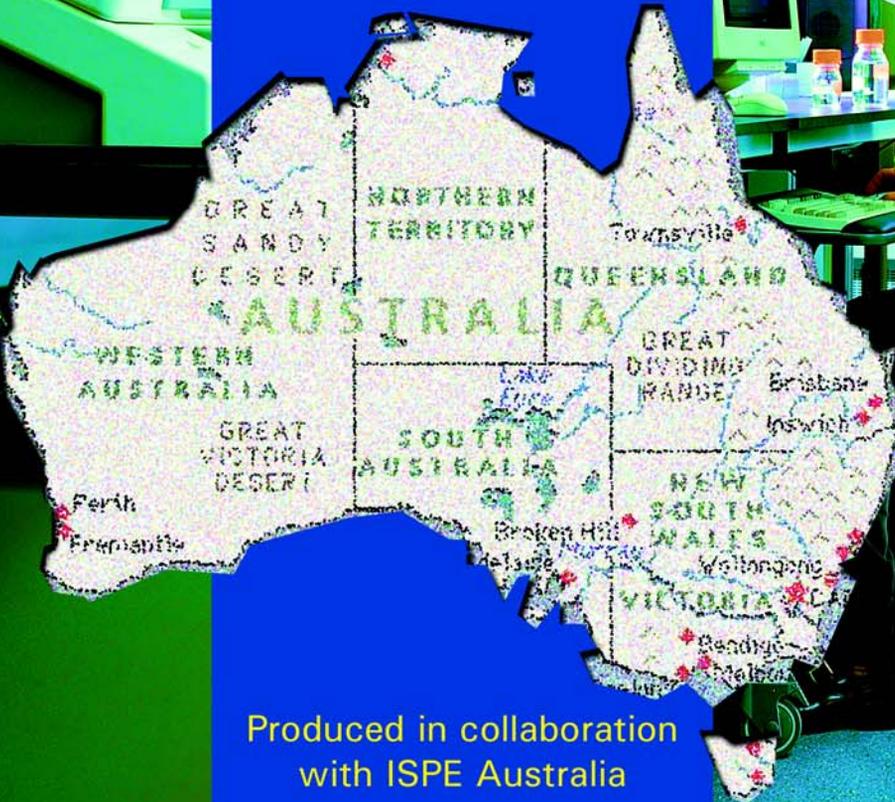


Country Profile

A look at the
Pharmaceutical Industry in

AUSTRALIA



Produced in collaboration
with ISPE Australia



THE SOCIETY FOR
LIFE SCIENCE PROFESSIONALS

Reprinted from
PHARMACEUTICAL ENGINEERING®

The Official Journal of ISPE
November/December 2003, Vol. 23 No. 6



ISPE Australia was established eight years ago and in that time, membership has increased to more than 200. Although Australia is a large country with a dispersed and relatively low population, we have representation from most state capital cities, with a number of members in New Zealand also. Chapter events are being held in Melbourne, Sydney, and Brisbane and are expanding into New Zealand.

Australia is well known as a tourist destination and its amenable climate and quality infrastructure makes it a great place to live. Australia is also a desirable place to work and do business with. This country profile includes a range of articles which reveal the unique character of our country, the depth of our local pharmaceutical industry, and the exciting opportunities ahead.

Australia is a very competitive global manufacturer with high quality and low costs. The local economy has remained robust in spite of worldwide recession. Strong growth in several key areas has seen pharmaceutical exports doubling in the five years to 2000-01 with plans to double our share of the global market over the next decade. Australian R&D and innovation is well-established and world-class, especially in the biotechnology area with a high number of biotech companies. This is sure to continue with our highly educated workforce, incredible biodiversity, and support from industry and government.

We trust that this feature on the Australian Pharmaceutical and Biotechnology Industry is of interest and increases your understanding of our dynamic and developing position in the world. We would welcome your comments and views, so please contact me to let us know what you think.

Yours truly,

Lucas Crabtree
President, ISPE Australia Affiliate



**This new feature in
*Pharmaceutical
Engineering* is
designed so that
you can tear it out,
three hole drill
(if desired),
and keep it with
other Country
Profiles as they are
published.**

**Look for the
Country Profile on
Germany/
Switzerland in the
January/February
issue of
*Pharmaceutical
Engineering.***

The Pharmaceutical Industry in Australia: A Profile

by Mark Donohoo

Introduction

Australia is a unique place of notable contrasts. Although it is the sixth largest country in the world by area, it also is the smallest continent, and with a population of 19.6 million, the most sparsely populated. The home of one of the most ancient indigenous peoples, Australia also has become the second most multicultural society in the world with migrants from more than 160 countries. While it is located in the Asia Pacific region, it has strong historical and cultural ties with the western world.

In relation to the pharmaceutical market, the contrasts continue. Even though Australia is the regional headquarters of many multinationals, its modern health system and health consumption patterns means the Australian pharmaceutical market is far more similar to European markets than any in Asia. In global terms, Australia's market is small yet it is also extremely well-developed. With only 0.3% of the world's population, the country still consumes around 1.25% of total global pharmaceutical output. This means that in 2000, Australia was the 18th largest pharmaceutical market by sales, while being 50th out of 187 countries ranked on population, and a little below the OECD average in terms of value of consumption.¹ The pharmaceutical manufacturing industry in Australia was worth more than \$5 billion in 2000, including over the counter products.²

The pharmaceutical industry is important in Australia. There are around 143 companies listed as suppliers to the Australian Pharmaceuticals Benefits Scheme (PBS), employing around 16,000 people.

Figure 1 illustrates the recent growth of the industry. While the value of imports has increased to more than \$3 billion, local production also has continued to expand, especially in export markets. At \$1.5 billion, pharmaceutical exports doubled over the five years to 2000-01 to become Australia's second largest

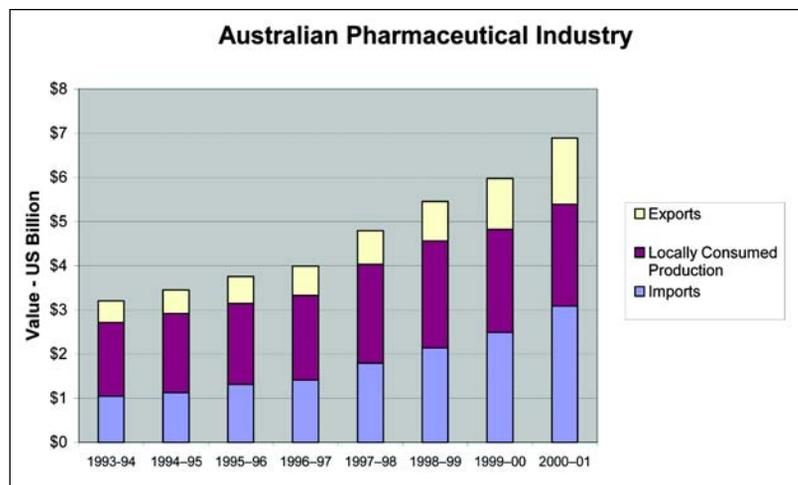


Figure 1. Growth of the Australian Pharmaceutical Industry.³

manufactured-export category.⁵

In addition to companies involved in the manufacture of pharmaceuticals in Australia, the industry includes biomedical researchers in universities, institutes and hospitals; biotechnology companies involved in research and development; and associated service sector partners. After including statistics from these other sectors, the full size of the industry is close to \$8 billion, employing 35,000 people across at least 300 firms and institutions.³ As shown in Table A, the Australian industry has participants along the complete pharmaceutical value chain.

Research and Development

The core of basic medical research in Australia is in public universities, medical research institutes, hospitals, the Australian Nuclear Science and Technology Organization (ANSTO), the Commonwealth Scientific and Industrial Research Organization (CSIRO), the Cooperative Research Centers (CRCs), and the National Health and Medical Research Council (NHMRC).

On a global scale, Australia's performance in research and research publishing is excellent. With just 0.3% of the world's population, Australia produces 2.5% of the world's research, has four laureates of Nobel Prizes for Medicine or Physiology, two others in related fields, and recipients of many other prestigious awards.⁶



The Pharmaceutical Industry in Australia: A Profile



Among Australia's research strengths is work in immunology, reproductive medicine, hypertension, genetics, molecular biology, and oncology.⁷

One long-term feature of Australian research and development funding is the relatively high proportion of government expenditure - *Figure 2*. Much of this support is spent on basic research. Expenditure by the industry itself is around 6% of sales, which is well under the 15-20% typical of the US industry. *Figure 2* also illustrates that expenditure by the Australian industry is relatively lower on basic research and higher on clinical trials and manufacturing. This is possibly because the largest Australian companies are multinationals that invest more basic research and development in home countries. (The collaboration between AstraZeneca and Griffith University to search for promising compounds from Queensland biota is a notable exception).

Investment in research and development continues to increase; one estimate is that industry expenditure is now almost double that shown in *Figure 2*.⁸ Government expenditure has kept pace; planned funding through the NHMRC, for instance, will double between 1999 and 2004.⁹ A large driver of this expenditure is the growth of leading-edge biomedical and

biotechnology capabilities within Australia.

This expansion is mostly from Australia's medical research base; 70% of biomedical companies formed in 2001 were spin-offs from research institutions.¹⁰ This is an important development which is starting to attract the interest of global pharmaceutical players. Merck, as one example, recently signed a license agreement with Amrad to develop new asthma drugs that could be worth more than \$112 million. Other companies (Biota and Kinacia) have developed their own proprietary substances while Proteome Systems has produced pharmaceutical development technology.

While Australia's pre-clinical sector is not as developed as the basic medical research sector, there are some areas of strength that have achieved high levels of global recognition. Australia also has pockets of strength in pharmaceutical delivery, both in some pharmacy schools and within industry. One example is the development by Fauldings (now part of Mayne), in partnership with Glaxo Wellcome, of Kapanol, a sustained-release, morphine-based product, now available on the world market.

The largest proportion of industry expenditure (approximately 42%) on research and development is on

	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5
Primary activity	Basic medical research; discovery research	Early development; proof of concept; Phase I; early Phase II	Development from early to later stages; Phase I, II and some Phase III	Final product development, manufacture, marketing including sales and distribution	Manufacture, marketing including sales and distribution
Secondary activity	Early proof of concept	Some discovery	Some sales, distribution; Some discovery, some proof of concept	If developed from own research: all stages. If licensed-in: later stage development, clinical trial.	Product development, formulation
Activity undertaken in Australia by	Universities, Cooperative Research Centres, Research Institutes	Biomedical start-ups, Biomedical expansion companies	Biomedical expansion companies, Multinational pharmaceutical companies	Multinational pharmaceutical companies	Generics manufacturers
Number of entities in Australia	Over 60; employing more than 14,800 researchers	150 private companies, 35 publicly listed companies; 5,700 people	20 publicly listed / private companies	50 companies; 12,000 people employed	6 companies; 1,500 people employed
Examples in Australia	Walter & Eliza Hall Institute, Monash University	Biota, Kinacia, Proteome Systems	Amrad, Thrombogenix	Eli Lilly, CSL, AstraZeneca, Merck Sharp and Dohme	Alphapharm, Mayne Health (Faulding)

Table A. The Australian industry along the pharmaceutical value chain.³

The Pharmaceutical Industry in Australia: A Profile

clinical trial activity.¹¹ Studies have shown Australia has major cost advantages for conducting high quality research and development.¹² Australia has good clinical capability because of its excellent hospital infrastructure, world-class medical scientists, and a tradition of sophisticated clinical research, excellent statisticians with access to follow-up medical treatment data, and a broad base of well educated health workers to assist in clinical trials. Our regulatory system is highly regarded internationally for rigor and efficiency. We have a diverse, ethnically heterogeneous and healthy population that has not been 'saturated' by clinical trial activity. Australians are eager to participate in scientific endeavor. Recruitment for trials is relatively easy because high levels of education mean that people understand the purpose of the trials and the controls surrounding them. The country's well developed IT infrastructure and relatively low cost structure also ensures efficient and cost-effective trial management.

The infrastructure to conduct clinical trials is continuing to develop. Many public hospitals and research institutes contract regularly with pharmaceuticals companies to conduct clinical trials. A few local companies focus their business model on selected parts of the trials process. A number of multinationals have placed specialized trial activity in Australia. One example is GlaxoSmithKline and its James Lance Phase 1 facility in Sydney. Others have established centers for analyzing clinical trial data for the Asia Pacific region, for example, Eli Lilly's Clinical Outcomes and Research Institute. Increasingly, Australia also is processing more compounds developed by local research institutes who now have the expertise to initiate their own trials.⁹

Figure 2 also shows that the Australian industry appears to invest proportionally more in manufacturing and processing research and development than the US. One example of this investment is Pharmacia, the only manufacturer in the world to package oncology pharmaceuticals in plastic. This technology was researched and developed in Australia, and is deployed at Pharmacia's Bentley facility.¹³

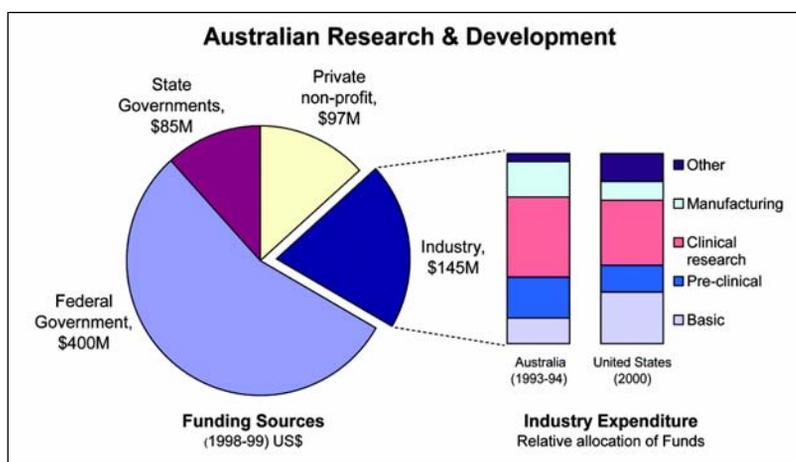


Figure 2. Australian expenditure on research and development.¹

Manufacturing

Over the last decade, some manufacturing activity in Australia has been lost due to plant closures resulting from mergers. At the same time, some new small-scale capacity has been created, some capacity has been reinforced, and in some cases, the disposal of plants by multinationals has created an opportunity for local manufacturers to take-over plants. As indicated in Figure 1, there has been a steady rise in the gross product and in exports from the manufacturing industry. The full range of manufacturing processes is undertaken in Australia though, as Figure 3 shows, the vast bulk of activity is in formulation and packaging of final form products.

Australian capacity for the manufacture of chemical actives is not large. Apart from radiopharmaceuticals manufactured by ANSTO, the largest primary manufacturing operations are for alkaloids (GlaxoSmithKline and Janssen-Cilag). Australia supplies a significant proportion of the world's medicinal opiate requirements for morphine production. The poppies are grown and processed to the straw stage and the opiates extracted. This is a classical Australian activity – adding value to an agricultural resource. The Institute of Drug Technology (IDT) is a more recent development, which has grown to become a significant FDA-approved Active Pharmaceutical Ingredient (API) development and manufacturing company. IDT has a diverse range of products, including parenteral grade cytotoxics, non-cytotoxics, antibiotics, veterinary products and biologics. Their client base lists several top 20 international pharmaceutical companies, including Pfizer and AstraZeneca.



The Pharmaceutical Industry in Australia: A Profile

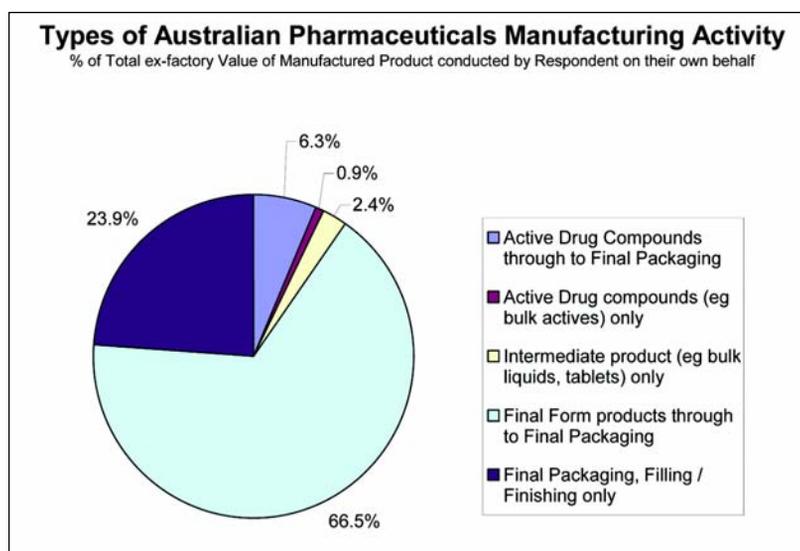


Figure 3. Types of Australian pharmaceutical manufacturing activity.¹⁴

Much of Australia's current specialized activity is for biological, as opposed to chemical, compounds. Australia is ranked sixth in the world for the number of biotech companies and it is estimated to have around 1% of the world's protein manufacturing capacity.¹⁰ Australia is well positioned to take advantage of the expected increase in demand for biopharmaceuticals due to its skills base, BSE-free source material, management capacity (especially the entrenched culture of quality assurance), and regulatory environment.

CSL, the largest biotechnology company in Australia (by capitalization), is one of its most successful and the only local vertically-integrated pharmaceutical company (active in all the value chain). Originally, a Government authority, CSL was privatized in 1994 and has now ventured internationally, using its purchase of the Swiss ZLB plant to enter the US plasma products market. It is a world leader in plasma technology and has strength in immunotherapy, immunology, protein chemistry, and protein-based novel human therapeutics to develop a number of novel products. CSL manufactures its own products as well as under license to major international corporations such as Merck, Biogen, and Schering.

As noted above, secondary manufacturing (formulation and final form production) comprises most of Australian pharmaceutical manufacturing value. Studies have shown that Australia is one of the most cost-competitive places in the world to build and operate a plant³ and the strength of the regulatory environment and work force skills lead to high quality assurance.

More than 10 companies, both local and multinational, operate at least one secondary manufacturing facility supplying local and export markets. These include GlaxoSmithKline, Pfizer, Pharmacia, Sigma, Roche, Alphapharm, Merck, AstraZeneca, Mayne, Bristol-Myers Squibb, and Schering-Plough.

Government development programs have encouraged the expansion of secondary manufacturing capabilities, especially with a focus on generating exports. For instance, the local subsidiaries of multinationals Merck (MSD) and AstraZeneca (AZA) have both invested in new state-of-the-art manufacturing plants in Sydney. AZA

has spent around \$100 million in infrastructure, opening their new sterile-pharmaceutical manufacturing facility in 1998. This plant is currently being expanded to more than double its original capacity, and also will serve as a regional packing center for solid-dosage forms. More than 400 people are employed in the plant where tablets, injectables, respiratory products, and fluids for inhalation are manufactured, including the use of Blow-Fill-Seal technology. Output from AZA supplies more than 17 export countries. MSD employs 850 people and has spent almost \$80 million since 1993. In 2000, their factory supplied more than 1000 solid-dose presentations to 37 countries. This represents around 23% of Australia's total pharmaceutical export value and makes MSD one of Australia's top 100 exporters.

In the global manufacturing world, Australia has developed a niche expertise in packaging and formulation with many plants becoming skilled at short manufacturing runs and quick changes between products. This flexibility suits many regional export markets where orders are of smaller volumes and may become an advantage with the predicted development of 'targeted pharmaceuticals' produced for small patient populations.

Flexibility and short runs is a particular strength of generics manufacturers. Australia has a significant generics manufacturing sector, conducted by such firms as Sigma and Faulding (locally owned), Alphapharm (owned by Merck KgaA). The Australian generic medicines industry undertakes significant research and

The Pharmaceutical Industry in Australia: A Profile

development and has enjoyed substantial growth in both the Australian and export markets. This growth has been fuelled by a legislative framework that enshrines consumer choice and promotes Government cost savings. One estimate is that generic medicines have saved Australian taxpayers more than \$550 million since 1995 by reducing the benchmark price of medicines.³ (Generic export is restricted by Australian intellectual property laws which require agreement of the patent holder, while the medicine is under patent in Australia).

Faulding, started in 1845, has developed as a manufacturer of generic medicines specializing in novel delivery mechanisms. It has both research and manufacturing facilities. Sigma is another sizeable local company that manufactures both patented and generic pharmaceuticals in some cases, under contract to other companies. Arrow Pharmaceuticals has established a world center for research and development for generic medicines in Melbourne, compiling registration files for submission in Asia, Europe and the USA.

Alphapharm began in 1982 and has grown to become Australia's largest manufacturer of generic pharmaceuticals and the largest supplier (by number of prescriptions) to the Pharmaceutical Benefits Scheme, supplying more than 200 products. At its Brisbane pharmaceutical manufacturing technology base, generic products are developed, scaled up into production quantities, manufactured, and sold domestically as well as being exported to 26 international markets including Asia, Europe, and the USA.

Services

Service inputs within Australia are well developed and are typically of a high quality. Capabilities along the value chain have been developed both by dedicated suppliers who sell into the industry and within pharmaceutical companies themselves. Much of this capability is exported to the Asian region and further afield; some notable examples of services provided are:

- Research and development services - for example, Covance, Kendle, and Quintiles organize clinical trials in Australia and elsewhere; CMAX provides specialized Phase 1 trial expertise; and AstraZeneca and Griffith University provide a high speed screening service for the company's headquarters.

- Data services - for example, Eli Lilly's Clinical Outcomes and Research Institute (CORI), and its Asia-Pacific Data Management Centre, provide services for the company's clinical work in Australia and overseas.
- Training and staff development services - for example, Roche's Australian office provides staff development modules by data stream to the Asia-Pacific offices of the company; GSK operates a global center of excellence for health outcomes and exports its health economics expertise.
- Management services - several multinational companies have their Asia-Pacific regional headquarters based in Australia (for example, Bristol-Myers Squibb provides Financial Shared Services to some of the corporation's key markets in the Asia/Pacific region from its Australian base).
- Architectural and Project Management services - a number of Australian firms (such as Hooker Cockram, S2F and Bovis Lend Lease) provide design, construction, and management services all over the world.
- Process Engineering services - for example, Newpulse Systems (now Kinetics Australia) is a leading provider of complete design-build process and piping systems to biotechnology and pharmaceutical industries in Australia and Asia.
- Equipment supply - Bosspak (now part of the Romaco group) designs and manufactures tablet filling lines and developed the world's first rotary tablet counter. Bosspak has received several industry awards for design excellence and now exports 80% of its output to global markets, including Europe. Several other OEM suppliers have had both interest and success from export customers.

Sales and Marketing

The Australian market is different from the United States. For instance, there are restrictions on direct-to-consumer advertising. Most Australian marketing activity is directed to doctors since they are the decision makers because of their power to prescribe. Government regulations also restrict non-pharmacy establishments from dispensing prescriptions and scheduled OTC medicines as well as the locations and ownership of pharmacies. (Despite this obstacle, at least one major supermarket chain has plans to locate stand-alone pharmacies in its stores).



The Pharmaceutical Industry in Australia: A Profile



The Australian market for prescription products is dominated by the Pharmaceutical Benefits Scheme (PBS). The purpose of the Scheme is 'to provide timely, reliable, and affordable access for the Australian community to necessary and cost effective medicines.' Drugs sold under the PBS are supplied at a government-subsidized price, with consumers making a co-payment based on their socioeconomic circumstances. In 2002, government spending accounted for 84% of the total cost of the PBS (\$2.9 billion) with around 80% of this amount directed to concessional patients.¹⁵

Many OECD countries have similar schemes and while some governments determine prices through negotiation, Australia applies a cost effectiveness methodology, combined with reference pricing for therapeutic clusters of drugs. A committee (PBAC) advises the government on product additions (or deletions) to the PBS after assessing the clinical need, effectiveness, and cost-effectiveness in comparison with alternative treatments. The government then negotiates prices with suppliers, based on the recommendations of a pricing body (PBPA). To further constrain government costs, wholesaler mark-ups and pharmacist remuneration are controlled.

A recent study concluded that Australia pays less for drugs than most other developed countries.¹⁶ For instance, prices in the USA are from 80% to 160% higher than in Australia, and those in UK and Sweden are around 50% higher. (The differential for

innovative pharmaceuticals tends to be less than for the 'me-too' and generic categories). Despite this price difference, consumption is only slightly below the OECD average. In 1997, Australians consumed the equivalent of \$213 worth of final product each, which was close to the OECD average of \$245 per capita. It has therefore been argued that the PBS also provides a guaranteed market, underwriting broad access to drugs for which demand would otherwise be limited.

Cost increases in the PBS in recent years reflect a continuing trend for doctors to prescribe newer and more expensive drugs. From 1995 to 2002, the cost of the PBS more than doubled. The market is still growing although government pressure is being felt; in 2002, expenditure increased by 9.5% compared to 17.4% the previous year.¹⁵ By contrast, the volume of prescriptions rose by less than half this rate.

During 2001-2, the largest firm by PBS sales value was Pfizer; however, it represented only 10% of the total benefit paid. The top 10 suppliers accounted for around 70% of the total PBS cost. Alphapharm was the largest supplier to the PBS by number of prescriptions. The top 10 firms again supplied around 68% of the total prescriptions written.¹⁷ Figure 5 illustrates the distribution of PBS costs (and their relative growth) in 2002 by therapy category. The drug groups with the most increase were lipid-lowering agents, drugs for acid-related disorders, and anticancer agents.

Regulation

Responsibility for the regulation of therapeutic goods within Australia lies with the Therapeutic Goods Administration (TGA). The TGA carries out a range of assessment and monitoring activities to ensure marketed goods meet high standards and that therapeutic advances are made available to the community in a timely manner. Products covered by the TGA include pharmaceuticals, medical devices, and complementary medicines (such as herbal, vitamin and mineral products). The Australian Register of Therapeutic Goods (ARTG) lists almost 60,000 healthcare products; just under half of which are medicines.¹⁸



Figure 4. An example of a locally developed identification and inspection machine.

The Pharmaceutical Industry in Australia: A Profile

Overall control of the supply of medicinal drugs in Australia is exerted through three main processes: the pre-market evaluation and approval of products intended for supply in Australia; the licensing of manufacturers; and post market surveillance (including investigating reported problems, laboratory testing of products on the market, and monitoring of compliance with the legislation).

In the review and approval of drug-products, the TGA uses a 'risk-management' approach. Risk-factors considered include the strength of a product, side effects, potential harm through prolonged use, toxicity, and the seriousness of the medical condition for which the product is intended to be used. Products used to treat serious conditions, or which need to be used under a doctor's supervision, are subject to a high level of scrutiny and are evaluated for quality, safety, and efficacy. Once approved, these products are included in the ARTG as 'registered' products. Lower-risk 'listed' products, i.e., many non-prescription medicines and complementary medicines, are not generally subject to the same level of evaluation and are assessed only for quality and safety.

TGA inspectors regularly inspect licensed Australian manufacturers to ensure compliance with the *Australian Code of Good Manufacturing Practice for Medicinal Products*. The current code, adopted in 2002, replaces a well-developed local set of documents with an entirely international standard published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S). This development is a further step in the efforts at global harmonization in which the TGA has played a committed, long term, and sometimes leading role. It also specifically increases the alignment of Australia with European Community markets (our largest trading partner) where the same code had already been mandated and assists in the licensing of overseas suppliers to our market.

The TGA is well respected world wide as a rigorous regulator. A Mutual Recognition Agreement (MRA) signed with the European Community in 1998, confirmed TGA audit and inspection processes as adequate for export

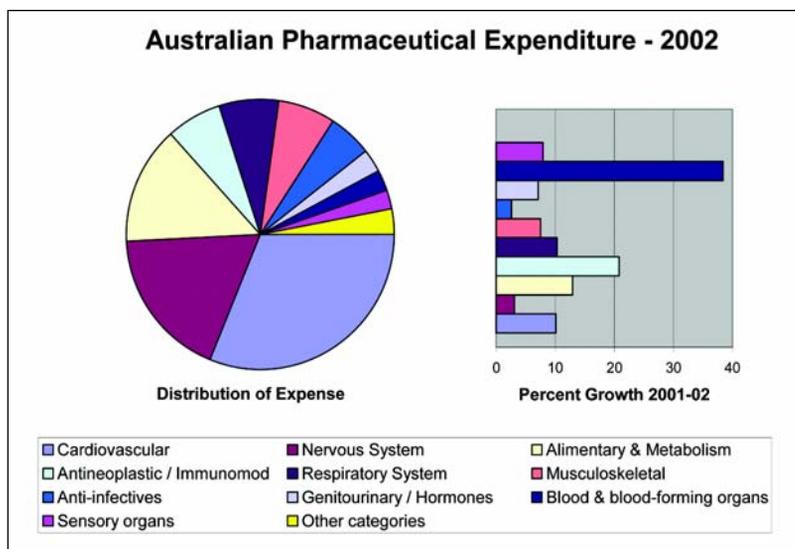


Figure 5. PBS sales value by anatomical group.¹⁵

to that market. Agreements with other regulators have followed, most notably including a Memorandum of Understanding with the US FDA in 2000. Plans have been confirmed for a Trans-Tasman therapeutic goods agency, in combination with New Zealand. As a center of excellence in the regulation of medicines and medical devices the TGA also regularly provides training programs and consultation with regulatory agencies and the pharmaceutical industry of countries in the region. These include China, Hong Kong, Japan, Malaysia, Indonesia, United Arab Emirates, Thailand, Vietnam, Singapore, Taiwan, Nepal, and the WHO.¹⁸

Industry Development and the Future

Since 1988, successive Australian governments have taken steps to give positive encouragement to the pharmaceuticals industry, and to companies willing to invest in the industry. The first of these programs, the Factor (f) Scheme, paid more than \$1.1 billion over 11 years to pharmaceutical companies operating in Australia. This expenditure was intended to recognize and reward activity, including new investment, production and R&D, undertaken by companies attempting to list their products on the PBS.

In 1999 a subsequent program, the Pharmaceutical Industry Investment Program (PIIP), commenced with a budget of \$195 million over five years. This assistance was provided to participating companies, in the form of higher prices for their products, in return for their making commitments to undertake certain activities in Australia, including manufacturing and R&D.



The Pharmaceutical Industry in Australia: A Profile



Both programs were designed to provide partial compensation to the industry for the price suppression of medicines on the PBS resulting from the government's purchasing power and were important in addressing the sustainability of local activity. As a result of these investments, the industry has grown an export base, stimulated R&D opportunities on a world platform, embarked on major capital investment in facilities, and created employment opportunities for highly skilled people.

Since 2001, a committee has been developing a Pharmaceutical Industry Action Agenda (PIAA). The group included representatives of the Commonwealth Department of Industry, Tourism and Resources; Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association) representing most manufacturers of prescription pharmaceuticals; the Generic Medicines Industry Association and AusBiotech (formerly the Australian Biotechnology Association) which brings together companies and individuals involved in the biosciences.

The PIAA was launched in late 2002 with the aim of doubling Australia's share of the global industry by 2012, through the collaborative efforts of Industry, Government, and Research by:

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

The Chairman of Medicines Australia, Mr. Jeays Lilley, has said "*The PIAA can sustain pharmaceuticals as one of Australia's largest export businesses, create more jobs, keep young talented scientists in Australia and hopefully double the output of Australian research.*"¹⁹

In support of the PIAA, the government has announced another five year R&D assistance scheme, the Pharmaceuticals Partnerships Program (P3), to commence mid-2004. It is a competitive entry program focused on developing medicines for global markets and encouraging international firms to foster partnerships with local companies.

The supporting statement by the chair of the PIAA,

Mr. Graeme Blackman, represents a useful summary of this article and the future for the Australian pharmaceutical industry.

*"The Australian pharmaceutical industry can double its share of the global pharmaceutical industry by 2012. Industry's vision for 10 years hence is bold and challenging. It recognizes that we have a strong base from which to grow the pharmaceutical industry. It demonstrates the commitment of all parts of the Australian pharmaceutical industry to work together, and to work with governments, to increase investment in Australia, to become a global hub for research, development and commercialization, and to develop Australia as a key global exporter."*³

Note

Dollars shown are US dollars; exchange rate used in this article is AUD 1 = USD 0.65.

References

1. Department of Industry, Science and Resources, "Pharmaceutical Industry Action Agenda Discussion Paper," 2001 on www.industry.gov.au.
2. Australian Pharmaceutical Manufacturers Association, "APMA Fact Sheet," on www.apma.com.au.
3. Department of Industry, Tourism and Resources, "Pharmaceutical Industry Action Agenda," 2002 on www.industry.gov.au.
4. Department of Industry, Tourism and Resources, "Pharmaceuticals Industry Profile," 2003 on www.industry.gov.au.
5. Reserve Bank of Australia, "Bulletin," April 2002.
6. Commonwealth of Australia, "Health and Medical Research Strategic Review," 1999.
7. Commonwealth of Australia, "Health and Medical Research Strategic Review Discussion Document," 1998.
8. Beattie, P., "NSW-Vic-Qld work together to promote Aussie biotechnology to the world," 13 June 2003.
9. Department of Industry Science and Resources, "Australian Biotechnology Report 2001," 2001, Ernst & Young.

The Pharmaceutical Industry in Australia: A Profile

10. Hopper, K. and Thorburn, L., "2001 Australian Bioindustry Review," Aoris Nova Pty Ltd., 2001.
11. Australian Pharmaceutical Manufacturers Association, "Survey of the Australian Pharmaceutical Industry," 1995.
12. Ernst & Young, Hay Group, Strategic Research Foundation, "Benchmarking Study of R&D Costs in Selected Segments of Australian Biotechnology (Final Report)," January 2001.
13. Commonwealth of Australia, "Pharmaceutical Benefits Pricing Authority Supplementary Annual Report for the year ended 30 June 2001," 2002.
14. Australian Economic Analysis Ltd, "Pharmaceuticals and Australia's Knowledge Economy Vol. 1," 1998.
15. Scrip Magazine, "Australian PBS growth slips back to single figures," 12 June 2003.
16. Productivity Commission, "International Pharmaceutical Price Differences," 2001.
17. Department of Health and Aged Care, "Schedule of Pharmaceutical Benefits," August 2002.
18. Department of Health and Aged Care, "TGA Annual Report 2002," 2002.
19. Lilley, J., "Medicines and Healthy Ageing", National Press Club Telstra Address, 12 August 2003.

Acknowledgement

The author would like to acknowledge the assistance of Steve Haynes of Medicines Australia in the preparation of this article.

About the Author

Mark Donohoo is the Secretary of ISPE Australia. He has worked for AstraZeneca Australia since 1997, initially as a Project Engineer and Project Manager. Recently he was appointed Computer Systems Validation Manager. Donohoo has a Bachelor in mechanical engineering (First Class Honours and University Medal) and is currently completing a Masters of Management. 



Competitive Australia - An Advantage for the Pharmaceutical Industry



by Malcolm Tipping

Australia has become well known globally as an ideal location to travel and has even been rated the number one place in the world where expatriate staff want to live and work.¹ Australia also is recognized as a nation who not only love sport, but also strive to excel at a wide range of artistic and technical pursuits.

What many may perhaps find surprising is that Australia is also a very attractive place to conduct business. In fact, Australia is ranked among the top performing economies in industrialized nations. Over the last five years, Australia's international competitiveness, as measured by IMD International, has been in the top three countries with populations

greater than 20 million, and rose to second behind the United States in 2003.² As Figure 1 highlights, Australia remains ahead of many of the global economic powerhouses, including Germany, France, the United Kingdom, and Japan. IMD measures competitiveness against eight major categories – domestic economy, internationalization, government, finance, infrastructure, management, science and technology, and people. Many of the factors that underpin this result are highly relevant and useful to the development of the pharmaceutical industry.

The Australian Economy is Robust and Sophisticated

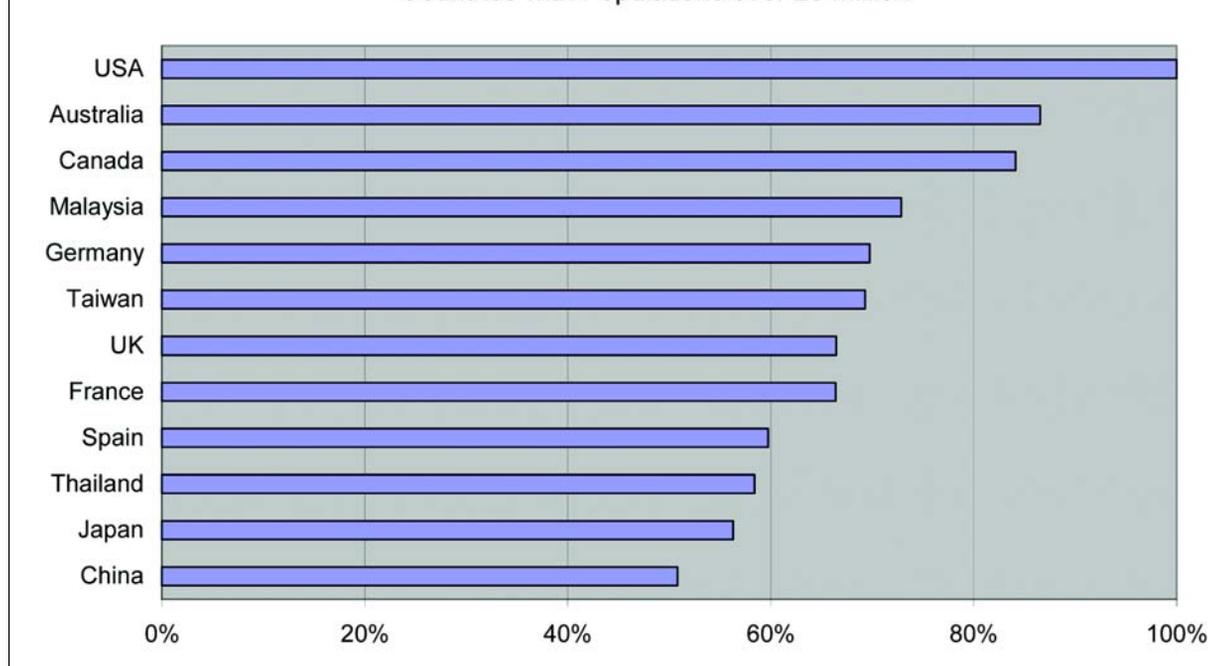
The Australian economy is the 14th

largest in the world and the 11th largest in the OECD. It is the fourth largest economy in Asia, after Japan, China, and Korea.³ It has experienced strong economic growth over the late 1990s with the trend growth rate in the four years to 1999-2000 exceeding 4% per annum, well above the OECD average. Unemployment is low and the outlook for inflation remains within the Reserve Bank target of 2-3% per annum. These factors make Australia an attractive environment for business generally.

Australia has been remarkably successful over the nineties in sustaining strong economic growth and lifting competitiveness and productivity. We have been amongst the fastest growing econo-

World Competitiveness 2003

Countries with Populations over 20 Million



Competitive Australia - An Advantage...

mies in the OECD in terms of growth in overall GDP and GDP per capita. On this latter measure, Australia ranks equal to the United States.⁶

Australia moved from being one of the most highly regulated and closed economies in the '70s to one of the least regulated and more open economies from the '80s.⁴ Australia now retains a record as being amongst the strongest economies with the Federal Government's Budget being one of the few in surplus, a low inflationary environment, a stable political system, and a AAA-rated Australian dollar. Low interest rates also have ensured that firms have access to low cost capital. Interest rates are forecast to remain low, at 2-3%, into 2004.⁷

As *The Economist* recently observed:

*"to a visitor from the northern hemisphere, Australia is like another planet. Not only does the sun shine there much more at this time of year, but even as the economies of America, Europe and Japan appear to be stumbling for the second time in three years, Australia continues to boom. The country is now in its 12th year of uninterrupted economic expansion..."*⁵

The strength of the Australian economy has seen exports (particularly for manufactured goods) grow strongly, assisted by a low and competitive Australian dollar.⁴ Indeed, over the second half of the '90s, Australia's manufactured exports grew by one third, helping Australian business to capture a large share of its export markets.⁴

The pharmaceuticals indus-

try is a significant contributor to economic growth with increasing employment, manufacturing exports, and R&D activity. Four of the top 10 Australian companies (ranked by profitability) are pharmaceutical companies.⁸ Pharmaceutical exports doubled over the five years to 2000-01 and have now become Australia's second largest manufactured-export category.⁴

Basic Scientific Research in Certain Fields is Among the Best in the World

The Australian Government is committed to fostering a world-class innovation culture and R&D infrastructure. Australia's innovation policy aims to build world competitive firms and research capability; to strengthen international competitiveness; and to increase national prosperity through focus on developing medicines for global markets. Encompassed in a A\$3 billion, five year strategy, Australia's innovation policy provides a number of cutting edge initiatives, including:

- substantial R&D tax concessions to encourage an increase in the amount of R&D performed by businesses in Australia
- development of a world-class Information and Communications Technology (ICT) Centre of Excellence
- establishment of a Biotechnology Centre of Excellence
- a Major National Research Facilities program that will see investment in research infrastructure of national and international significance

- tailored research and development tax rebates for small companies
- new advantageous rules for expenditure on plant and assets used for R&D

Commonwealth funding for biotechnology research alone is estimated at US\$300 million a year,⁹ which is roughly equivalent to the total spent by industry on research and development into human use pharmaceuticals.

Most of Australia's basic research is conducted in public universities or funded through Government mechanisms. Much of the infrastructure for clinical trials is in the public health systems, especially hospitals. Government also has established specific programs to assist in commercializing Australian research. State Governments continue to play significant roles in the development of the pharmaceuticals industry.

Australia has a record of first class scientific research, which is disproportionate to its size. This includes excellent capability in critical new knowledge areas and platform technologies such as genomics, bio-informatics fast screening; natural products etc. Many good drug candidates are now emerging from R&D on national biota.

Australia's innovative culture and support for R&D pave the way to the future with Australian research organizations such as the Commonwealth Scientific and Industrial Research Organization (CSIRO) ranked third in the world for environmental research.¹⁰



Competitive Australia - An Advantage...

Cost Competitive, High Quality Location

Cost competitiveness and commitment to quality makes Australia a highly efficient and productive location with cost structures for research and development among the lowest. Office space in Australian cities can be a fraction of the cost of comparable properties in London, New York, Tokyo, Hong Kong, and Singapore¹ and have frequent, reliable, and cost effective transport links to the rest of the world.

Australia has the highest availability of IT and finance skills of all countries, the most competitive telecommunications system in the Asia Pacific,⁴ after the US the highest e-commerce usage,¹¹ fifth highest ranked physical infrastructure, among the lowest costs for industrial electricity and natural gas,¹⁰ and an acceleration in labor productivity achieved through a decentralization of labor markets and the impacts of Information and Communications Technologies (ICT).⁴

Productivity

Australia has achieved one of the fastest rises in productivity, aided by the benefits of a strong labor market, microeconomic and taxation reform, and a rapid uptake of information and communication technologies.⁴ Australia recorded an impressive labor productivity growth of an average of 3.0% from 1996 to 2002. This increased to 3.8% in 2002, compared with an estimated OECD average of 2.0%.¹⁰ The US Federal Reserve has singled Australia out as one of the few economies to have improved productivity growth in recent times. In fact, it showed that Australian productivity growth rates

were higher than rates recorded in the G7 countries over the last decade.¹²

Accompanied by a trend toward falling labor costs, this has provided a significant incentive for businesses to invest in Australia. Real unit labor costs have declined due to strong productivity and modest wages growth; industrial disputes are also at the lowest level in 20 years.¹³ Australian on-costs are low by international standards with a high availability of low cost skilled labor (second to India).¹⁴

A study in 2001, by the Department of Industry Science and Resources, compared Australia with 14 other countries as an investment destination for research and development intensive activities.¹⁵ The study modeled seven factors in setting up a 30-person research facility in a number of fields, including pharmaceuticals, clinical trials, and biotechnology research. The factors were:

- salaries, laboratory set up and running costs, rents, infrastructure and communications
- access to world-class human resources and intellectual capital
- supportive business environment such as R&D incentives and research infrastructure
- ability to engage with and benefit from local technical alliances and business networks
- regulatory issues
- communications infrastructure and time zone issues

- lifestyle, culture and language capabilities

Australia was ranked high on its knowledge base, efficiency of international communications, links to high technology manufacturing capability, access to capital and financial markets, and reliable industry intelligence about life-sciences capability. The study concluded that Australia was the lowest cost country in all fields.¹⁵

Australia is located conveniently to the South East Asian and Pacific regions, making it a likely candidate for a regional clinical trial base, primary or secondary manufacturing of innovative and generic products or for the distribution of finished goods to the region for either larger multinational, and specialized smaller pharmaceutical companies.

Standard of Living

A study by Ernst and Young in 2000 concluded that Australia had both the lowest cost of living and the highest quality of life.¹⁵ Five of Australia's mainland capital cities are ranked in the top 10 livable cities in the world². Australia has an excellent public health system, and is one of the top 10 spenders on healthcare as a proportion of GDP.¹

The Workforce is Educated, Sophisticated, and English Speaking

Knowledge intensive industries require access to a skilled workforce. The pharmaceutical industry is one of the most knowledge intensive in the world and the level of skills demanded at all points along the value chain is getting higher. Australia's workforce has been a particular strength for the industry.



Competitive Australia - An Advantage...

The Australian labor force is multilingual, highly educated, and computer literate. Indeed, Australia has the second most skilled labor force and ranks fourth in terms of higher education enrolment.¹⁶ Australian tertiary institutions produce a higher proportion of health and science graduates than the USA, the UK, Canada, Germany, or Singapore.¹⁵

Australian scientists and researchers are responsible for many advances in business and industry, and have made significant contributions in medical science. Their discoveries through the years have won prestigious international awards, including six Nobel Prizes.

Intellectual Property Protection Measures Among the Best in the World

Intellectual Property (IP) rights are respected and enforced in Australia. Australia's modern and effective IP regime is ranked more highly than countries such as the UK, Japan, Hong Kong, and Singapore,¹ having a ranking of number one in Asia and fourth internationally. Australian based firms benefit from the most comprehensive protection possible. Firms can therefore invest in R&D, transfer technology, and develop new products with confidence.

Pharmaceutical specific intellectual property protection is also strong. The *Intellectual Property Laws Amendments Act 1998* contained two amendments relevant to the pharmaceutical industry: the extension of the effective patent life by up to five years; and the introduction of 'spring boarding' for the manufacturers of generic or

off-patent pharmaceuticals. The amendments attempted to balance the interests of generic and innovative manufacturers.

Laws are Effective and Enforceable

Australia's democratic society, stable system of government, and harmonious social environment can provide your business with the certainty it needs. The Australian political environment is considered one of the most stable in the world, ranked third behind only Finland and Luxembourg.¹

Australia's strong system of checks and balances also ensures that the risk of corruption is low. Our strong and highly respected judicial and law enforcement systems provide a safety net to deter and punish corruption where appropriate.¹

Australia's regulatory system is one of the most transparent and democratic in the world, providing predictability for business planning and operations. Unlike many countries in the region, there are no foreign exchange controls and the Australian currency is fully internationalized. In Australia, capital flows, profit remittances, capital repatriation, transfer of royalties, and trade-related payments are largely free from regulation.

Globally Respected Therapeutic Goods Regulations

Australia's excellent pharmaceutical regulatory environment is on a par with the best in North America and Europe. The FDA recently endorsed the high standard of control over Australian manufacturing exerted by the Therapeutic Goods Administration (TGA), through the signing of a memorandum of understanding

between the two authorities. This signifies mutual recognition of each body's audit and inspection processes.

A Free Market for Pharmaceuticals Based on Competition and Choice

Australia has a competitive pharmaceutical market. Drivers are pricing, taxation and business costs. The Pharmaceutical Benefits Scheme (PBS) dominates the Australian market for prescription pharmaceutical products. The PBS underwrites demand; this means that for most multinationals, Australia is a reasonably sized market with an estimated \$4.25 billion spent in 2000-01. This can be seen as a guaranteed market for the industry.

Conclusion

Australia is a stable, democratic society with a skilled workforce and a strong, competitive economy with the benefits of:

- understanding of and proximity to the growing Asian market (with a cost effective infrastructure for transport)
- Good Manufacturing Practice standards recognized by the USA and many Asian and European countries.
- centers for R&D in pharmaceuticals, biotechnology, medical devices, and generics
- clinical trial expertise
- infrastructure for education, training, and manufacture
- political stability



Competitive Australia - An Advantage...

- strong Intellectual Property laws
- reputation for high quality manufacture
- low cost of investment

The Australian pharmaceutical 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. This will be achieved by:

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

References

1. IMD, "World Competitiveness Yearbook 2002," 2002.
2. IMD, "World Competitiveness Yearbook 2003," 2003.
3. Department of Industry Science and Resources, "Invest Australia: Your Guide," p.4.

4. Australian Industry Group Economics, "How Competitive is Australia," June 2003.
5. The Economist, 8 March 2003, p. 72.
6. OECD, "Recent Growth Trends in OECD Countries," Economic Outlook, no. 67, June 2000, pp. 174-192 and OECD, "The Sources of Economic Growth in OECD Countries," 2003, pp. 32-33.
7. Reserve Bank of Australia, "Statement on Monetary Policy," February 2003.
8. BRW Top 1000 on <http://www.brw.com.au/>. Note: There is a lack of data on the pharmaceutical industry profitability in Australia due to the global nature of the industry.
9. Department of Industry Science and Resources, "Australian Biotechnology Report 2001," Ernst & Young, 2001, pp. 10-11.
10. OECD, Bulletin, April 2003.
11. Department of Communications, Information Technology and the Arts, "Australia: A Wealth of Opportunity," 2003.

12. United States Federal Reserve, Bulletin, October 2000.
13. Australian Bureau of Statistics, November 2002.
14. Asian Intelligence, Political and Economic Consulting Ltd, August 2000.
15. Department of Industry Science and Resources, "Benchmarking Study of R&D Costs in Selected Segments of Australian Biotechnology," prepared by Ernst and Young, the Hay Group and Strategic Industry Research Foundation, Canberra, January 2001.
16. IMD, "The World Competitiveness Yearbook 2000," 2000.

Acknowledgement

The author would like to acknowledge the assistance of Mark Donohoo of AstraZeneca Australia.

About the Author

Malcolm Tipping is the Quality Manager at Synertec - Life Science Solutions with more than 15 years of experience in the pharmaceutical industry working in production, validation, and quality roles. Tipping has a Bachelor in applied science. 



Australia's Biodiversity - A Natural Opportunity for Drug Development

by Mark Donohoo

Introduction

The vast, ancient island continent of Australia has produced many unusual, rare, and sometimes unique examples of flora and fauna. Australia is one of only 17 mega-diverse countries with a unique proportion of botanical diversity (80%) found nowhere else in the world. The distribution of climates, topography, and soils that has produced the variation in Australian vegetation is also reflected in the distribution of animal life. Australia probably has between 200,000 and 300,000 species, about 100,000 of which have been described.¹ While this diversity presented a storehouse of healthcare goods for the original indigenous peoples, exposure to scientific analysis is a far more recent development.

In the search for new therapeutic compounds, Australia has become considered a key source. About 25% of modern drugs are derived from natural products and the wide diversity of Australian fauna and flora have been exposed to relatively minor investigation. It is estimated that the 23,000 species of vascular plants in Australia represent about 10% of the world's plant diversity. More than 85% of these are thought to be unique.²

The rainforests of Queensland, for instance, contain an estimated 9,000 plant species – 75% of which are found only in Australia. Western Australia alone has more than 5% of the world's plant species. Only 1% of our plants have

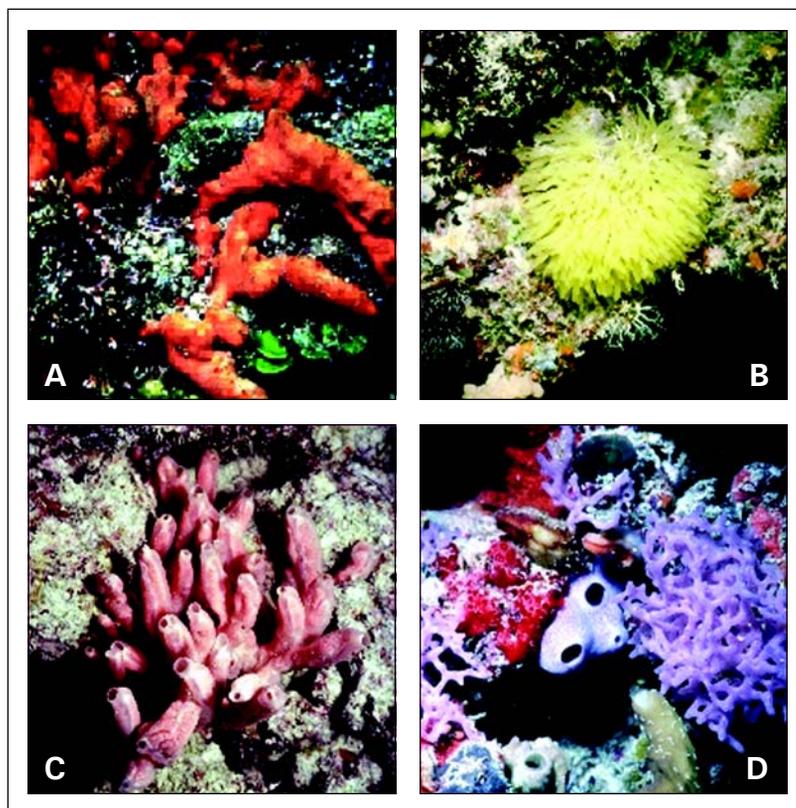


Figure 1. Marine Sponges - these new species were discovered on the Great Barrier Reef as part of NPD bio-prospecting (all photographs J.N.A. Hooper, Queensland Museum).³

- A. *Clathria (Thalysias) craspedia* - an orange-brown siliceous microcionid sponge.
 B. *Sycetta n.sp.* - a yellow calcareous sponge.
 C. *Echinochalina (Protophilitaspongia) isaaci* - a pale pink branching siliceous sponge.
 D. *(Leucaltisn.sp.)* - A mauve calcareous sponge.

been mined for natural compounds.

Probably the most notable Australian bio-discovery program is Natural Product Discovery (NPD), collaboration between AstraZeneca and Griffith University in Queensland. NPD (formerly AstraZeneca R&D Griffith University) was established in 1993 and is recognized as one of the top five natural product institutes in the world. The program's goal is to

find potential therapeutic drugs from the biological compounds that occur in plants from Queensland's rainforests and marine organisms from the Great Barrier Reef.

Samples are extracted to form NPD's substantial extract library. Using an automated screening process, the extracts are screened for a "hit" (a substance that binds with a target protein). This high-throughput screening identifies a



Australia's Biodiversity



Figure 2. Funnel-Web Spider (copyright Dr Julian White, State Toxinology Services, South Australia).

significant number of active compounds, which are then isolated and their structure determined.

Once their structure has been understood, these natural compounds can be made synthetically in large quantities (to reduce the need to harvest large sample quantities). The scope of the project was expanded in 2000 with the addition of a Medicinal Chemistry section to undertake combinatorial chemistry on promising bioactive compounds. The addition of this section has resulted in the development of local expertise in yet another link in the drug discovery chain. As well as expertise in collection, screening, isolation and structure determination of natural products, NPD also can now boast lead optimization capabilities for commercial application.⁴

NPD has established an extensive database and has discovered more than 700 biologically active compounds.⁵ Scientists collecting flora and fauna samples also have discovered and catalogued more than 60 new species of plants and 2000 new species of marine sponges. AstraZeneca has committed more than \$65 million to this collaboration, and has recently confirmed its involvement to the end of 2007. The success of the program also has allowed NPD to extend its sample collection activities to

Papua New Guinea, India, and China, placing this Australian research initiative at the forefront of global bio-discovery.

Some of the earliest research was necessitated by the presence of a wide range of venomous animals in Australia. These include some of the world's most poisonous snakes (the taipan, tiger snake, brown snake, and death adder) and spiders (red back spider and funnel web spider), as well as a number of marine stingers (the box jellyfish, stonefish, and sea snake). All of these are dangerous to humans and have caused deaths. Research and development of antivenoms began in 1928 with collaboration between scientists at the Walter and Eliza Hall Institute and the Commonwealth Serum Laboratories (CSL).⁶ Although antidotes for all snakebites had been developed by 1962, it was not until 1980 that one became available for the funnel web spider. When CSL was privatized in 1994, the investigation work was transferred to Melbourne University and the Australian Venom Research Unit.⁷ CSL has gone on to become Australia's largest biotechnology company and continues to manufacture and supply antivenoms to hospitals.⁸

In a major contrast to the early work by CSL, one Australian company is looking for drugs in venomous animals, using the latest in genome to drug technologies. Xenome, a spin-off from the University of Queensland, has leading edge expertise in the characterization of venom genomes and has an exclusive worldwide royalty free license to a large portfolio of novel venom peptide compounds, including those from coneshells, spiders, snakes, scorpions, and

centipedes. Among Xenome's important drug leads are several coneshell peptides targeted at pain modulation. Over the course of 2002, Xenome signed agreements with companies from Europe, the UK, and the US to use this knowledge base in the development of a range of therapeutics and pharmaceuticals.⁹

Other bio-prospecting programs are developing from research bodies with government funding. These may lead to partnerships with pharmaceutical and biotech companies, or to spin-off commercialization ventures.

The Commonwealth Scientific and Industrial Research Organization (CSIRO) is involved in a project to collect samples of insects and develop a library of extracts. More than 1000 species of insects have been collected and extractions, validation and chemical profiling are well underway.⁹ Work to date has yielded several anti-microbial and potential anti-cancer actives.¹⁰ This activity has led to the recent formation of Entocism, as a spin-off from CSIRO. Entocism use a technology platform licensed from the CSIRO with the intention of exploiting insect biological and chemical diversity for a range of therapeutic applications. Entocism also are collaborating with experts in infectious diseases and natural products chemistry from Canberra Hospital, and the Australian National University (ANU).

Cooperative Research Centers (CRCs) are another government funded program set up in 1990 to establish formal strategic long-term agreements between industry, research, and government to support R&D and education objec-



Australia's Biodiversity

tives. The CRC for Bioproducts was established in 1999 to focus on developing commercially valuable materials produced by plants and other living organisms, for various uses including complementary medicines, nutraceuticals, and pharmaceutical intermediaries.¹²

Another initiative is the CRC for Discovery of Genes for Common Human Diseases.¹³ Cerylid Biosciences is the industry partner for this CRC and are integrating genomics and natural product screening to discover and develop drugs to treat common human diseases. Cerylid's internal screening program is focused on the identification of new anti-cancer drugs from its Natural Products Library. It also has two ongoing gene discovery projects for endometriosis and type-1 diabetes.

Biota specimens are sourced from Australia, and South East Asia as well as Antarctica. From these regions, Cerylid Biosciences has generated extensive and proprietary libraries of about 600,000 natural product samples.¹⁴ The libraries are deployed in collaborative drug discovery partnerships with leading pharmaceutical and biotechnology companies, such as Aventis.

Cerylid also has access to the Tasmanian human population for genetic studies through an exclusive relationship with the Menzies Research Institute in Tasmania.

Bioprospect Limited is a company that provides nature derived chemicals for various discovery programs, from nutraceuticals to front-line pharmaceuticals. Collections are

expanding its extensive extracts library by around 2000 species per year. With a landmark license from the state government of Washington, Bioprospect is the broker of unique and largely unexplored biota. The company has signed a number of agreements with US based companies. An alliance with Apath LLC is intended to develop potential treatments for the Hepatitis C virus and other viral pathogens.¹⁵

Australia's rich biodiversity means companies have the benefit of one of the world's most diverse ecosystems at their doorstep. In combination with local access to leading-edge research expertise and technology, the bio-prospecting industry has grown rapidly in Australia and is likely to remain the subject of strategic investment.

References

1. Britannica 2001, "Australian Animals," Oxford University Press.
2. World Conservation Monitoring Centre.
3. NPD, "NPD Tour - Reef - Marine Sponges," www.az.gu.edu.au/marine_sponges.asp.
4. "AstraZeneca - Drug Discovery Technologies," www.astrazeneca.com/mainnav1/s_research/c_research/drug-discovery-technologies.html#IDAK5VDB.
5. "NPD Tour," www.az.gu.edu.au.
6. "Antivenoms for the Australian Population," www.dhs.vic.gov.au/nph/key/key16/body16.htm.
7. "About AVRU," www.avru.unimelb.edu.au/avruweb/aboutav.htm.
8. "About CSL," www.csl.com.au.
9. "Science Overview," www.xenome.com.
10. "Bioprospecting - Finding Gold in Australia's Biodiversity," www.investaustralia.gov.au/index.cfm?id=56E756B4-9027-E533-1F3873EA407A5129.
11. "Drug Discovery: Discovering Antibiotics and other Pharmaceuticals from Insects," www.bio2003.csiro.au/Projects/4entocsm.htm.
12. "CRC for Bioproducts," www.crc.gov.au/centres/man/bioproducts.htm.
13. "CRC for Discovery of Genes for Common Human Diseases," www.crc.gov.au/centres/medical/genes.htm.
14. "Welcome to Cerylid Biosciences," www.cerylid.com.au.
15. "Bioprospect - Company Profile," www.bioprospect.com/flash_section/corporate.html.

Acknowledgement

The author would like to acknowledge the assistance of Kelly Sims from Invest Australia in the preparation of this article.

About the Author

Mark Donohoo is the Secretary of ISPE Australia. He has worked for AstraZeneca Australia since 1997, initially as a Project Engineer and Manager. Recently, he was appointed Computer Systems Validation Manager. Donohoo has a Bachelor in mechanical engineering (First Class Honors and University Medal) and is currently completing a Masters of Management. 



Australian Government

Department of Health and Aged Care

GPO Box 9848
Canberra, ACT, 2601
Tel: +61 2 6289 1555
Fax: +61 2 6281 6946
www.health.gov.au

Department of Industry, Tourism, and Resources

GPO Box 9839
Canberra, ACT, 2601
Tel: +61 2 6213 6000
Fax: +61 2 6213 7000
www.industry.gov.au

Australian Regulatory/ Standards Bodies

Therapeutic Goods Administration

PO Box 100
Woden, ACT, 2606
Tel: +61 2 6232 8438
Fax: +61 2 6232 8605
www.tga.gov.au

Standards Australia

GPO Box 5420
Sydney, NSW, 2001
Tel: +61 2 8206 6000
Fax: +61 2 8206 6001
www.standards.com.au

Australian Industry Associations

Medicines Australia

Level 1, 16 Napier Close
Deakin, ACT, 2600
Tel: +61 2 6282 6888
Fax: +61 2 6282 6299
www.medicinesaustralia.com.au

AusBiotech

576 Swan Street
Richmond, Victoria, 3121
Tel: +61 3 9208 4200
Fax: +61 3 9208 4201
www.ausbiotech.org

Medical Industry Association of Australia Inc

PO Box 497
Roseville, NSW, 2069
Tel: +61 2 9415 1151
Fax: +61 2 9415 2130
www.miaa.org.au

Complementary Healthcare Council of Australia

PO Box 104
Deakin West, ACT, 2600
Tel: +61 2 6260 4022
Fax: +61 2 6260 4122
www.chc.org.au

Australian Packaging Machinery Association

PO Box 2076
Rose Bay North, NSW, 2030
Tel: +61 2 9416 5126
Fax: +61 2 9416 5126
www.apma.asn.au

