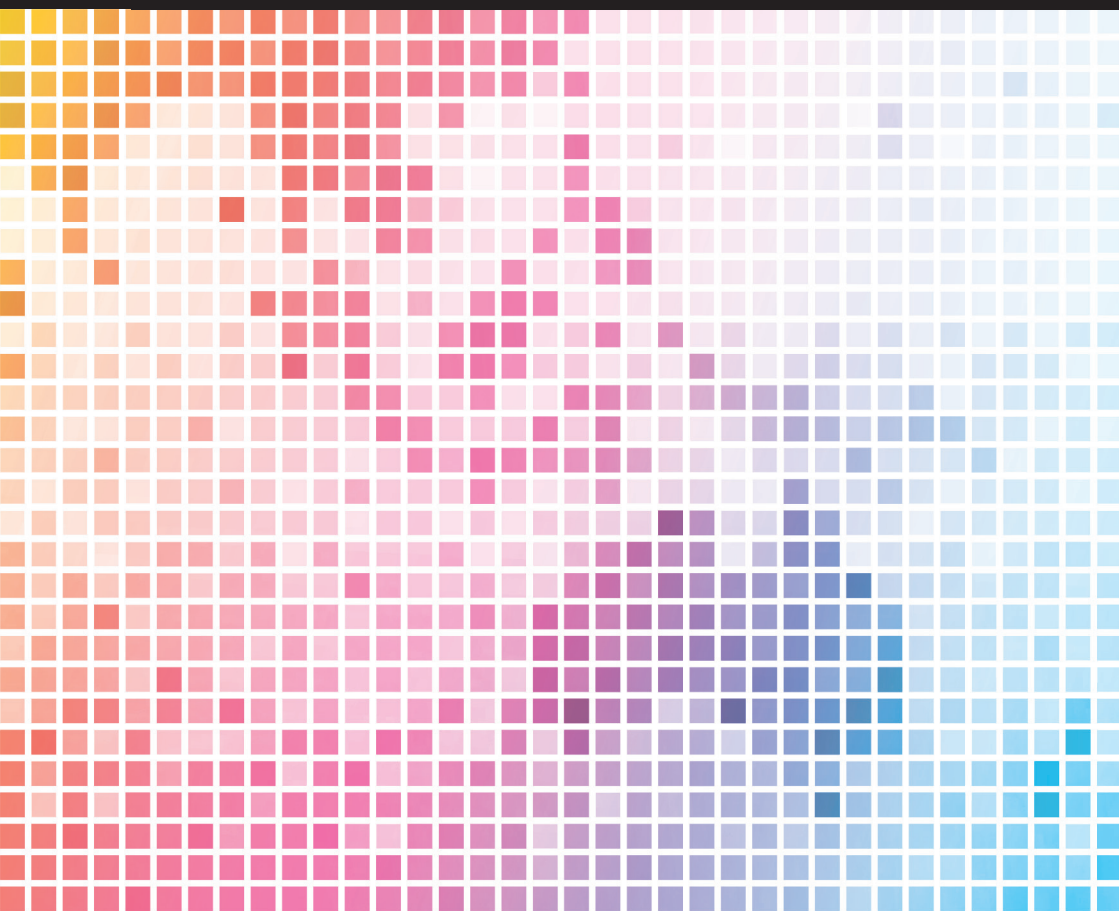


MEDICINES AUSTRALIA
→ FactsBook 4 FOURTH EDITION



MEDICINES
Australia

MEDICINES AUSTRALIA FactsBook FOURTH EDITION

This is the fourth edition of the *Medicines Australia Facts Book*. It updates and builds on the third edition of the *Facts Book*, which was published in March 2013.

I would like to thank my colleagues Elizabeth de Somer (Director, Policy and Advocacy), Omar Ali Khan (former Manager, Industry Policy) and members of the Medicines Australia Industry Policy Working Group for their work preparing this document.

Please do not hesitate to contact us if you have any queries or feedback. I hope you find this a useful resource.

Yours faithfully,



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Introduction

The pharmaceutical industry in Australia

The pharmaceutical industry is one of Australia's most innovative industries. Currently, around 50 global research-based pharmaceutical companies and more than 400 locally-owned biotechnology firms operate in Australia. The industry employs thousands of highly-skilled Australians, generates billions in exports, invests millions of dollars in research and development and, most importantly, delivers medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives.

Playing our part to keep Australia's healthcare system sustainable

Australia is not immune to certain trends affecting other advanced economies. Like many of them, Australia is home to an ageing population and the Australian Government, like other governments around the world, faces the challenge of dealing with the issue of rising healthcare costs.

However, successive Australian governments, in close partnership with industry, have implemented reforms to ensure the long-term sustainability of the Pharmaceutical Benefits Scheme (PBS), which provides Australians with universal and subsidised access to over 3000 medicines and which accounts for approximately 80 per cent of the market for medicines in Australia. Fortunately, Government expenditure on the PBS as a percentage of GDP has remained stable for the past decade.

Challenges and opportunities

Despite its successes, the pharmaceutical industry's future in Australia remains uncertain. It faces a number of challenges which are threatening its future viability and its capacity to contribute to the health and wealth of this nation. For instance, an increasingly unstable and unpredictable operating environment is putting extraordinary pressures on companies and, in many cases, discouraging them from investing in Australia. This has already contributed stagnant or declining investment in research and development and declining exports.

Unfortunately, this comes at a time of immense opportunity for Australia. Much of the growth in the market for medicines and vaccines over the next decade will come from Asia and Australia is uniquely placed to meet this demand. With the right policies in place, Australia could double its share of the global pharmaceutical market over the next decade. Without them however, Australia will most likely miss out on this once-in-a-generation opportunity.

Medicines Australia has called on Australian policymakers to:

- ensure a stable, predictable and efficient business operating environment;
- strengthen Australia's intellectual property system;
- enable growth in the Australian biotechnology sector; and
- enact globally competitive incentives to encourage investment in R&D, high-tech manufacturing and public-private partnerships.

Part 1

Research and Development



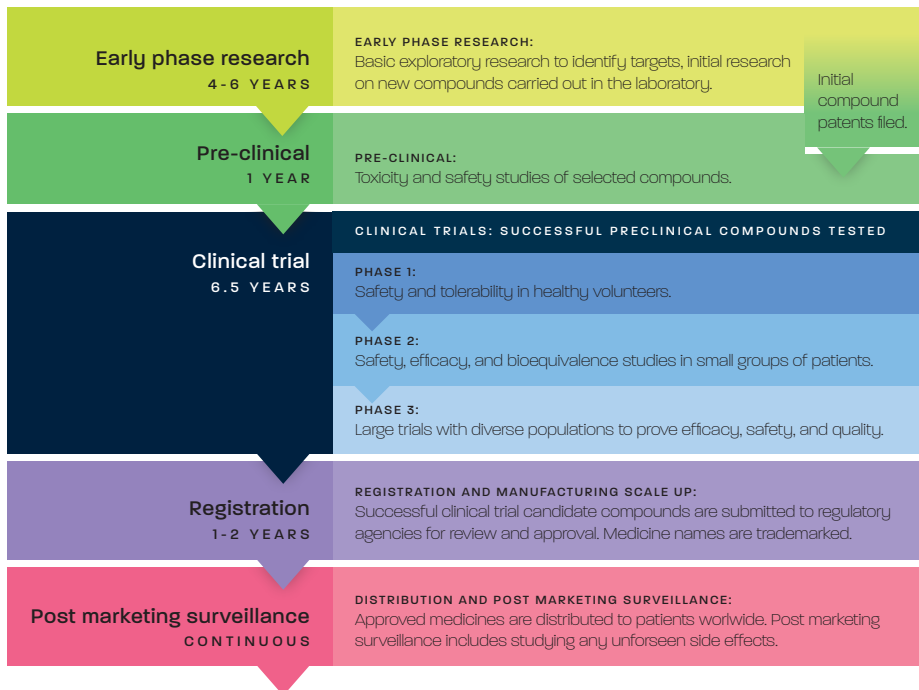
Australia's tradition of excellence in medical research has made it an important component of the global healthcare continuum. It has attracted billions in global investment in research and development over the past 10 years, and collaborations between global pharmaceutical companies and Australian entities have enabled the development and world-wide distribution of ground-breaking Australian discoveries such as the HPV vaccine, which is helping protect women around the world from cervical cancer, and an antiviral drug used around the world to prevent or shorten the duration of flu infections.

Research and Development

1. Bringing new medicines and vaccines to market is expensive, time consuming and incredibly risky

The process of bringing new medicines and vaccines to market is expensive, time consuming and incredibly risky. On average, the cost of bringing a new medicine or vaccine to market is approximately US\$2.6 billion (including the cost of failed research and development projects), and it can take between 10 to 15 years to complete the process.

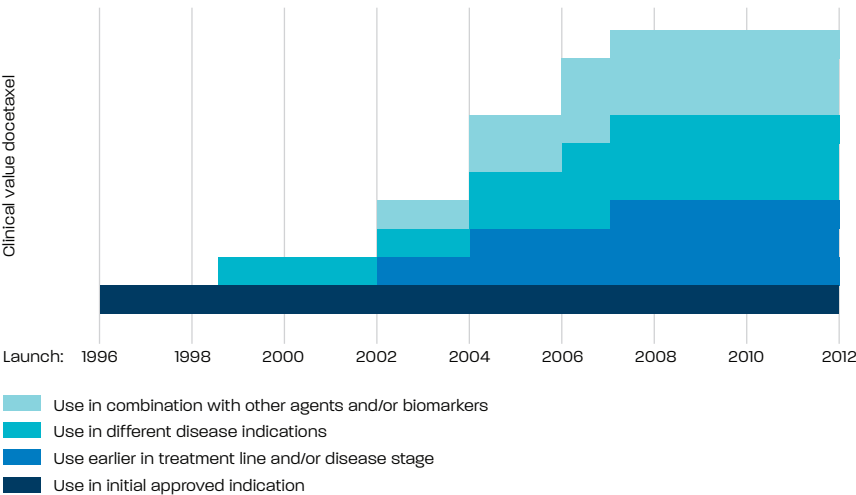
FIGURE 1.1 From research to market



2. Incremental innovation plays a vital role in improving health over time

Pharmaceutical innovation does not stop at discovery of the basic molecule, but continues on for 10 to 15 years before launch and beyond. For example, in 1996, the US Food and Drug Administration approved docetaxel, a small-molecule medicine, as a treatment for locally advanced or metastatic breast cancer. Over the next 10 years, it was also approved for use in certain types of lung, gastric, prostate, head and neck cancers.

FIGURE 1.2 Approval process (docetaxel)



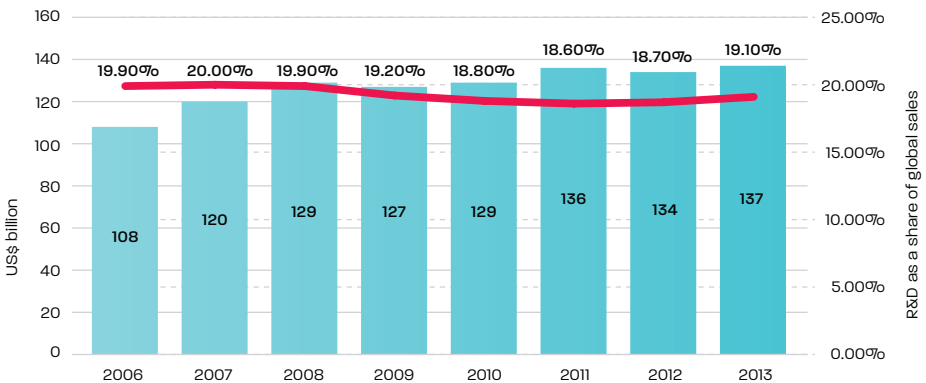
SOURCE Boston Healthcare Associates, Boston, 2012, Recognising Value in Oncology Innovation.

Research and Development

3. The pharmaceutical industry invests over US\$100 billion globally in research and development each year

The pharmaceutical industry invests more in research and development than any other business sector in the world (US\$ 137 billion in 2013). Between 2006 and 2013, the industry's investment in research and development grew by an average of 3.4 per cent and accounted for approximately 19 per cent of the industry's global sales.

FIGURE 1.3 Business expenditure on pharmaceutical R&D (global)

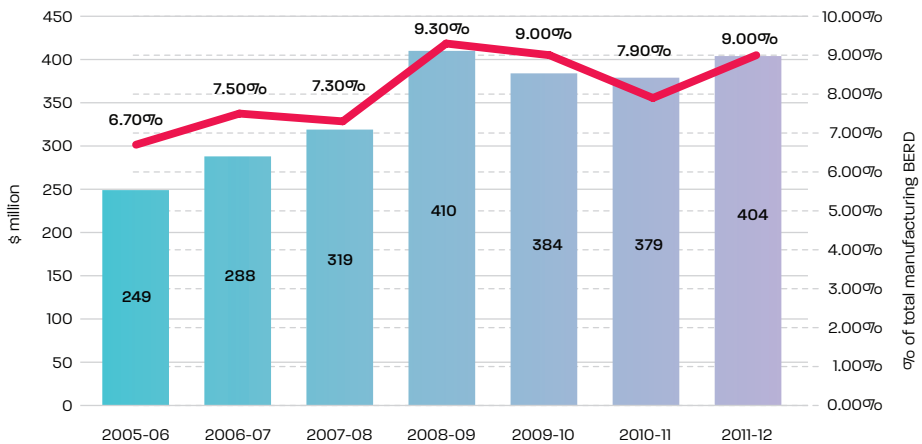


SOURCES EvaluatePharma, London, 2014, *World Preview 2014, Outlook to 2020*.
European Commission Joint Research Centre, Seville, 2013, EU R&D Scoreboard: The 2013 EU Industrial R&D Investment Scoreboard.

4. The pharmaceutical industry is one of Australia's biggest investors in research and development

The pharmaceutical industry is one of Australia's biggest investors in research and development. Since 2005-06, this investment has grown by more than 60 per cent. In 2011-12, the pharmaceutical industry accounted for 9 per cent of all business expenditure on research and development in Australia.

FIGURE 1.4 Business expenditure on pharmaceutical R&D (Australia)



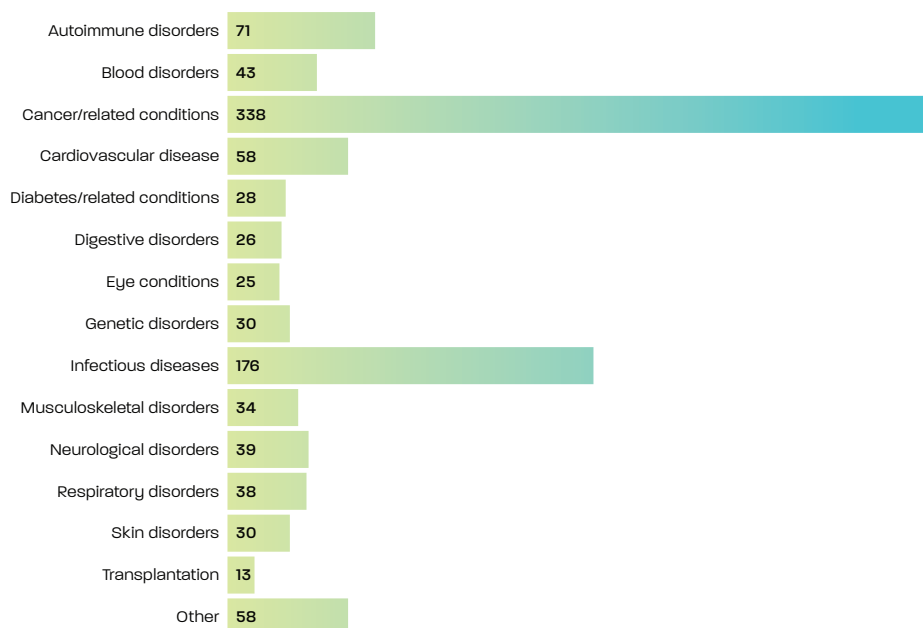
SOURCE Department of Industry, Canberra, 2014, *Australian Pharmaceuticals Industry Data Card 2014*.

Research and Development

5. The pharmaceutical industry is currently developing thousands of new medicines and vaccines

The global pharmaceutical industry is currently developing thousands of new medicines and vaccines, including over 900 new 'biologics'. Biologics are complex molecules derived from living cells and they represent the cutting edge of modern medicine. Biologics have already revolutionised the field and, in time, they could deliver the most effective means of treating a variety of illnesses and disabilities.

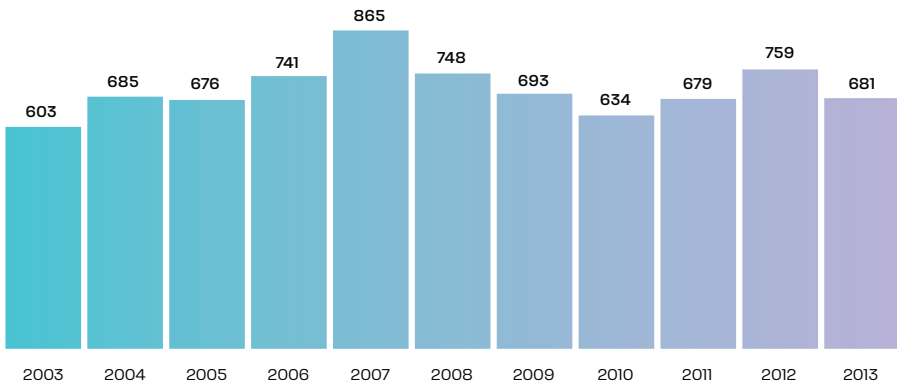
FIGURE 1.5 Number of biologics in development, 2013



6. Number of pharmaceutical industry initiated new clinical trials in Australia is in decline

Each year, the pharmaceutical industry initiates hundreds of new clinical trials in Australia, supporting thousands of high-paying jobs and playing a vital role in improving the health and wellbeing of Australians. Unfortunately, Australia has been struggling to attract clinical trial investment in recent years. It is vital that all initiatives currently underway to improve Australia's competitiveness as a destination for clinical trial investment are completed within a reasonable timeframe.

FIGURE 1.6 Number of new clinical trials (medicines), Australia



SOURCES Therapeutic Goods Administration, Canberra, 2014, *Half Yearly Performance Report, Jul-Dec 2013*.
 Department of Industry, Canberra, 2011, *Clinically Competitive: Boosting the Business of Clinical Trials in Australia*.

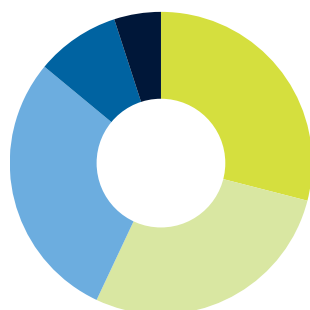
Research and Development

7. Industry-sponsored clinical trials subsidise the delivery of healthcare in Australia

The pharmaceutical industry conducts a full range of clinical trials in Australia, from first-in-human trials (Phase 1) to post-market studies (Phase 4). This investment is not only an additional funding source for Australia's health system, but also a way of subsidising the delivery of healthcare to Australian patients.

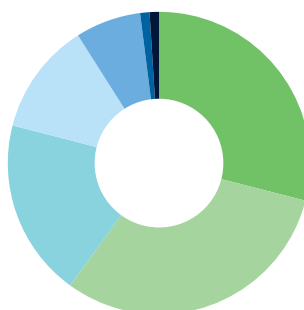
FIGURE 1.7 New clinical trials in Australia

New clinical trials (medicines),
by phase, 2013



Phase 1, 29%
Phase 2, 28%
Phase 3, 29%
Phase 4, 9%
Other, 5%

New clinical trials (medicines),
by location, 2013



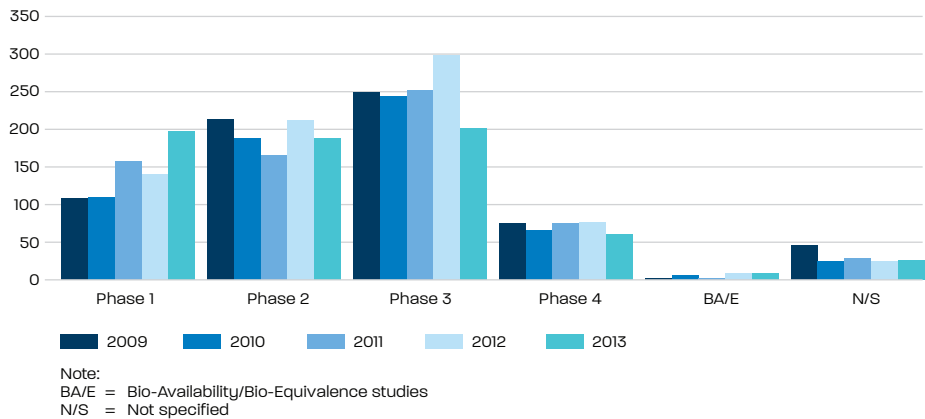
New South Wales, 29%
Victoria, 31%
Queensland, 19%
South Australia, 12%
Western Australia, 7%
Tasmania, 1%
Australian Capital Territory, 1%

SOURCE Therapeutic Goods Administration, Canberra, 2014, *Half Yearly Performance Report, Jul-Dec 2013*.

8. Despite significant growth in 'early phase' clinical research in Australia, there is a decline in late phase activity

Between 2009 and 2013, Phase 1 activity in Australia grew by more than 80 per cent. However, activity in other areas declined, including by around 20 per cent in Phase 3. The Australian Government, in partnership with industry and other stakeholders, is implementing reforms to ensure Australia remains a leading destination for clinical trial investment.

FIGURE 1.8 Number of new clinical trials (medicines), by phase, 2009-2013



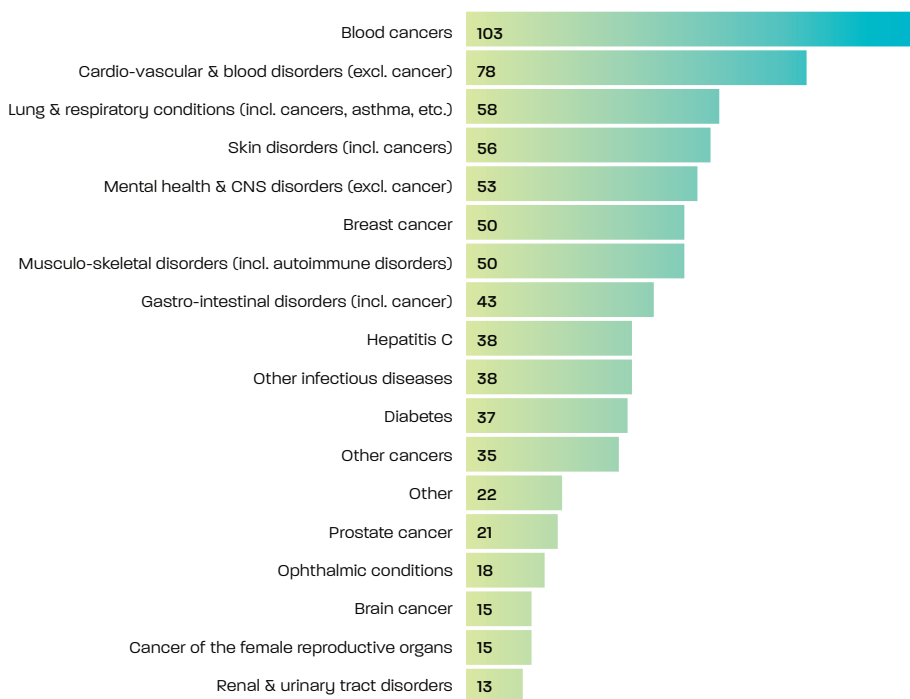
SOURCES Therapeutic Goods Administration, Canberra, 2014, *Half Yearly Performance Report, Jul-Dec 2013*.
 National Health and Medical Research Council, Canberra, 2014, *Update: NHMRC Clinical Trial Initiatives, September 2014*.

Research and Development

9. Clinical trials often give Australian patients early access to innovative therapies

The pharmaceutical industry in Australia conducts clinical trials in numerous therapeutic areas. Patients involved in these trials often get early access to innovative therapies which may be years away from being available to the general public.

FIGURE 1.9 Number of active* research studies in Australia (Class 1 Medicines Australia members), July 2014



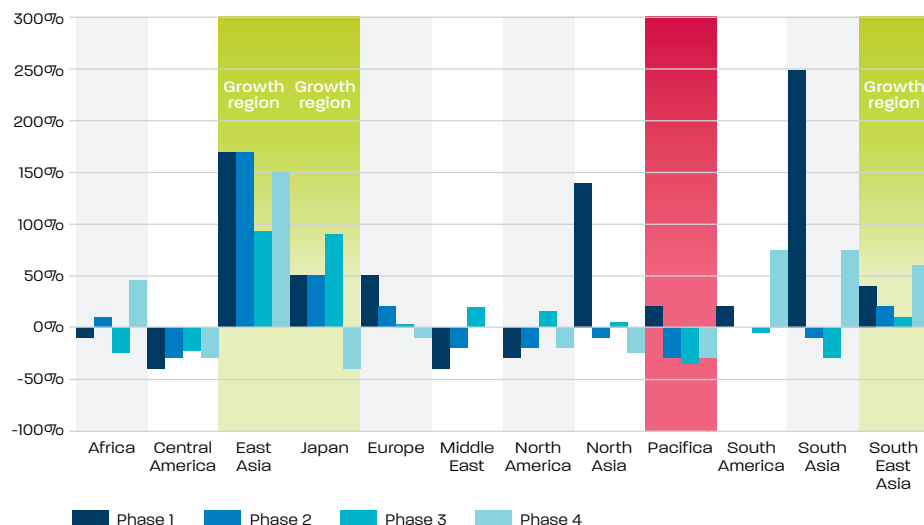
*Active = "Not Yet Recruiting" + "Recruiting" + "Recruiting By Invitation" + "Active, Not Recruiting"

SOURCES Clinicaltrials.gov
Department of Industry, Canberra, 2011, *Clinically Competitive: Boosting the Business of Clinical Trials in Australia*.

10. Government reforms to boost Australia's competitiveness as a destination for clinical trial investment must accelerate

Since 2006, growth in clinical trial activity has mostly centred on Asia, with East Asia leading the way. Clearly, the pendulum of global R&D investment has been shifting towards the Asia-Pacific region. Implementing reforms will ensure Australia is able to capitalise on this shift.

FIGURE 1.10 Regional changes in clinical trial activity, 2006 v 2012: Phase 1, Phase 2, Phase 3, Phase 4



Key:

East Asia (China, Hong Kong, South Korea, Mongolia, Taiwan)

North America (Canada, USA, Mexico)

North Asia (Russia, Ukraine, ex-Soviet states)

Pacifica (Australia, New Zealand)

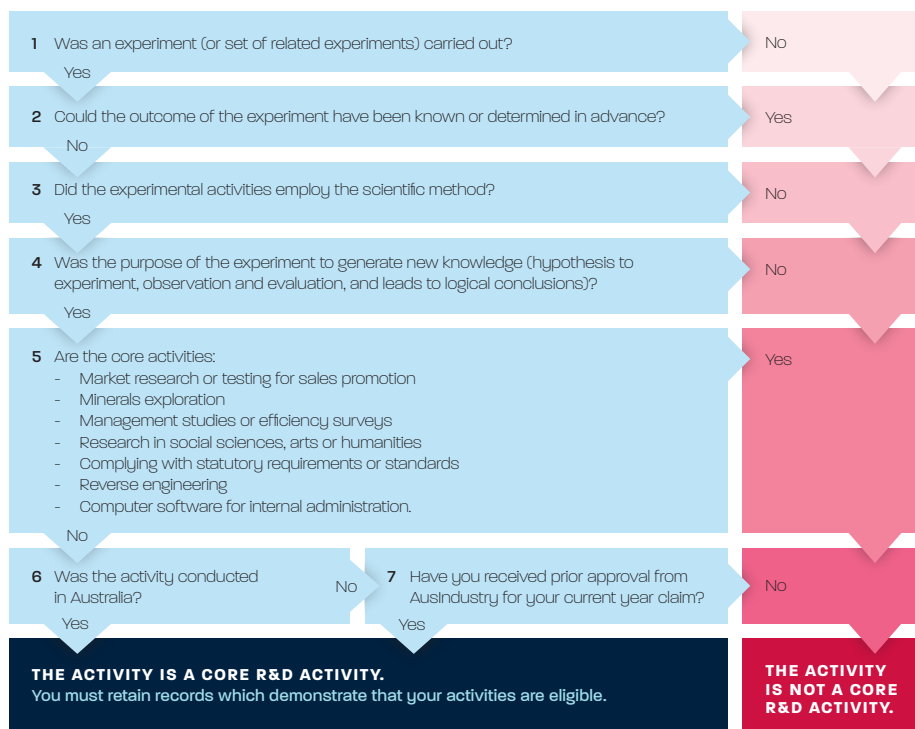
South East Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam)

Research and Development

11. The R&D tax incentive has improved Australia's attractiveness as a destination for investment in research and development

The R&D Tax Incentive is designed to encourage private sector investment in research and development in Australia. It offers companies with an annual turnover of less than \$20 million a 43.5 per cent refundable tax offset, and companies with an annual turnover of more than \$20 million a 38.5 per cent non-refundable tax offset on eligible expenditure.

FIGURE 1.11 Is your company eligible for the R&D tax incentive?



Part 2

Registration and reimbursement



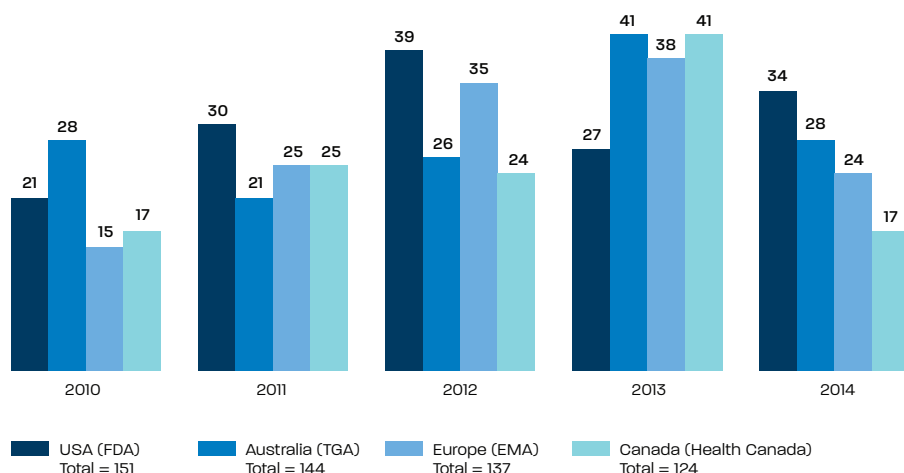
For most people in Australia, having access to new medicines and vaccines means having them approved by the Therapeutic Goods Administration and then listed on the Pharmaceutical Benefits Scheme. The faster new medicines or vaccines are approved and listed, the faster Australian patients can have access to new and innovative treatments.

Registration and reimbursement

1. The Australian Therapeutic Goods Administration is globally recognised as a sophisticated regulator

The Therapeutic Goods Administration is the Australian Government agency responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods in Australia. Like its counterparts in the US (Food and Drug Administration), the EU (European Medicines Agency), Canada (Health Canada) and other countries, the TGA reviews complex data on safety, quality and efficacy when considering whether to grant marketing authorisation to new therapies.

FIGURE 2.1 Number of new molecular entities given market authorisation, 2010-2014 (as at 31 October 2014)

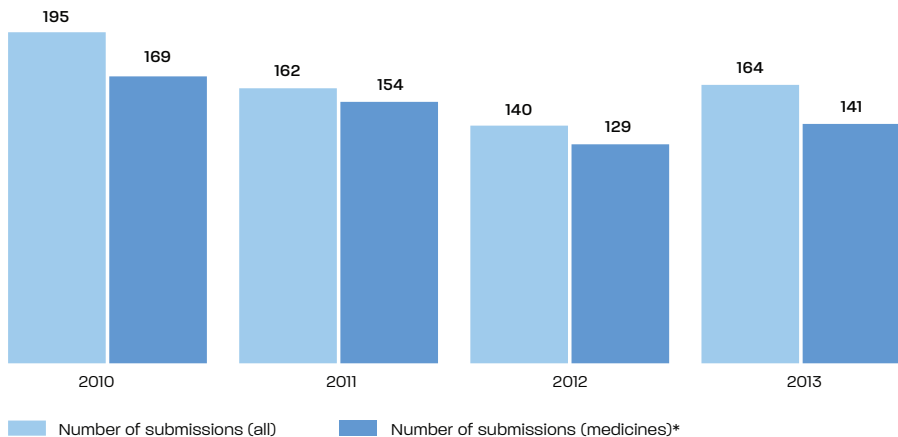


SOURCES United States Food and Drug Administration, Washington DC.
Therapeutic Goods Administration, Canberra.
European Medicines Agency, London.
Health Canada, Ottawa.

2. Number of submissions to the Pharmaceutical Benefits Advisory Committee is trending marginally upwards, after two years of decline

The Pharmaceutical Benefits Advisory Committee is an independent expert body appointed by the Australian Government. Its primary role is to recommend new medicines for listing on the Pharmaceutical Benefits Scheme. In making its recommendations, the PBAC considers whether new medicines are safe, effective and cost-effective compared to other treatments.

FIGURE 2.2 Number of submissions considered by the PBAC, 2010-2013



* excluding medical devices such as glucose test strips and nutritional supplements

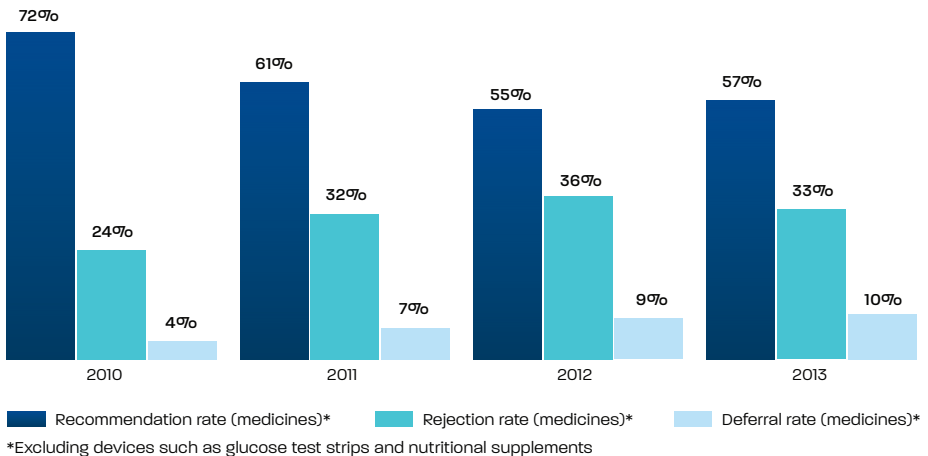
SOURCES Department of Health, Canberra, Various Years, *PBAC Outcomes*.
 Wonder Drug Consulting, Sydney, 2014, *Development of Industry Relevant Key Performance Indicators for the Pharmaceutical Benefits Scheme - 2010-13*.

Registration and reimbursement

3. The number of positive recommendations by the Pharmaceutical Benefits Advisory Committee has been declining in recent years

No new medicine can be listed on the Pharmaceutical Benefits Scheme unless it receives a positive recommendation from the PBAC. The number of positive recommendations by the PBAC has been declining in recent years. In addition to time delays, the cost associated with making multiple PBAC submissions is substantial, including around \$130,000 for 'major' submissions.

FIGURE 2.3 Outcomes of PBAC submissions (medicines), 2010-2013

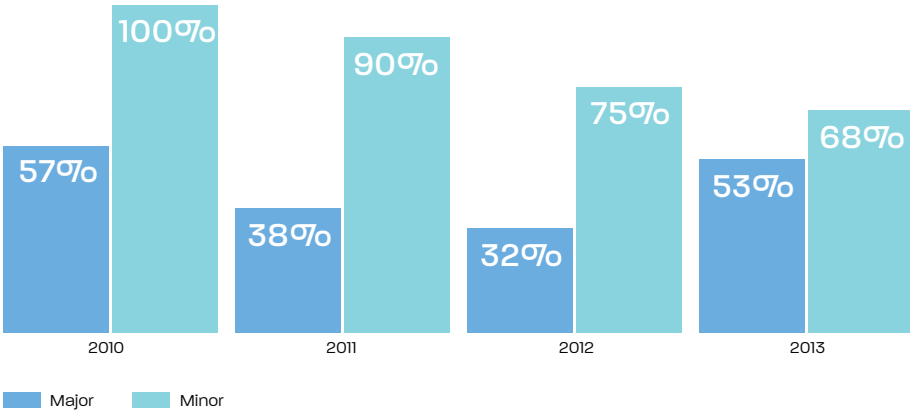


SOURCES Department of Health, Canberra, Various Years, *PBAC Outcomes*.
 Wonder Drug Consulting, Sydney, 2014, *Development of Industry Relevant Key Performance Indicators for the Pharmaceutical Benefits Scheme, 2010-13*.

4. Rejections by the Pharmaceutical Benefits Advisory Committee significantly delay patient access to new treatments

In general, the purpose of ‘major’ PBAC submissions is to seek new listings on the Pharmaceutical Benefits Scheme. ‘Minor’ submissions, on the other hand, are more commonly used to seek relatively small changes to existing listings.

FIGURE 2.4 Success rate for major and minor PBAC submissions (medicines) 2010-2013



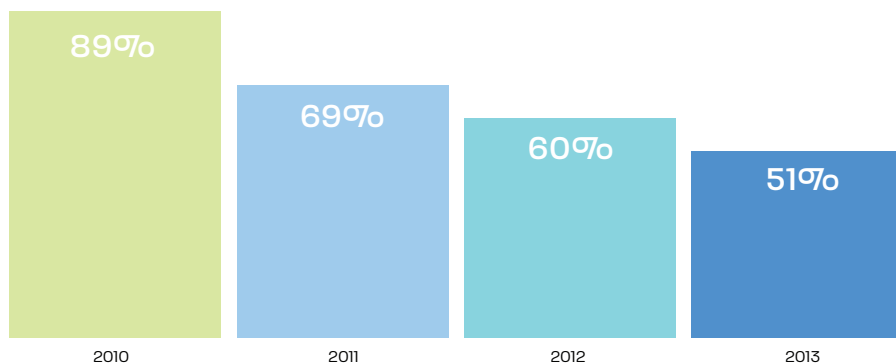
SOURCES Department of Health, Canberra, Various Years, *PBAC Outcomes*.
 Wonder Drug Consulting, Sydney, 2014, *Development of Industry Relevant Key Performance Indicators for the Pharmaceutical Benefits Scheme, 2010-13*.

Registration and reimbursement

5. On average, it takes an estimated 22 months to get a new medicine listed on the Pharmaceutical Benefits Scheme

It is becoming more frequent for pharmaceutical companies (or other 'sponsors') to have to make multiple submissions to get new medicines listed on the Pharmaceutical Benefits Scheme. Unfortunately, this adds to the 'cost of doing business' in Australia and, more importantly, delays patient access to new treatments. On average, it takes an estimated 22 months to get a new medicine listed on the PBS.

FIGURE 2.5 Success rate for initial PBAC submissions (medicines) 2010-2013



SOURCES Department of Health, Canberra, Various Years, *PBAC Outcomes*.
Wonder Drug Consulting, Sydney, 2014, *Development of Industry Relevant Key Performance Indicators for the Pharmaceutical Benefits Scheme, 2010-13*.

Part 3

Manufacturing and sales



Medicines and vaccines are one of Australia's largest manufactured exports. However, pharmaceutical manufacturing in Australia faces an uncertain future. One reason for this is the lack of Government incentives; another reason is the lack of robust growth in the domestic market for medicines and vaccines.

Manufacturing and sales

1. Maintaining pharmaceutical manufacturing capacity in Australia continues to be a challenge

Australia has a well-established reputation around the world for manufacturing safe, high-quality medicines and vaccines. Whilst in recent years, several pharmaceutical companies have closed manufacturing facilities in Australia, others have made significant investments in new and existing facilities.

FIGURE 3.1 Manufacturing investment and job losses since 2007

Manufacturing plant closures and associated job losses in Australia since 2007		New manufacturing investment in Australia since 2008	
Herron	150 Jobs	CSL	\$250 million
Pfizer*	140 Jobs	Leo Pharma	\$130 million
Johnson & Johnson	135 Jobs	GSK	\$91 million
GSK*	120 Jobs	AstraZeneca	\$80 million
MSD	110 Jobs	DSM Biologics	\$65 million
Schering Plough	84 Jobs	Hospira	\$50 million
Roche	60 Jobs	Fresenius Kabi	\$47 million
iNova	55 Jobs	Phebra	\$25 million
		Johnson & Johnson	\$21 million
		Baxter	\$12 million
		Pharmaxis	\$10 million

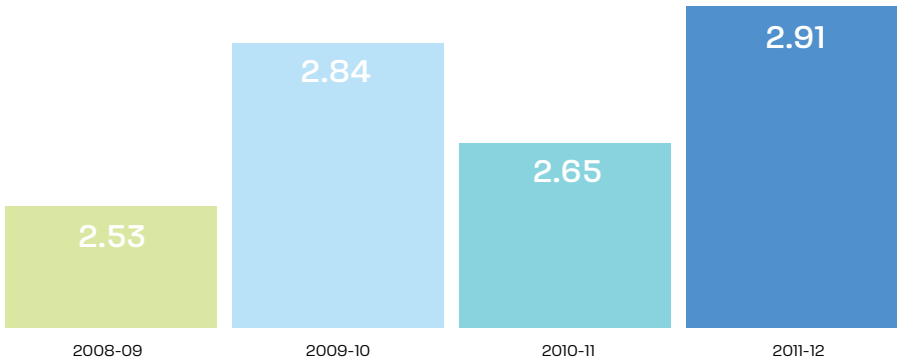
* Partial

SOURCE Medicines Australia internal survey.

2. Pharmaceutical manufacturing in Australia adds significant value to the Australian economy

Despite a difficult operating environment, the pharmaceutical industry in Australia continues to invest in high-tech manufacturing, the added value of which to the Australian economy now stands at close to \$3 billion annually.

FIGURE 3.2 Industry value add (\$ billion)



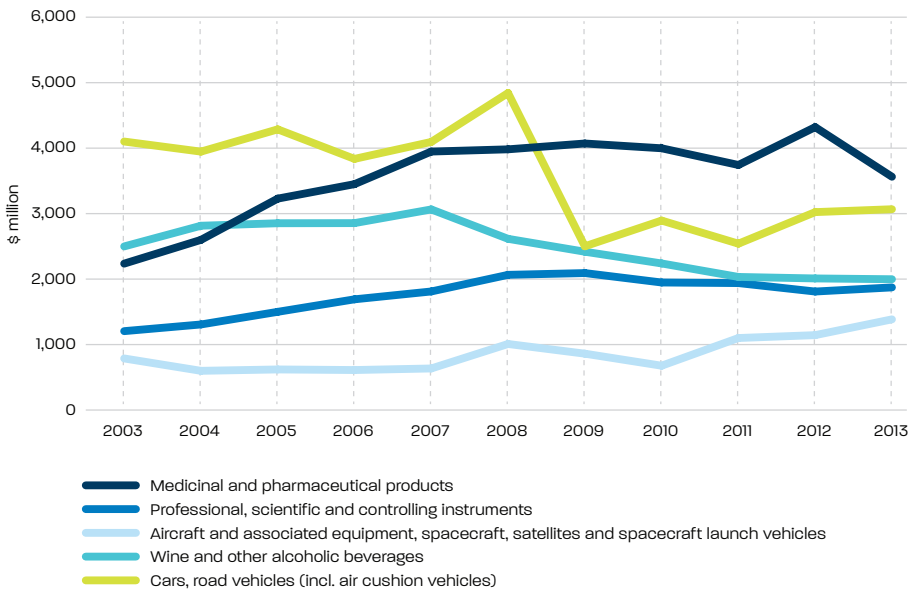
SOURCE Department of Industry, Canberra, 2014, *Australian Pharmaceuticals Industry Data Card 2014*.

Manufacturing and sales

3. Pharmaceuticals are one of Australia's biggest manufactured exports

Despite a recent decline, medicines and vaccines remain one of Australia's biggest manufactured exports. The global market for these products is set to double over the next decade, with much of the growth coming from Asia. This presents a significant opportunity for Australia to grow its pharmaceutical exports.

FIGURE 3.3 Pharmaceutical exports v. other manufactured exports, Australia, 2003-2013

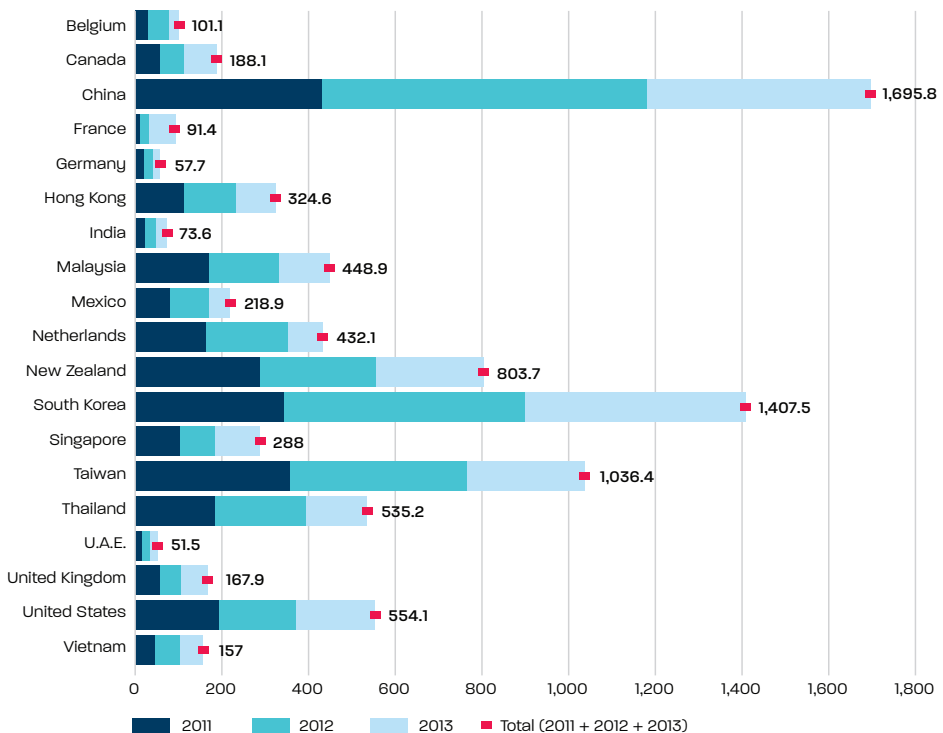


SOURCE Australian Bureau of Statistics, Canberra, 2014, Catalogue 5368.0, *International Trade In Goods and Services*.

4. Asia is a large and growing market for Australian pharmaceutical exports

China is Australia's largest market for medicines and vaccines, followed by South Korea, Taiwan and New Zealand. Recent free trade agreements with China and South Korea will make it more competitive for Australian manufacturers to export pharmaceutical products there.

FIGURE 3.4 Australian pharmaceutical export destinations, 2011-2013, \$ million

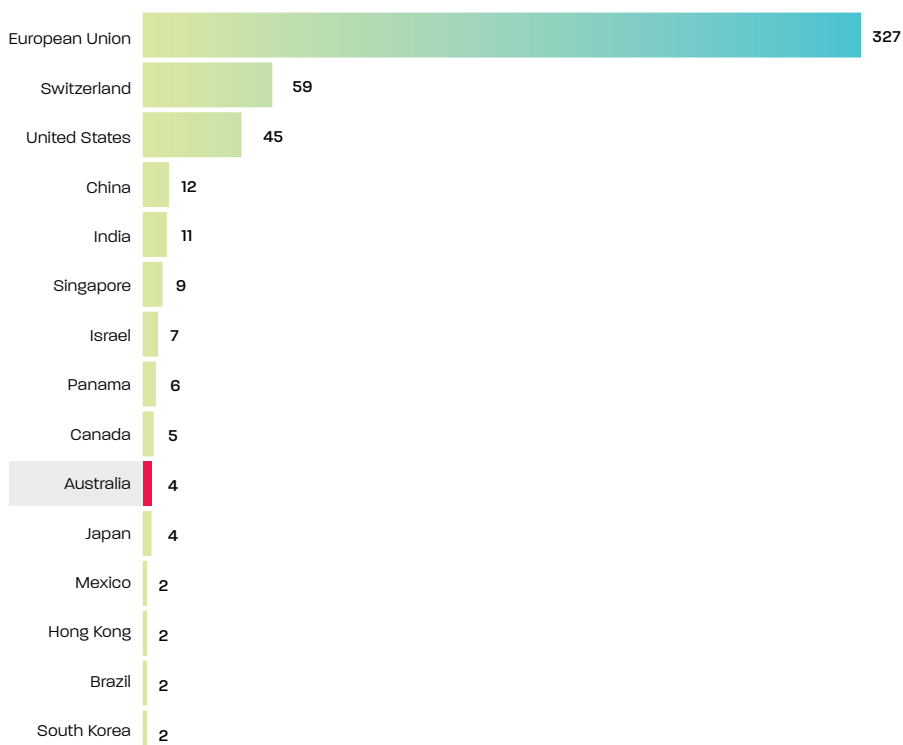


Manufacturing and sales

5. Australia's share of global outward trade in pharmaceutical goods and services is less than 1 per cent

Australia faces stiff competition for investment in pharmaceutical manufacturing. Countries such as Singapore offer significant incentives to attract this type of investment. Currently, Australia's share of global outward trade in pharmaceutical goods and services is less than 1 per cent.

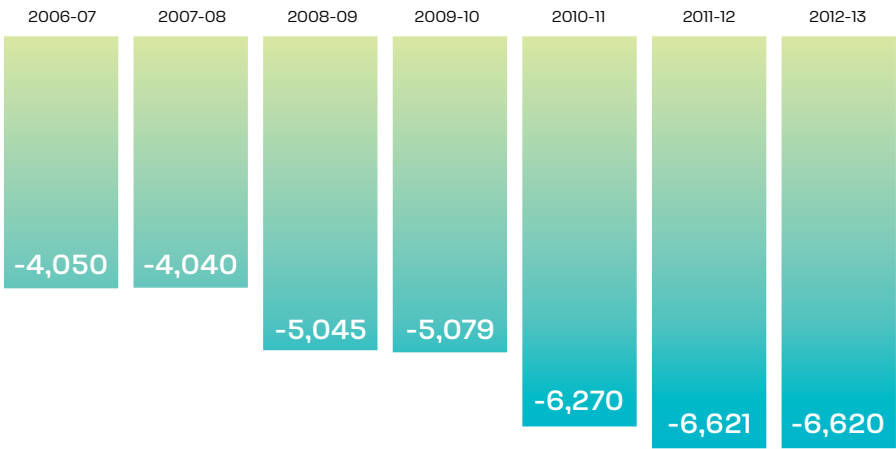
FIGURE 3.5 Leading exporters of pharmaceutical products, 2013, US\$ billion



6. Australia currently has a large and growing trade deficit in pharmaceutical goods and services

Despite its reputation for manufacturing safe, high-quality medicines and vaccines, Australia currently imports significantly more of these products than it exports. Growing manufacturing capacity would help Australia to maintain a healthy balance of trade in pharmaceutical goods and services in the future.

FIGURE 3.6 Balance of trade in pharmaceutical goods and services (\$ million)



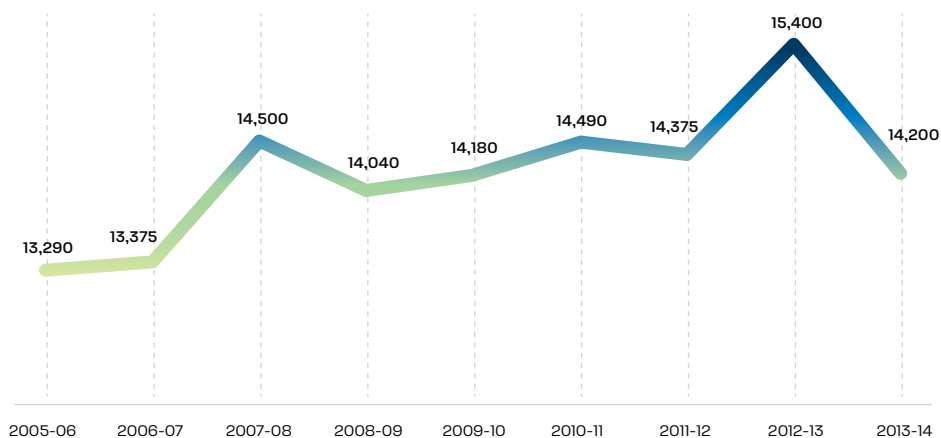
SOURCE Department of Industry, Canberra, 2014, *Australian Pharmaceuticals Industry Data Card 2014*.

Manufacturing and sales

7. There have been notable job losses in the pharmaceutical industry in Australia in recent years

The pharmaceutical industry in Australia creates high-skilled, high-paying jobs in a range of fields, from sales and marketing to health economics to clinical research. In recent years, there have been job losses in the industry, mainly due to commercial restructuring caused by patent expiries.

FIGURE 3.7 Pharmaceutical industry employment in Australia

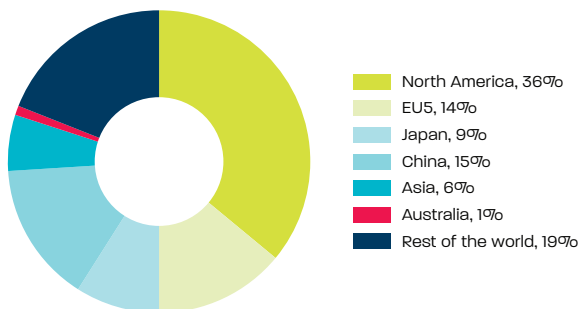


SOURCE IBIS World, Melbourne, 2014, Pharmaceutical Product Manufacturing in Australia: Market Research Report.

8. Australia accounts for only around 1 per cent of the global market for pharmaceutical products

At around 1 per cent, Australia's share of the global market for pharmaceutical products has remained stable over the past decade. However, it is projected to decline slightly over the coming years, mainly due to the lack of growth in the domestic market and the high rate of growth in other markets (particularly China, Brazil, Russia and India).

FIGURE 3.8 Australia's share of the global pharmaceutical market



Key:

North America (Canada, USA, Mexico)

EU 5 (France, Germany, Italy, Spain, UK)

Asia (South Korea, Taiwan, Hong Kong, India, Pakistan, Singapore, Indonesia, Malaysia, Philippines, Vietnam and Thailand)














































SOURCE IMS Institute for Healthcare Informatics, Parsippany, 2013, Market Prognosis.

Manufacturing and sales

9. Australia is currently the twelfth largest market in the world for medicines and vaccines

Australia is currently the twelfth largest market in the world for medicines and vaccines. It is projected to remain among the top 20 for at least the next three years.

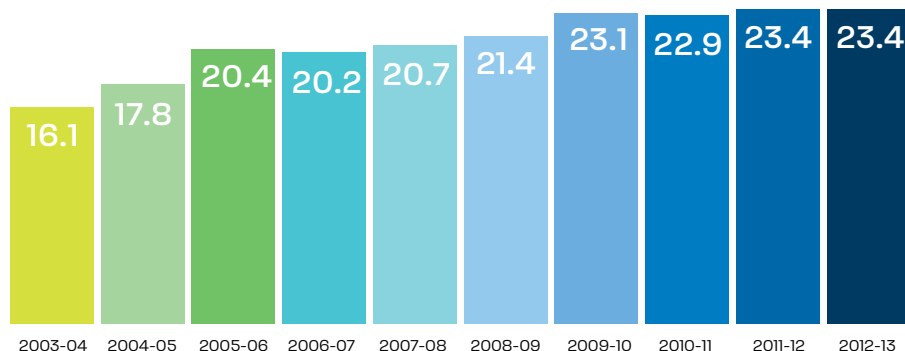
FIGURE 3.9 Top 20 markets for pharmaceutical goods and services, trends and projections

RANK 2007 INDEX			RANK 2012 INDEX			RANK 2017 INDEX		
1	US	100	1	US	100	1	US	100
2	Japan	27	2	Japan	27	2 	China	45
3 	France	13	3 	China	25	3 	Japan	29
4 	Germany	13	4	Germany	13	4 	Brazil	13
5 	China	11	5 	France	11	5 	Germany	13
6 	Italy	8	6 	Brazil	8	6 	France	10
7	UK	7	7 	Italy	8	7	Italy	8
8 	Spain	7	8 	UK	7	8 	Russia	7
9 	Canada	7	9	Canada	7	9 	UK	7
10	Brazil	5	10 	Spain	6	10 	Canada	7
11	Mexico	4	11 	Russia	5	11 	India	6
12	Australia	4	12	Australia	4	12 	Spain	5
13	South Korea	3	13 	India	4	13 	Mexico	4
14 	Russia	3	14 	Mexico	4	14 	South Korea	4
15 	Turkey	2	15 	South Korea	3	15 	Australia	4
16 	India	2	16 	Venezuela	3	16 	Turkey	3
17 	Netherlands	2	17 	Turkey	3	17 	Venezuela	2
18 	Greece	2	18 	Poland	2	18 	Argentina	2
19 	Poland	2	19 	Argentina	2	19 	Indonesia	2
20 	Belgium	2	20	Belgium	2	20 	Poland	2

10. There has been virtually no growth in the pharmaceutical industry's turnover in Australia in recent years

Over the last four years, there has been virtually no growth in the pharmaceutical industry's turnover in Australia. If this trend continues, it could turn Australia into a 'second tier' market for medicines and vaccines in the future.

FIGURE 3.10 Pharmaceutical industry turnover in Australia (\$ billion)



SOURCE Department of Industry, Canberra, 2014, *Australian Pharmaceuticals Industry Data Card 2014*.

Manufacturing and sales

11. Pharmaceutical Benefits Scheme: Key sales statistics

FIGURE 3.11 PBS top suppliers and sales

Top 10 supplier by value YEAR ENDING JUNE 2014			Top 10 supplier by script volume YEAR ENDING JUNE 2014		
1	Pfizer	\$690 million	1	Alphapharm	28.2 million
2	AstraZeneca	\$627 million	2	Apotex	25.1 million
3	Novartis	\$507 million	3	Aspen	19.3 million
4	Sanofi	\$371 million	4	AstraZeneca	17.6 million
5	MSD	\$359 million	5	Pfizer	16.4 million
6	AbbVie	\$358 million	6	Sanofi	12.7 million
7	Apotex	\$357 million	7	Sandoz	10.1 million
8	Alphapharm	\$294 million	8	GSK	9.9 million
9	Janssen	\$290 million	9	MSD	8.6 million
10	GSK	\$275 million	10	Boehringer Ingelheim	7.1 million

Derived ex-manufacturer sales (\$)

Top 10 selling medicines by total cost YEAR ENDING JUNE 2014			Top 10 selling medicines by script volume YEAR ENDING JUNE 2014		
1	Rosuvastatin	\$392 million	1	Atorvastatin	8.9 million
2	Atorvastatin	\$357 million	2	Rosuvastatin	7.8 million
3	Adalimumab	\$276 million	3	Esomeprazole	6.9 million
4	Esomeprazole	\$265 million	4	Paracetamol	6.1 million
5	Fluticasone + Salmeterol	\$231 million	5	Pantoprazole	4.1 million
6	Etanercept	\$156 million	6	Perindopril	3.9 million
7	Alibercept	\$153 million	7	Metformin	3.6 million
8	Ranibizumab	\$149 million	8	Fluticasone + Salmeterol	3.2 million
9	Tiotropium	\$144 million	9	Irbesartan	3.1 million
10	Insulin Glargine	\$139 million	10	Simvastatin	3.0 million

Total cost includes cost the patient and the cost to the government

Total for all forms and strengths for each drug

Part 4

Health outcomes and expenditure



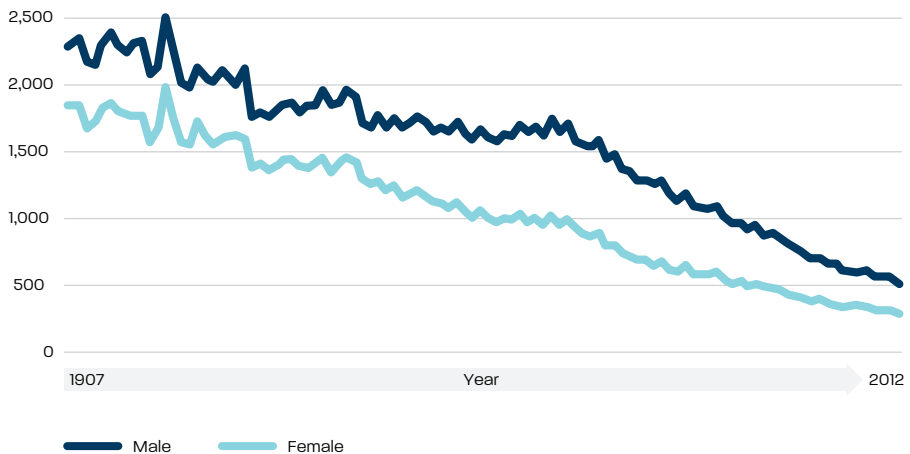
Australia is one of the few countries in the world which has a comprehensive strategy in relation to pharmaceuticals. The strategy, known as the National Medicines Policy (NMP), is designed to ensure not only ongoing and affordable access to new medicines and vaccines, with the consequent benefits for health outcomes, but also a viable pharmaceutical industry in Australia. The main benefit of the NMP is that all stakeholders, including the Australian Government, the pharmaceutical industry, the broader healthcare sector and the general community, are required to work together to ensure the greatest possible alignment between national health and industry policies.

Health outcomes and expenditure

1. The availability of new medicines and vaccines has contributed to the significant decline in death rates in Australia over the past 100 years

There has been a significant decline in death rates in Australia over the past 100 years. Since 1907, deaths from all causes have declined by more than 80 per cent in Australia, with particularly significant declines in deaths caused by infections, cardiovascular diseases and stroke.

FIGURE 4.1 Deaths per 100,00 population



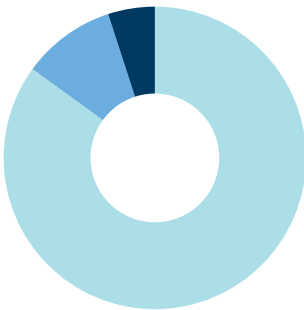
SOURCE Australian Institute of Health and Welfare, Canberra, 2014, *Australia's Health 2014*.

2. Chronic disease is the leading cause of morbidity and mortality in Australia

Most deaths in Australia today are caused by chronic disease rather than by acute illnesses, which were the leading cause of death and disability a hundred years ago.

FIGURE 4.2 Burden of disease

Burden of disease in Australia



Non-communicable diseases, 85%
 Injuries, 10%
 Communicable, maternal, neonatal and nutritional disorders, 5%

Major contributors to the burden of disease in Australia



Cancer, 16%
 Musculoskeletal disorders, 15%
 Cardiovascular diseases, 14%
 Mental and behavioural disorders, 13%
 Other, 42%

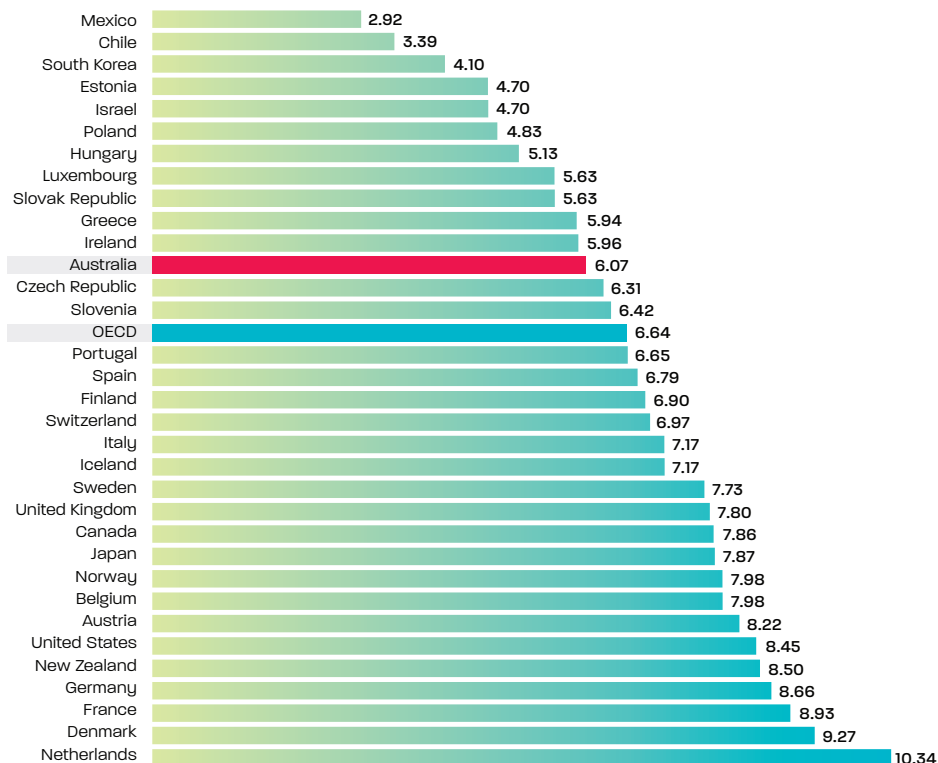
SOURCE Australian Institute of Health and Welfare, Canberra, 2014, *Australia's Health 2014*.

Health outcomes and expenditure

3. Australians enjoy one of the longest life expectancies in the world

Despite spending less on healthcare than most other developed countries (as a percentage of national GDP), Australians today enjoy one of the longest life expectancies in the world. The average life expectancy for Australian men is 79.7 years, sixth highest in the world, and for Australian women 84.2 years, seventh highest in the world.

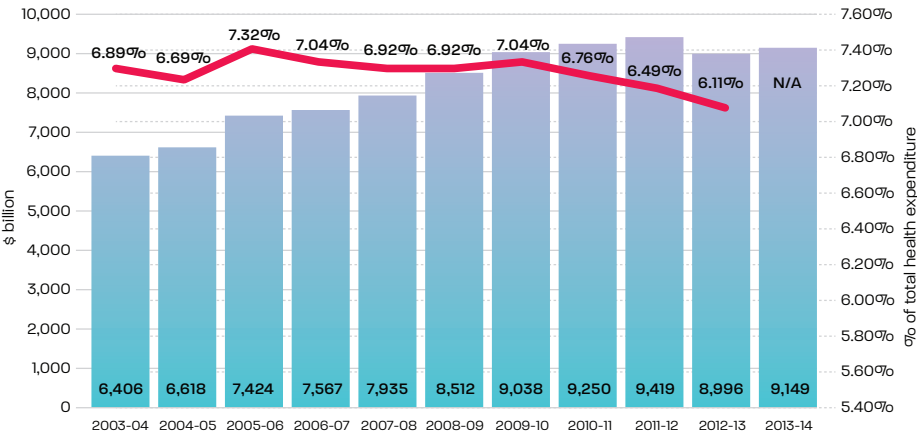
FIGURE 4.3 Government expenditure on health as a percentage of GDP, OECD



4. Government expenditure on the Pharmaceutical Benefits Scheme as a share of gross domestic product has remained stable over the past decade

The Pharmaceutical Benefits Scheme gives Australians subsidised access to innovative medicines. It is one of the pillars of Australia's healthcare system. Over the past 10 years, on average, Government expenditure on the PBS has grown by around 4 per cent per annum in real terms. However, as a share of total health expenditure, expenditure on the PBS has remained stable over the past decade.

FIGURE 4.4 Government expenditure on the PBS, 2013 dollars, 2003-2013



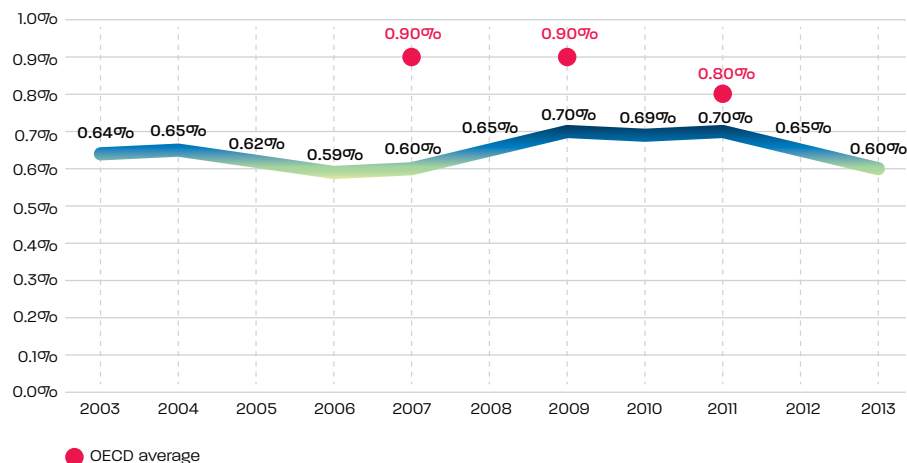
SOURCES Department of Health, Canberra, 2003-2013, *Expenditure and Prescriptions*.
 Reserve Bank of Australia, Sydney, Online Inflation Calculator.
 Australian Institute of Health and Welfare, Canberra, 2014, *Health Expenditure Australia 2012-13*.

Health outcomes and expenditure

5. The pharmaceutical industry has worked with successive Australian governments to ensure the sustainability of the Pharmaceutical Benefits Scheme

Despite growth, Government expenditure on the PBS has as a percentage of GDP has remained stable over the past decade. Over the same period, however, overall expenditure on health in Australia as a percentage of GDP has increased from around 8.5 per cent to around 9.5 per cent. The pharmaceutical industry has worked with successive Australian Governments to ensure both the sustainability of the PBS as well as ongoing patient access to new and innovative medicines and vaccines.

FIGURE 4.5 PBS expenditure as a percentage of GDP (+ OECD average)

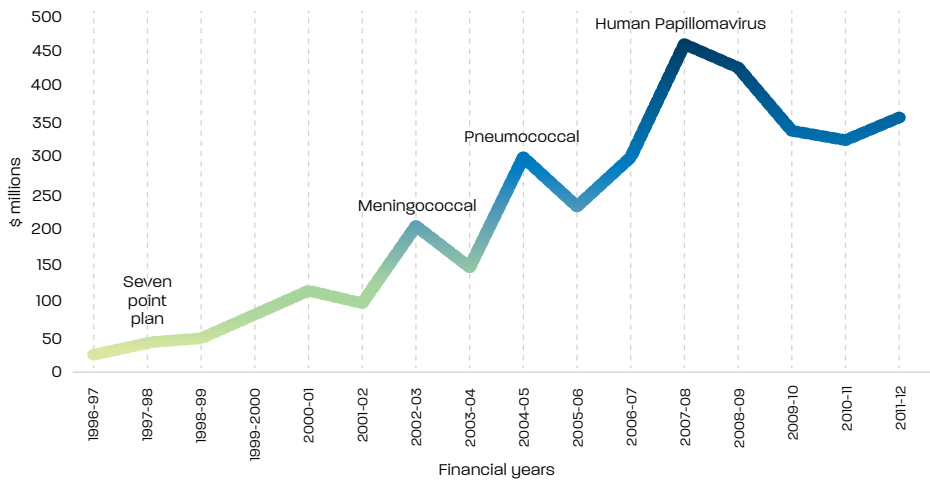


SOURCES Organisation for Economic Co-operation and Development, Paris, 2014, *OECD Factbook: Economic, Environmental and Social Statistics*.
 Australian Institute of Health and Welfare, Canberra, 2014, *Australia's Health 2014*.
 Department of Health, Canberra, 2003-2013, *Expenditure and Prescriptions*.
 Australian Bureau of Statistics, Canberra, 2014, Catalogue 5206.0, *Australian National Accounts: National Income, Expenditure and Product*.

6. Australians enjoy some of the highest immunisation rates against infectious diseases in the world

Funding for vaccine purchasing under Australia's National Immunisation Program has increased from \$10 million per annum in the mid-1990s to over \$350 million in recent years. This has enabled Australians to enjoy some of the highest immunisation rates against infectious diseases in the world.

FIGURE 4.6 Funding for NIP vaccine program



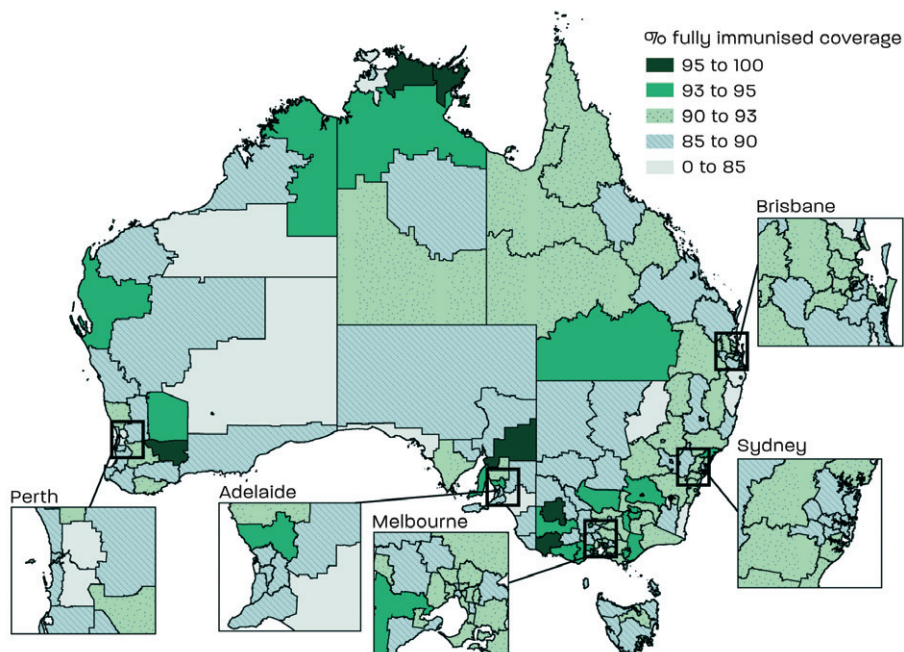
SOURCES Department of Health, Canberra, 2013, *National Immunisation Strategy for Australia: 2013-2018*.
 Australian Institute of Health and Welfare, Canberra, 2014, *Australia's Health 2014*.

Health outcomes and expenditure

7. The success of the National Immunisation Programme has led to dramatic reductions in the incidence of many infectious diseases in Australia

The NIP Schedule covers 16 diseases, including Hep B, diphtheria, tetanus, pertussis, Hib disease, poliomyelitis, pneumococcal, rotavirus, measles, mumps, rubella, meningococcal C, chickenpox, Hep A, HPV and influenza. Due to the success of the immunisation programme, many diseases such as tetanus, diphtheria, Hep B and measles are extremely rare in Australia.

FIGURE 4.7 Coverage of fully immunised children in Australia

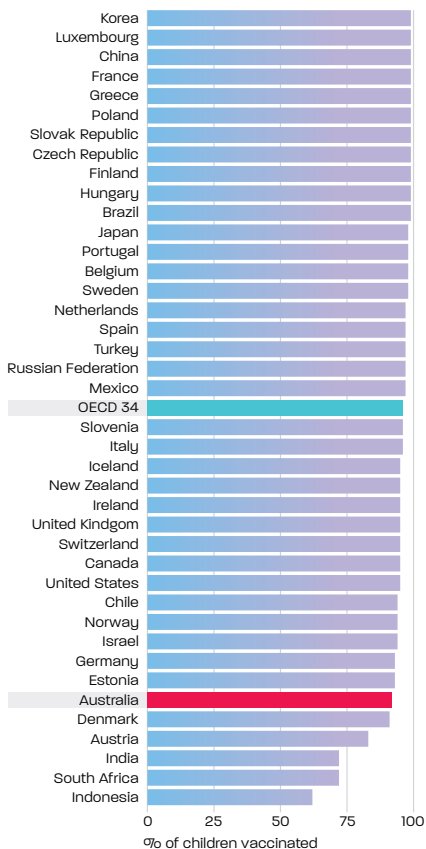


SOURCE Brynley P Gull et al, Canberra, 2011, Immunisation Coverage Annual Report.

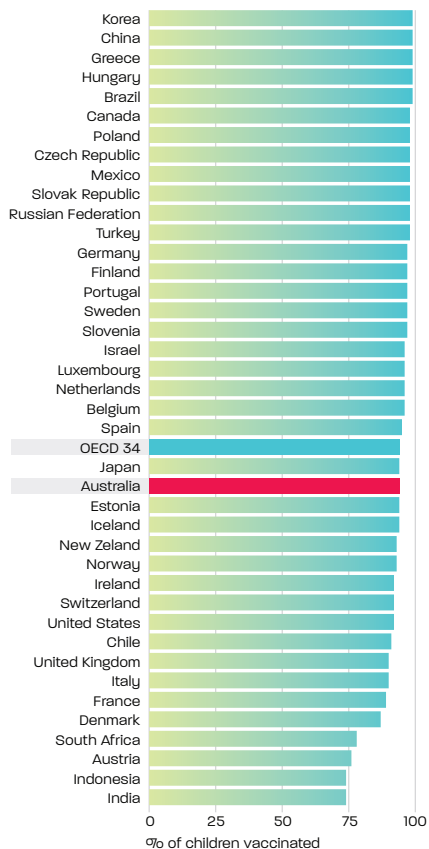
8. Vaccination rates in children in Australia are comparable to other OECD countries, but there is room for improvement

FIGURE 4.8 Global vaccination rates (children aged 1)

Vaccination rates in children aged 1:
Diphtheria, Tetanus and Pertussis



Vaccination rates in children aged 1:
Measles



Part 5

Biotechnology and the broader medical research sector in Australia

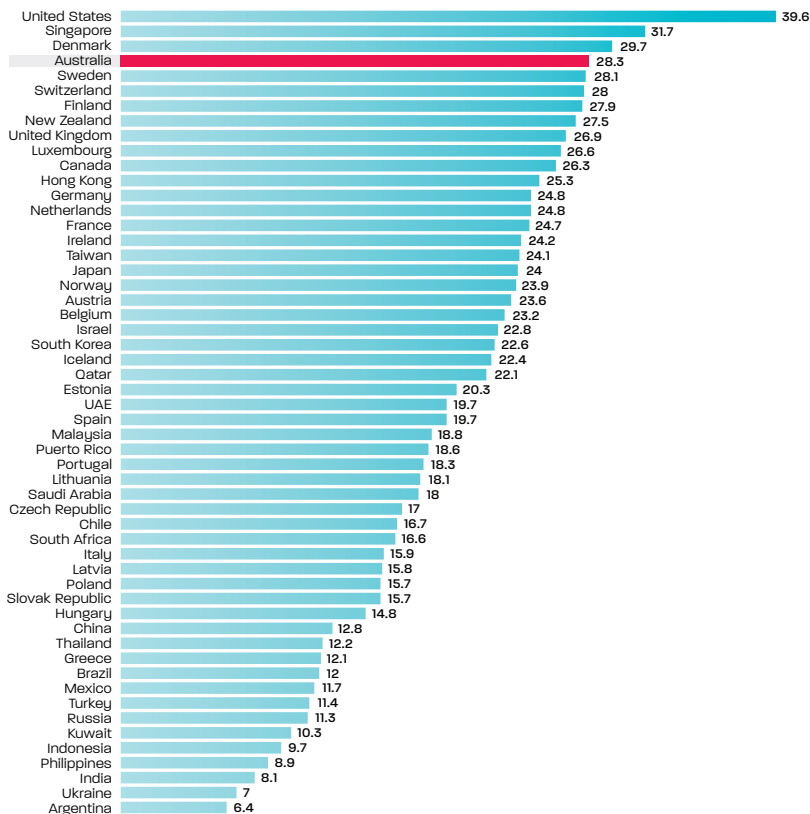


As a result of decades of investment, including by successive governments, Australia today is home to some of the world's best research universities, medical scientists and healthcare professionals. It also boasts a world-class medical research infrastructure, a stable socio-economic environment, a historically strong intellectual property regime and a relatively efficient regulatory system. These are all factors that have contributed to the growth of both Australia's medical research capabilities and its indigenous medical biotechnology sector.

1. Australia is a leading global hub for biotech innovation

Despite fierce competition, Australia remains a leading global hub for biotech innovation. Australian biotechnology companies have played a critical role in the development of several ground-breaking therapies such as Gardasil® (CSL), Relenza® (Biota), Axiron® (Acrux), Bronchitol® (Pharmaxis) and Picato® (Peplin).

FIGURE 5.1 2014 Scientific American Worldview overall scores

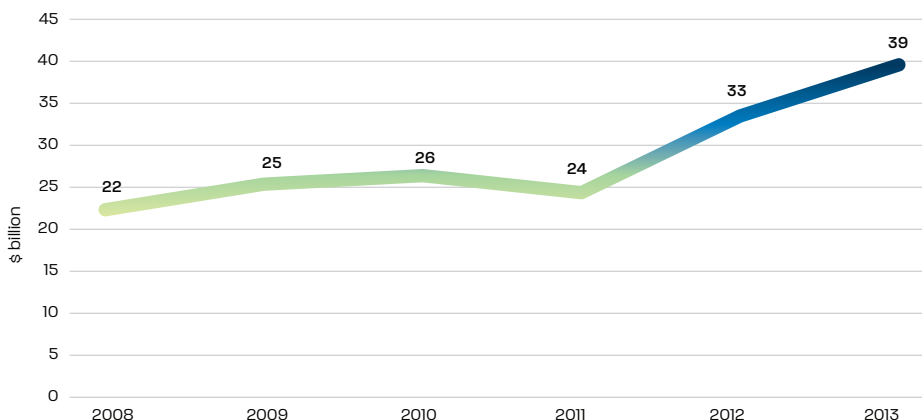


Biotechnology and the broader medical research sector in Australia

2. There are currently more than 50 medical biotechnology companies listed on the Australian Securities Exchange

There are currently more than 50 medical biotechnology companies listed on the Australian Securities Exchange, 12 of which had, as of August 2014, market capitalisation of more than \$100 million: **CSL** (\$32 billion), **Mesoblast** (\$1.5 billion), **Sirtex** (\$948 million), **Mayne** (\$502 million), **Bionomics** (\$239 million), **Alchemia** (\$188 million), **Acrux** (\$167 million), **Starparma** (\$163 million), **Benitec** (\$134 million), **Neuren** (\$128 million), **Psivida** (\$121 million), **Prana** (\$108 million).

FIGURE 5.2 Market capitalisation of ASX-listed medical biotechnology companies, 2008 – (Dec) 2013

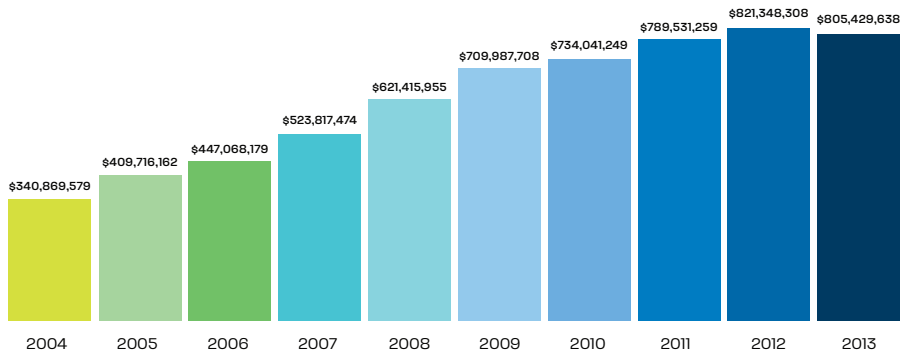


SOURCES PricewaterhouseCoopers, Sydney, 2014, *BioForum 48: Collaboration as a Source of Strength for the Life Sciences Sector*.
Department of Industry, Canberra, 2014, *Biotech Business Indicators: Q4 2013*.

3. The National Health and Medical Research Council is a leading funder of medical research in Australia

The National Health and Medical Research Council is a leading funder of medical research in Australia. Nearly 80 per cent of its funding goes to basic sciences and investigator-driven clinical research. The NHMRC also works with stakeholders to develop and implement national policies in fields such research ethics, science training and public health.

FIGURE 5.3 NHMRC research funding: Expenditure on active grants by calendar year



SOURCE National Health and Medical Research Council, Canberra, 2014, *Annual Report*.

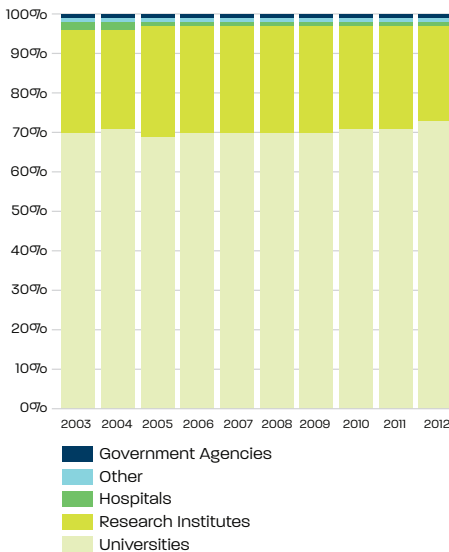
Biotechnology and the broader medical research sector in Australia

4. Like the pharmaceutical industry in Australia, the National Health and Medical Research Council funds projects in a wide range of therapeutic areas, with a particular focus on the country's National Health Priorities

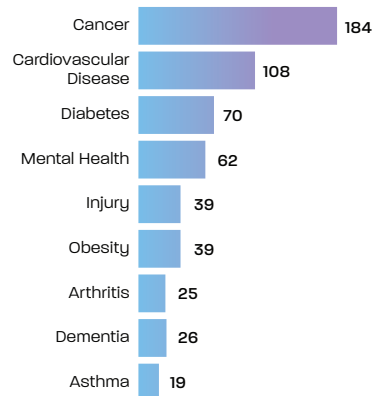
The main beneficiaries of NHMRC funding are Australian universities and research institutes, many of which are among the world's best. In recent years, the NHMRC has increased funding for translational research, which is an area where, historically, Australia has performed poorly.

FIGURE 5.4 NHMRC research funding

**NHMRC research funding:
Allocation of funding by sector**

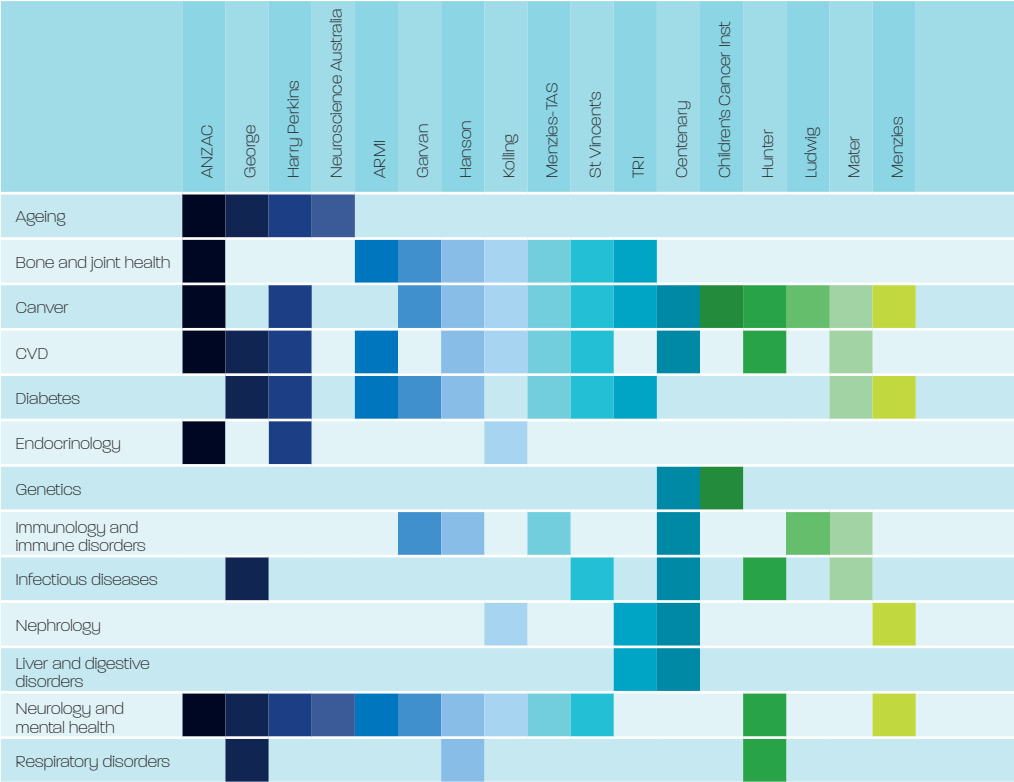


**NHMRC research funding: Allocation
of funding by National Health priority
area, 2012 (\$ million)**



5. Independent medical research institutes in Australia offer significant opportunities for collaboration between academia and the pharmaceutical industry to develop new therapies

FIGURE 5.5 Major independent medical research institutes in Australia, by area of specialty



SOURCE Association of Australian Medical Research Institutes, Melbourne.

Biotechnology and the broader medical research sector in Australia

Independent medical research institutes are a major source of health innovation in Australia. Many of them have partnered with pharmaceutical companies to develop new medicines and vaccines.

