



Executive summary

The pharmaceuticals industry is the most innovative, knowledge-based industry in Australia today¹. It is global, with prospects for continued strong growth as it enters a new phase of drug discovery and development in biopharmaceuticals. For Australia, this industry is a significant contributor to economic growth. In addition, it has the ability to build knowledge and skills for a modern economy, to commercialise research and development, and to make a substantial contribution to the health of all Australians.

The Australian pharmaceuticals industry consists of manufacturers, research institutions, biomedical research and development firms and associated services sectors. With a turnover of around \$A12 billion a year, the industry employs 35 000 people in more than 300 companies and institutions. It is currently the second largest exporter of manufactured goods in Australia, and has the potential to grow more.

The industry is one of the fastest growing in the world. Ageing populations, increasing incomes, continuing innovation and rising expectations for better health in developed and developing countries mean that it will continue to expand and be an important generator of wealth.

The pharmaceuticals industry is a global value chain, and therefore the Australian industry must have a global perspective. At each stage of activity—research, clinical trials, manufacturing or related services—value is added, innovation takes place, resources are used and people employed. Each stage represents a market within the overall pharmaceuticals market. Increasing globalisation of this industry means companies are not constrained in their choices about the location of their activities. This creates opportunities and continuing challenges for activity to be retained and grown within Australia.

Given the changing dynamics of the pharmaceutical industry worldwide, Australia has reached a critical turning point in terms of its place in the global marketplace. Australia must consider its capacity to not only retain and maintain current levels of investment in innovative research and development, but also to develop and build on these activities. There are significant opportunities to capitalise on features in the operating environment that can generate growth.

There are opportunities for Australia's pharmaceuticals industry to become stronger, more dynamic and more internationally competitive—promoting world best practice. Australia can achieve this by focusing on those parts of the global value chain where it is, or can become, among the best in the world, and by building mutually beneficial alliances and partnerships.

The pharmaceuticals industry is one of the fastest growing in the world.

¹ *The Economic Contribution of the Australian Prescription Pharmaceutical Industry*, Ecotech Pty Ltd, March 2002

This *Action Agenda* signals that industry and government are committed to growing the Australian pharmaceuticals industry

Australia already has competitive advantages in high-quality research, well-developed infrastructure, an educated and skilled workforce, a stable political environment, strong intellectual property laws, a reputation for high-quality products and services and a low cost investment environment.

To make the most of these opportunities, however, Australia must address a number of challenges. To compete effectively, Australia, like other countries, must embrace the biotechnology revolution by investing heavily in research and development and actively targeting specific steps in the industry value chain.

There is room for improvement in Australia's commercialisation culture, there are some gaps in the specific skills base required for the pharmaceuticals industry, and there is a need to attract greater levels of investment. These issues currently impede industry's ability to capitalise on its strong research base and hinder companies from creating world-class facilities that would attract further investment.

This *Action Agenda* signals that industry and government are committed to growing the Australian pharmaceuticals industry, and recognises that further growth in this industry is unlikely to eventuate by chance. The consequences of failing to grasp the opportunities are that the Australian industry becomes a smaller player in the global market, reducing its capacity to generate significant wealth and health outcomes.

The *Action Agenda* establishes an achievable, focused 10-year growth strategy for the pharmaceuticals industry by:

- identifying issues of strategic importance to the industry and recommending actions and strategies to address them
- building on Government's commitment to Australia's innovation industries, apparent in the Government's innovation statement *Backing Australia's Ability*, the Government's *National Biotechnology Strategy* and the commitment to medical research evident through the implementation of the Wills report *Health and Medical Research Strategic Review*
- providing a vehicle to help capitalise on the significant public sector investment in health and medical research and development
- expanding the industry's commitment to investment in production of medicines, research and development, services in Australia, and building closer alliances and partnerships within Australia and with global partners.

The Australian pharmaceuticals industry has embraced this *Action Agenda*. The industry's commitment to developing partnerships throughout the value chain underpins the agreed actions.

The industry's vision statement sets the challenge of doubling Australia's share of the global pharmaceuticals industry.

Industry vision

The pharmaceuticals industry is dedicated to providing innovative health care solutions that improve people's lives and to making a major contribution to Australia's economic vitality. The industry's vision is to double Australia's share of the global pharmaceuticals industry by 2012 through the collaborative efforts of the industry, government and research by:

- **increasing investment in Australia to capture innovation and knowledge**
- **becoming a global hub for research, development and commercialisation**
- **developing Australia as a key global exporter of goods and services.**

The *Pharmaceuticals Industry Action Agenda* provides the framework for the industry to achieve its vision. It establishes five key goals and develops strategies and actions to deliver these goals. These goals are:

Goal 1: Implement a 10-year *Action Agenda* through industry and government partnerships.

Goal 2: Position Australia as a global pharmaceuticals hub.

Goal 3: Create a globally competitive operating environment.

Goal 4: Strengthen Australia's ability to commercialise research by investing in skills.

Goal 5: Foster and project a positive culture, image and profile for growth.

Goal 1: *Implement a 10-year Action Agenda through industry and Government partnerships.*

The *Action Agenda* seeks to influence the policy framework with a long-term plan that communicates a clear message to investors that Australia is serious about further growing the industry. Stronger long-term partnerships within the industry and between government and industry, are important components of this goal. The *Action Agenda* proposes, for example, that a high-level Government and industry forum should oversee progress on implementing the 10-year plan.

Goal 2: *Position Australia as a global pharmaceuticals hub.*

Australia needs to build the necessary critical mass to enable the industry to compete globally. Implementation of the *Action Agenda* will increase the existing level of industry activity and create opportunities for further investment and activity. Over the next 10 years, Australia will strive to become a global hub for research and development and commercialisation, and must further develop as a global exporter of pharmaceutical products and services. The proposal to develop an industry development program to replace the Pharmaceutical Industry Investment Program when it concludes in 2004 would build on the best features of previous schemes and encourage activities that strengthen Australia's international competitiveness. Key principles that could underpin any such replacement industry development program include ensuring accessibility by all parts of the value chain, encouraging partnerships, improving commercialisation, addressing infrastructure gaps and establishing global hubs.

Goal 3: *Create a globally competitive operating environment.*

The *Action Agenda* aims to maintain and enhance the operating environment of the Australian pharmaceuticals industry. This operating environment must be internationally competitive. Although Australia has world-leading capabilities in areas like the conduct of clinical trials and in the regulatory system, other aspects are less competitive. This is particularly important given that competitor countries have built, and will continue to build capabilities and offer significant government assistance, in particular tax incentives.

Goal 4: *Strengthen Australia's ability to commercialise research by investing in skills.*

The high technology pharmaceuticals industry is more reliant than many industries upon a highly skilled workforce. As a result, developing and retaining skilled people in Australia is imperative to ensure the sustained growth of the industry. The *Action Agenda* details initiatives directed to ensure a consistent and coordinated national approach to addressing these skills needs through the establishment of a Pharmaceuticals Education Council. Australia must anticipate and act on meeting its future skills needs, work to capture intellectual property, and improve its commercialisation skills.

Goal 5: *Foster and project a positive culture, image and profile for growth.*

The *Action Agenda* stresses that governments and industry must work together to improve the marketing of the advantages of doing business in Australia. Many overseas investors are not aware of the many opportunities and strengths of the Australian business environment. The Australian industry must operate within the global market and therefore must compete and showcase its capabilities internationally with simple powerful marketing messages. The *Action Agenda* proposes the development and implementation

The *Pharmaceuticals Industry Action Agenda* provides the framework for the industry to achieve its vision.

Australia must anticipate and act on meeting its future skills needs.

of a coordinated international marketing campaign to sell Australia's competitive advantages to investors. Creating a positive image and understanding of the value of the Australian industry is fundamental to attracting people and resources critical for achieving the industry vision.

Implementation: The *Action Agenda* provided the ideal opportunity for industry to identify its vision for the future, and develop the long-term plan, including setting specific goals and identifying strategies and actions to achieve its vision. Industry is committed to establishing an Implementation Group of senior representatives to oversee the implementation of the strategies and actions for which industry is taking prime responsibility.

These actions, and governments' role in supporting them, are detailed below.

Actions to meet the industry vision

No	Action	Prime responsibility	By when	Section with more information	Operational plan at Attachment C
Goal 1: Implement a 10-year Action Agenda through industry and Government partnerships					
1	The Commonwealth to reconvene a high-level Government/industry forum (currently the Pharmaceutical Industry Working Group) that meets three times a year to oversee progress on the <i>Action Agenda</i> and monitor progress in the forums addressing the Pharmaceutical Benefits Scheme sustainability and process issues.	Government and industry	3 rd quarter 2002	See 2.8, 4.4	yes
2	Promote increased investment and exports of pharmaceuticals goods and services through Invest Australia's and Austrade's priorities and work with State Governments to provide coordinated support.	Government	4 th quarter 2002	See 4.4, 6.1	yes
3	Medicines Australia, the Generic Medicines Industry Association and AusBiotech to form a working party to examine areas for collaboration, including building on the annual industry forum run by AusBiotech, as the industry flagship event.	industry	4 th quarter 2002	See 4.4	no
Goal 2: Position Australia as a global pharmaceuticals hub					
4	The Commonwealth Department of Industry, Tourism and Resources, in consultation with industry, to develop a proposal for an industry development program as a successor to the Pharmaceutical Industry Investment Program that expires in 2004.	Government and industry	4 th quarter 2002	See 2.8, 4.5	yes
5	Industry to conduct a study to assess the opportunity, costs, benefits, incentives needed, and skills requirements in the areas of preclinical infrastructure; biopharmaceuticals manufacturing; and scale-up manufacturing.	industry	3 rd quarter 2003	See 3.3, 3.4, 4.5	yes

No	Action	Prime responsibility	By when	Section with more information	Operational plan at Attachment C
6	Explore mechanisms whereby generic medicines manufacturers' ability to export is not hampered by Australia's patent extension policy, whilst ensuring Australia's reputation and integrity with regard to intellectual property is maintained.	Government and industry	4 th quarter 2002	See 3.5.1, 4.5	no
7	Identify opportunities and facilitate growth in the export of pharmaceuticals industry services.	Government and industry	2 nd quarter 2003	See 3.6, 4.5	no
Goal 3: Create a globally competitive operating environment					
8	Industry to establish a joint working party to report to the Implementation Group and Pharmaceutical Industry Working Group within six months on those parts of the tax system that are impeding industry growth.	industry	1 st quarter 2003	See 3.8, 4.6	yes
9	Further streamline ethics approval processes in conducting health and medical research including clinical trials.	Government (National Health and Medical Research Council)	4 th quarter 2004	See 3.3.2, 4.6	no
Goal 4: Strengthen Australia's ability to commercialise research by investing in skills					
10	Establish a Pharmaceuticals Education Council to strengthen the skills and capabilities of the pharmaceuticals industry.	industry	1 st quarter 2003	See 3.2.3, 3.7, 4.7.2	yes
11	Promote two-way movement between industry and academia.	Government and industry	1 st quarter 2004	See 3.2.3, 3.7, 4.7.1	no
Goal 5: Foster and project a positive culture, image and profile for growth					
12	Develop and implement through coordinated Commonwealth, State and Industry activities an international marketing campaign to sell Australia's competitive advantages to investors and the global industry.	Commonwealth, States and industry	4 th quarter 2003	See 4.8	yes
13	Undertake a benchmarking study that compares and monitors Australia's competitive advantages against competing countries.	Government and industry	2 nd quarter 2003	See 4.8	yes
14	Align relevant industry activity with the National Innovation Awareness Strategy.	Government and industry	2 nd quarter 2003	See 3.7, 4.8	no

No	Action	Prime responsibility	By when	Section with more information	Operational plan at Attachment C
Implementation					
15	Establish an Implementation Group to oversee implementation of the <i>Action Agenda</i> strategies and actions that are for industry and jointly by industry and government.	industry	4 th quarter 2002	See 6	no
16	The Implementation Group to provide an annual written report to Ministers on progress in implementing the Action Agenda for each of the first three years.	industry	4 th quarter 2003	See 6	no