets skyrocketed; over the ten years of the program, the industry achieved a cumulative increase of approximately $4 billion in production value added, over $600 million in additional R&D expenditure, and over 1,000 new jobs.

Factor F was instrumental in transforming the industry from a negligible part of the economic landscape into one of the most significant contributors to the socio-economic well-being of this nation. According to a 1995 Bureau of Industry Economics report, the Scheme was "successful in encouraging substantial increases in pharmaceutical activity, and many companies have undertaken strategic investment necessary to bring facilities up to world class standards."[6]

Then in 1999, the Government announced the Pharmaceuticals Industry Investment Program (or PIIP) as a follow-up to Factor F. This five-year program, with $300 million in available funding, operated from 1999 to 2004. In its 2003 report, the Productivity Commission stated that "The PIIP has been effective in stimulating R&D and, to lesser extent, value added in production. It has also has broader benefits for the capabilities of the industry, for example, by shifting R&D to more complex areas."[7]

It is evident that past programs to support the Australian biomedical and pharmaceutical industry have worked well, both for the industry as well as for Australia. The rapid growth of the industry over the last twenty years can be directly attributed to Government initiatives and policies to support an industry it has long recognised to be an important contributor to Australia's prosperity.

Once P3 ends in June 2009, further Government support for the industry is critical in order to improve its international competitiveness, stimulate investment, and develop Australia as a regional centre for research and development (R&D), manufacturing and export. An absence of direct Government support after 2009 would be the first time since 1986 that there will not be

[5] OECD, *Tax Effects on Foreign Direct Investment*, Policy Brief, 2008, p. 1
[6] Bureau of Industry Economics, *The Factor (f) Scheme: A Consultancy for the Industry Commission Inquiry into the Pharmaceutical Industry*, Canberra, 1995, p. iv
[7] Productivity Commission, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, AusInfo, Canberra, 2003, p. xx-xxi

a Government program to facilitate the growth of the Australian biomedical and pharmaceutical industry.

This support should continue so as to build a strong industry foundation and continue the growth trajectory of each of the sectors, particularly those nascent opportunities emerging through the biomedical and generics sectors. If this happens, Australia's position as a leading partner in the global biomedical and pharmaceutical industry will be ensured. This will result in the community's continued access to the very best of healthcare and the maintenance of a sustainable pharmaceuticals environment.

What further areas require Government attention and intervention?

First, according to the Pharmaceuticals Industry Action Agenda of 2002, there is room for improvement in Australia's commercialisation culture. The Council believes that this is still a major challenge for the Australian biomedical and pharmaceutical industry, and especially for the biotechnology sector. Significant gains from basic research and proof-of-concept activities are frequently lost because startups and small firms have inadequate access to advice and funding from multinational companies and the Government. The Commercial Ready and Commercial Ready Plus programs have provided valuable support in this regard, but grants have so far been too small to facilitate large-scale commercialisation projects. And Funding from multinational companies has been limited because Australia lacks local mechanisms to identify promising research and because of market failure associated with the R&D tax concession.

Second, research undertaken by the Pharmaceuticals Education Council, demonstrates that there is a considerable shortage of specific skills required not just by the biomedical and pharmaceutical industry but all innovative, science-based industries in Australia. The report identified skill gaps across the value chain, and especially noted that many recent university science graduates lack basic research, project management, clinical trial design, interpersonal, and marketing and negotiating skills, which are critical to research, development, and commercialisation of innovative products. It also argued that many Australian university students perceive there to be an imbalance between the cost of a science education and the earning potential it subsequently delivers.

In conjunction with the skill shortages the Australian contract research organisations (CROs) have experienced difficulties in participating in the various financial assistance schemes available to the broader biopharmaceuticals industry. The "A Call for Submissions" paper recognises the inherent importance of the service industry through acknowledging that there is a "dominance of service industries in advanced economies". This recognition is not reflected in the current financial support mechanisms available to the CROs in the biomedical and pharmaceutical industry. Whilst for example the Commercial Ready Schemes provide a "Services" category, the reality is the application process severely limits their participation because of the lack of "owned" intellectual property. It is argued that any new support schemes should specifically recognise the importance of CROs and their significant contribution to the economy.

Why does the biomedical and pharmaceutical industry need Government assistance?

The Australian biomedical and pharmaceutical industry is at a crossroad. During the 1990s, the Federal assistance programs, the Factor F scheme and the Pharmaceuticals Industry Investment Program, provided a powerful impetus for growth, and helped the industry invest billions of dollars to create what is today a significant contributor to the socio-economic health of Australia. But according to a recent survey[8] by Medicines Australia of its members, average investment levels in that sector have been declining since 2000; annual average new capital expenditure has declined from approximately $335 million in the 1990s to $165 million in 2006. And over the last four years, investment growth (on average, 6.2% annually between 2003 and 2007) has been below the average of the broader Australian manufacturing sector (on average, 19% annually over the same period). This may reflect the end of an investment cycle in Australia, following higher investment levels in 1990s, which demonstrates that over the next few years, if major investment is not encouraged and facilitated, the industry will face an environment of disinvestment, as foreign direct investment is diverted to competitor nations.

In the face of global rationalisation, the industry's ability to maintain its position as a leading generator of Australia's export earnings is tenuous at best. Almost 70% of Australia's total exports of medicinal and pharmaceutical products can be attributed to just a few companies: even if one of these were to close, the impact on Australia's export capacity would be dramatic.

Indeed, in mid-April 2008 Merck Sharp & Dohme decided to scale back its Australian manufacturing operations over the next two years. The South Granville plant will be ceasing solid dose manufacturing operations and will continue to focus on pharmaceutical product packaging. Merck Sharp & Dohme has been one of the leading pharmaceutical manufacturers in Australia, exporting goods to the value of $1 billion each year.

A lack of critical mass has made the Australian biomedical and pharmaceutical industry extremely vulnerable to the changing dynamics of global trade, especially within the context of the meteoric rise of emerging economies such as India and China. Aggressive regulatory, educational, tax, and macroeconomic reforms have transformed these economies; they are no longer cheap labour havens; they are sophisticated economies, which, on many levels, are suddenly at par with advanced economies.

According to the Australian Academy of Science[9], Australia's traditional comparative advantages, especially in science and technology and a highly skilled labour force, will quickly erode without bold leadership by the Government. And Australia will face increasingly fierce competition from these and other countries for foreign direct investment [which remains a significant determinant of economic growth] and domestic reinvestment by foreign-owned entities. The Council believes that without Government action several vital industries, including

[8] Medicines Australia, *Australian Pharmaceutical Industry at a Crossroad? Report of the 2007 Medicines Australia Member Economic Survey*, 2008, Canberra, p. 23-24.
[9] Australian Academy of Science, *Research and Innovation in Australia: A Policy Statement*, Canberra, 2007, p. 1-4

the biomedical and pharmaceutical industry, will face major disinvestment over the next decade.

The Government can assist the Australian biomedical and pharmaceutical industry achieve critical mass through programs and incentives that allow companies to:

a) Increase capital flows to earlier stages of the value chain to facilitate long-term self-sustainability, especially with respect to the biotechnology sector;
b) Maintain the existing R&D base and invest in additional R&D activity by the industry. At present, for example, less than 5% of the industry's annual R&D budget is allocated to basic and preclinical research, forcing some sectors of the industry to remain largely dependent on off-shore R&D pipelines for new chemical and biological molecules;[10]
c) Upgrade existing manufacturing and allied facilities;
d) In line with the National Medicines Policy, which recommends a "stable and conducive business environment for the pharmaceuticals industry", strengthen the capacity of locally operating companies to attract investment from global headquarters (by reducing operating costs to make Australian-made products competitive, especially in the export market).

<u>What does the biomedical and pharmaceutical industry deliver to Australia?</u>

The Australian biomedical and pharmaceutical industry:

- *Pushes Boundaries*: Drawing on both domestic and foreign resources, the industry invests hundreds of millions of dollars in research and development of new therapies that provide better health outcomes for Australians. In fact, its annual R&D expenditure of $752 million places it amongst Australia's leading investors in R&D.
- *Increases Value*: Every dollar spent by the industry on research and development produces approximately four dollars in community health benefits. And by attracting substantial foreign direct investment and export earnings, industry activities produce a net increase in domestic income that is shared with the Government through taxation of wages and profits.
- *Build Human Capital*: The industry employs over 34,000 exceptionally talented Australians, who together form a vast endowment of creative and innovative minds. It creates high-quality jobs, which build high-value skills, retain skilled professionals in Australia, and attract outstanding talent from overseas.
- *It Puts Innovation to Work*: Patients in thirty four countries benefit from innovative medicines manufactured in and exported from Australia; the industry generates nearly $4 billion annually in export earnings. Partnerships between the industry and public and semi-private research organisations [such as the National Center for HIV Epidemiology & Clinical Research] enhance Australia's overall contribution to the global research and development value chain.
- *Conducts Outcome Oriented Research*: The industry's research and development projects are necessarily outcome-oriented; indeed, innovative products almost exclusively determine the industry's long-term viability. The industry has helped develop and commercialise significant medicinal breakthroughs such as Gardasil® and Relenza®, and it

[10] Medicines Australia, *Australian Pharmaceutical Industry at a Crossroad? Report of the 2007 Medicines Australia Member Economic Survey*, 2008, Canberra, p. 27-30

continues to invest in broad ranging therapies for existing and emerging public health threats such as skin cancer [melanoma] and HIV.

- *Builds Social Capital*: Through innovative therapies, which are focused increasingly on preventive rather than curative care, the industry helps Australians become healthier, happier, and more productive citizens, who are better able to contribute to the growth of this nation.

Knowledge-intensive industries are key drivers of economic growth. They improve productivity, support the growth of real wages and high-value exports, and enhance competitive advantage. The biomedical and pharmaceutical industry is an excellent example of a knowledge-intensive industry. The Australian biomedical and pharmaceutical industry has consistently shown very strong economic performance over the last twenty years, especially when measured by indicators such as:

- Employment, which grew from approximately 10,000 in 1988 to over 34,000 in 2007.
- Investment, in which the industry's annual capital expenditure grew from ~$80 million in 1980s to ~$335 million during the 1990s;
- Output: annual turnover grew from ~$2 billion in 1988 to ~$17 billion in 2006;
- Research and development: annual R&D allocation grew from $70 million in 1988 to $752 million in 2007, or 7.5% (largest by a single industry sector) of Australia's business expenditure on research and development;
- Exports, which grew from $0.5 billion in 1989 to nearly $4 billion in 2007.
- And, of course, in its contributions to significantly improving health outcomes for Australian citizens.

Conclusion:

The constituent bodies of the Pharmaceuticals Industry Council will make individual submissions to the Review of the National Innovation System. The Council hopes that these separate submissions, and the proposals they make, will inform the Review Panel's deliberations on how best to achieve innovative results for the Australian biomedical and pharmaceutical industry, as well as for the Australian community. Above all, the Council hopes and looks forward to a productive engagement with the Australian Government, the Department of Innovation, Industry, Science, and Research, and, importantly with the Review Panel.