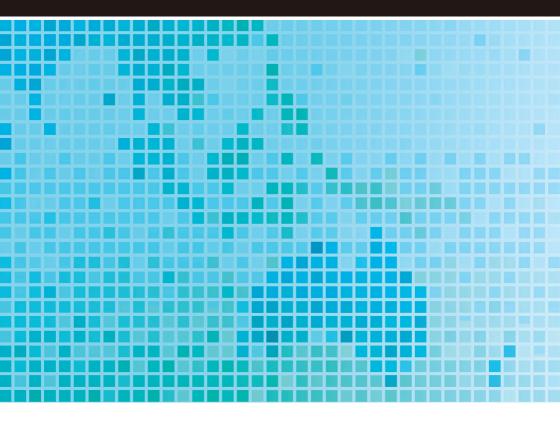
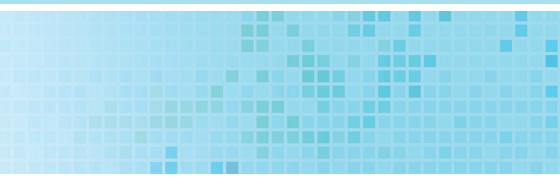
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Medicines Australia | March 2013 www.medicinesaustralia.com.au



INTRODUCTION

Welcome to the third edition of the *Medicines Australia Facts Book*, a snapshot of one of Australia's most dynamic, high-technology and knowledge-intensive industries.

This edition, published in March 2013, includes the most recent available data on aspects of the Australian and international medicines industry, and where possible compares it to the 2011 edition of the Facts Book. Its purpose is to provide an insight into the industry for government, media, researchers, students and anyone interested in the medicines industry in Australia. This publication is also available on the Medicines Australia website at www.medicinesaustralia.com.au

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ABOUT MEDICINES AUSTRALIA

Medicines Australia represents the discovery-driven medicines industry in Australia. Our member companies comprise more than 80 per cent of the prescription medicines market, and are engaged in the research, development, manufacture, supply and export of prescription medicines and vaccines.

Medicines and vaccines save lives and prevent, reduce and cure disease. Medicines Australia is committed to enhancing the health of Australians by providing access to medicines of the highest quality, safety and efficacy.

The medicines industry benefits Australians' health and the health of the economy. It is a high technology, knowledge-intensive sector which invests over \$1 billion in research and development every year. Based on our estimates, the innovative arm of the industry directly employs over 13,000 people in Australia.

In 2011-12, Australian medicines exports totalled over \$4 billion.

Medicines Australia represents the innovative medicines industry by:

- → participating in health and industry policy development;
- → building and maintaining relationships with Government for fair reimbursement of industry products (through the Pharmaceutical Benefits Scheme) and ensuring the continuation of a viable medicines industry;
- → administering the Medicines Australia Code of Conduct which sets the standard for the ethical marketing and promotion of prescription medicines; and
- → working alongside other health professional and consumer organisations to address issues of mutual concern.





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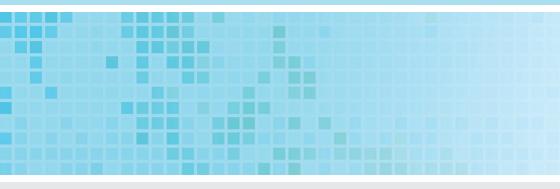




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Part 1

MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

The Australian medicines industry makes an enormous economic contribution to Australia by improving the health and wellbeing of its citizens and enabling them to participate and improve national productivity. In the last few years, the medicines industry has consistently led high-technology sector in exports from Australia and remains a keen investor in Australian research efforts.

Currently the medicines industry is:

- → the largest high-technology exporter from Australia—over \$4 billion in 2011-12;
- → the highest manufacturing industry investor in R&D—over \$1.0 billion in 2010-11; and
- → one of the largest employers of science graduates in Australia.

The following section illustrates the successes of this vibrant, growing industry and the challenges ahead.



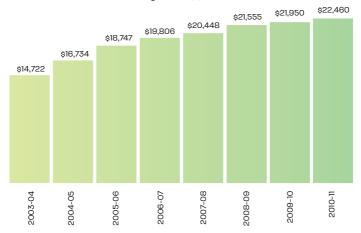
→ In 2010-11, the Australian medicines industry had a turnover of more than \$22 billion dollars.



FIGURE 1 Australian Medicines Industry Turnover

Source: Australian Pharmaceuticals Industry Data Card, Key Statistics: Pharmaceuticals Manufacturing in Australia, accessed on 20 November 2012, available at http://www.innovation.gov.au/INDUSTRY/PHARMACEUTICALSANDHEALTHTECHNOLOGIES/PHARMACEUTICALS/PAges/PharmaceuticalsIndustry.pdtaCard.aspx

Australian Pharmaceuticals Industry Turnover, \$ millions





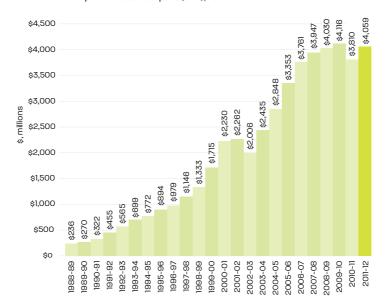
→ In 2011-12, the Australian medicines industry contributed over \$4 billion in export earnings to the Australian economy and led the high-technology exports sector for the fourth consecutive year despite the weak global economic environment.

02

FIGURE 2 Medicines Export by Financial Years 1988-2011

Source: Australian Bureau of Statistics, Catalogue 5368.0, International Trade in Goods and Services, various years







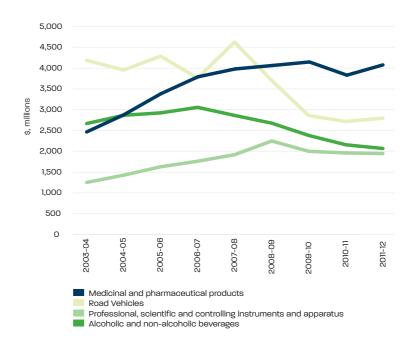
→ In 2011-12, medicines were the top hi-tech Australian export.

03

FIGURE 3 Medicines Exports vs. Other Manufactured Exports

Source: Australian Bureau of Statistics, Catalogue 5368.0, International Trade in Goods and Services, various years

Medicinal and pharmaceutical exports vs other manufactured Australian exports

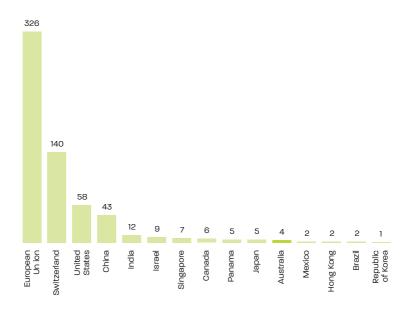




→ International comparison by the World Trade Organisation shows that in 2011, the EU, Switzerland and USA were the world's leading exporters of medicines. Closer to home, in value terms, Singapore exported nearly twice as much as Australia.

${\sf FIGURE} \ \, 4 \qquad \, {\bf Leading\ Exporters\ of\ Medicines\ in\ 2011}$

Source: World Trade Organisation, International Trade Statistics, Merchandise Trade, 2012



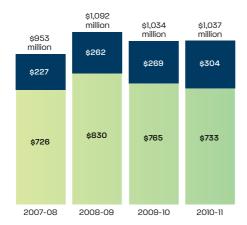


→ Since 2008, the Australian medicines industry has consistently invested over \$1 billion per annum in research and development.

05

FIGURE 5 Medicines R&D in Australia

Source: Australian Bureau of Statistics, Catalogue 8104, Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2010-11. *Includes human pharmaceutical products and veterinary pharmaceutical products manufacturing R&D expenditures



- Clinical health (organs, diseases and abnormal conditions)
- Pharmaceutical products manufacturing (includes human pharmaceutical products and veterinary pharmaceutical products manufacturing R&D expenditures)



→ Medicines remain amongst the top areas of business Investment in Australian R&D.



TABLE 6 Top 5 Areas of Business R&D Investments in Australia

Source: Australian Bureau of Statistics, Catalogue 8104, Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2010-11

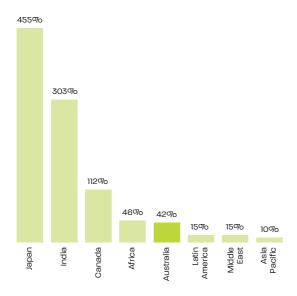
	Sector	Area of R&D expenditure	2007-08 Business Expenditure (\$,000)	2008-09 Business Expenditure (\$,000)	2009-10 Business Expenditure (\$,000)	2010-11 Business Expenditure (\$,000)
1	Financial and insurance services	Financial services	\$1,376,067	\$2,058,292	\$2,738,924	\$2,898,387
2	Mining	Mining and extraction of energy resources	\$1,168,740	\$1,465,429	\$1,514,828	\$1,415,506
3	Mining	Primary mining and extraction of mineral resources	\$1,195,695	\$1,508,876	\$1,075,978	\$1,315,815
4	Manufacturing	Medicines R&D (pharmaceutical products manufacturing and clinical health)	\$952,384	\$1,091,754	\$1,033,458	\$1,036,483
5	Services	Computer software and services	\$903,052	\$831,196	\$895,726	\$972,031



→ Bio-pharmaceutical industry investment in R&D is growing, particularly in Asian markets. Australia needs to tap into this global R&D investment pool.

FIGURE 7 Growth in R&D Investment by European and North American Bio-Pharmaceutical Companies, by destination (2005-2010)

Source: Charles River Associates, 2012, Policies That Encourage Innovation in Middle Income Countries





CLINICAL TRIALS IN AUSTRALIA: A SNAPSHOT

→ Australia is one of many destinations chosen by the global medicines industry to conduct clinical trials. This helps Australian patients as they gain early access to breakthrough therapies.

FIGURE 8 Geographic Locations of Clinical Trials Conducted in Australia

Source: Pharmaceuticals Industry Council, Benchmarking Survey of Clinical Research in Australia (2010)

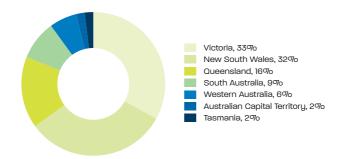
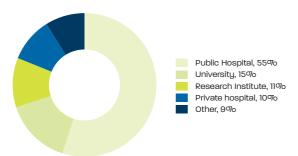


FIGURE 9 Types of Institutions Involved in Conducting Industry Sponsored Clinical Research in Australia

Source: NSW Clinical Trials Business Development Centre, Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research (2009)

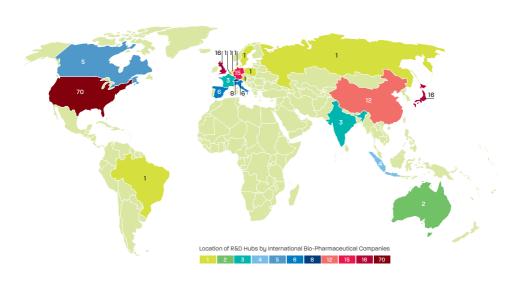




→ Australia is home to just two commercial bio-pharmaceutical R&D hubs, compared to India's three, Singapore's four, China's 12 and Japan's 16.

FIGURE 10 Locations of International Bio-Pharmaceutical Companies R&D Hubs*

Source: Charles River Associates, Policies that Encourage Innovation in Middle Income Countries, 2012



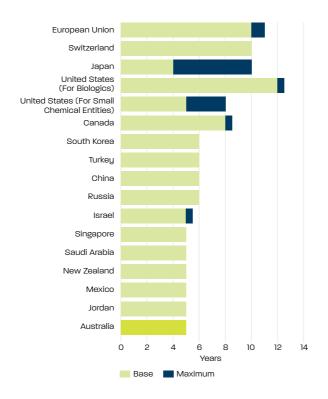
* R&D Hubs are defined as a concentration of facilities and personnel, belonging to particular bio-pharmaceutical company, involved in conducting discovery-stage, pre-clinical and early-stage clinical R&D



Data exclusivity is an independent form of intellectual property protection that operates alongside patents to protect the intellectual property in medicine clinical trial data against unauthorised use for a fixed period of time. Australia currently lags behind its peers in intellectual property protection for medicines through the provision of data exclusivity.

FIGURE 11 Data Exclusivity in Australia Vs. Other Countries

Source: Legislation relating to the provision of data exclusivity, individual countries, 2010





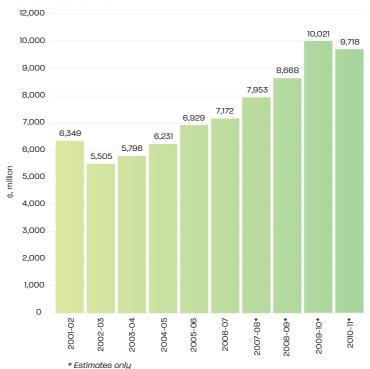
→ In 2010-11, Australian medicines manufacturing contributed an estimated \$9.7 billion to the economy.

12

FIGURE 12 Medicines Sales and Service Income

Source: Australian Bureau of Statistics, Catalogue 8221, Manufacturing Industry Australia, 2006-07, August 2008, Catalogue 8159, Experimental Estimates for the Manufacturing Industry, 2006-2010, Dec 2011; Catalogue 8155, Manufacturing Industry by ANZSIC class, 2010-11, July 2012

Sales and Service Income

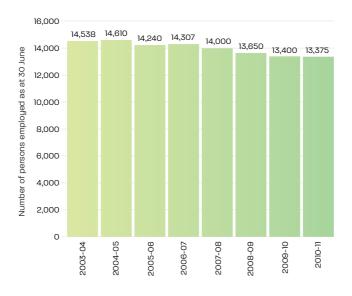




→ Between 2003 and 2011, over 1,100 jobs have been lost in the industry due to factory closures, increasing competitive pressures and industry restructuring.

${\sf FIGURE\ 13}\quad \textbf{Employment in Pharmaceutical Manufacturing}$

Source: Australian Pharmaceuticals Industry Fact Sheet, Key Statistics: Pharmaceuticals Manufacturing in Australia, accessed on 20 November 2012, available at http://www.innovation.gov.au/INDUSTRY/PHARMACEUTICALSANDHEALTH TECHNOLOGIES/PHARMACEUTICALS/Pages/PharmaceuticalsindustryDataCard.aspx

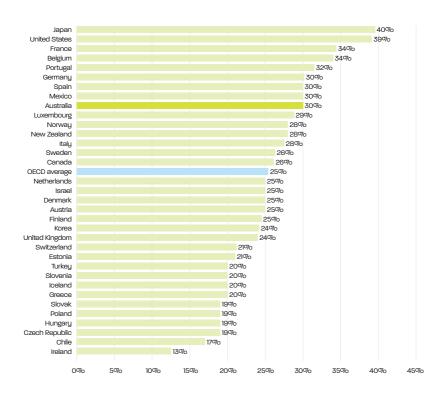




→ Company tax rates in Australia are among the highest in the OECD countries. While Australia's company tax rate is 30‰, the OECD average is 25‰.

FIGURE 14 Company Tax Rates of OECD countries in 2012

Source: OECD tax database, Corporate and capital income taxes, Basic (non-targeted) corporate income tax rates 2012, available at http://www.oecd.org/tax/taxpolicyanalysis/oecdtaxdatabase.htm accessed on 7 December 2012





→ In the first quarter of 2012, the market capitalisation of listed Australian biotechs was over \$24 billion. Biotechnology holds potential for new breakthrough therapies and cures in the future.

15

TABLE 15 Biotechnology Industry in Australia at a Glance

Source: Australian Government, Department of Industry, Innovation, Science, Research and Tertiary Education, Biotech Business Indicators, Q2 2012; **Source: Beyond Borders -Global biotechnology report 2012, Ernst & Young available at http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2012/\$FILE/Beyond_borders_2012.pdf, accessed on 20 Nov 2012

As at end of:	2004	2005	2006	2007	2008	2009	2010	2011	Q2 2012
Number of listed biotechs	65	74	72	75	75	65	63	58	58
Market Cap of listed biotechs (including CSL) (A\$bn)	9.9	11.9	16.7	24.9	22.4	23.4	24.5	21.2	24.7
Employment for publicly listed biotech companies (number)	9,180	8,350	8,820	9,770	10,480	11,060	12,620	13,140**	n/a



Part 2

MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

Over the last century, deaths due to illnesses have decreased dramatically. Investment in newer medicines has been a major contributor in the fight against deadly diseases.

This section illustrates the impact of investment in medicine, medical procedures and technology on death rates in Australia and looks at Australia's health expenditure and that of its OECD peers.

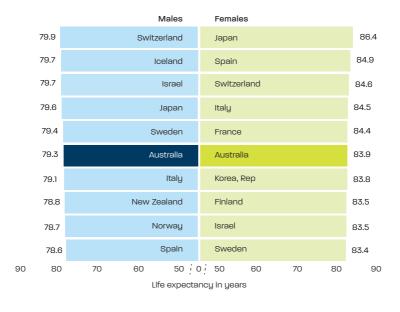


→ Australians enjoy one of the longest life expectancies in the world.



FIGURE 16 Australian Life Expectancy—OECD comparison

Source: Australian Institute of Health and Welfare, Australia's Health 2012, Figure 3.6





→ The rise in life expectancy reflects falls in death rates for all age groups over the past century.

17

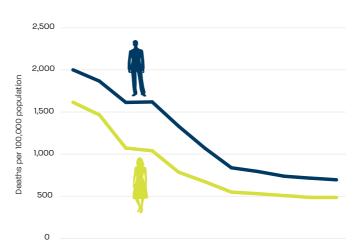
$FIGURE\ 17$ Age-Standardised Death Rates (All Causes), by Sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2010

All causes deaths: trends

1921 1941

1961 1971



1981

1991 2001 2004 2007 2009 2010

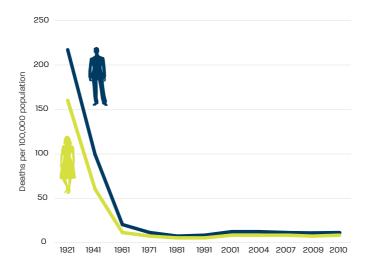


→ Advances in medicines and vaccines have contributed to the dramatic decline in infectious disease death rates—a 96% fall. Such diseases include polio, tetanus, whooping cough, diphtheria, typhoid, measles, mumps and rubella. Once incurable HIV/AIDS is now a chronic disease managed with medications.

FIGURE 18 Age-Standardised Death Rates (Infectious Diseases), by Sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2010

Infectious diseases deaths: trends





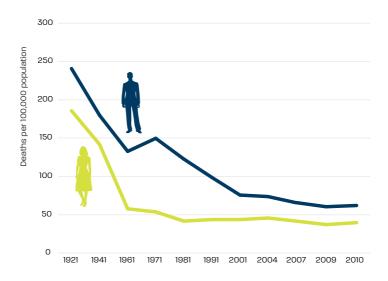
There has been a consistent fall in the number of deaths relating to respiratory diseases. A combination of awareness against smoking and medication to control/prevent respiratory diseases has led to the steady decline.

19

FIGURE 19 Age-Standardised Death Rates (Respiratory Diseases), by Sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2010

Respiratory diseases deaths: trends





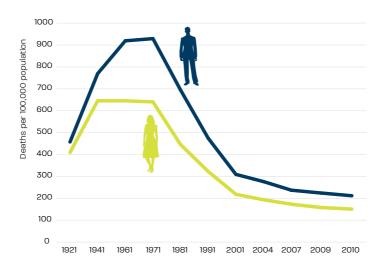
→ Over the past few decades Australia has achieved major gains in the fight against cardio-vascular disease (CVD). From 831 deaths per 100,000 of population in 1968 to 174 deaths per 100,000 in 2010— a 79% fall.

20

${\sf FIGURE}\ 2.0\$ Age-Standardised Death Rates (Cardiovascular Diseases), by Sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2010

Cardiovascular deaths: trends





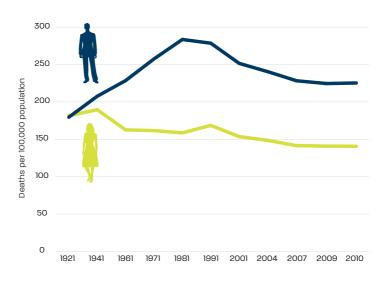
→ Over the past few decades Australia has achieved some gains in the fight against cancers. From 209 deaths per 100,000 of population in 1987 to 176 deaths per 100,000 in 2010—a 17% fall. The medicines industry has committed billions of dollars globally in the fight against cancers. Currently over 800 medicines are under development to treat or prevent cancers.

2

FIGURE 21 Age-Standardised Death Rates (Cancers), by Sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2010

Cancer deaths: trends



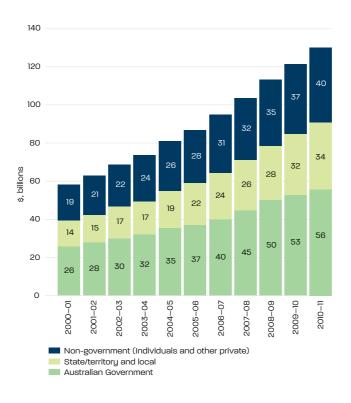


→ In 2010-11, Australia's total health expenditure was \$130 billion. Over two-thirds of this expenditure (69%) was government funded.

22

FIGURE 22 Health Expenditure in Australia

Source: Australian Institute of Health and Welfare, Health expenditure Australia 2010-11, at current prices, Table 3.1, 2012



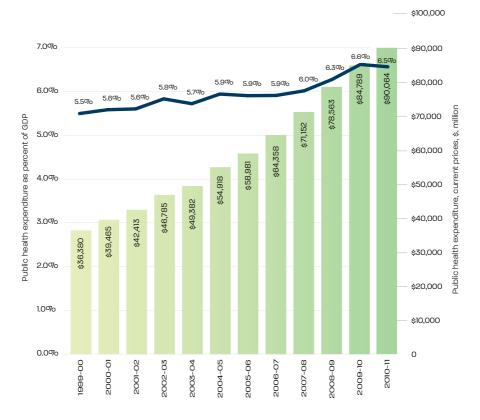


→ In 2010-11 total public health expenditure was \$90 billion or 6.5% of Australian GDP. For the first time since 2003-04, total Australian public sector spending on health fell as a share of GDP.

23

FIGURE 23 Public Health Expenditure in Australia

Source: Australian Institute of Health and Welfare, Health expenditure Australia 2010-11, at current prices, Table 3.1, 2012 and Australian Bureau of Statistics, Catalogue 5206.0 Australian National Accounts: National Income, Expenditure and Product, GDP at current prices, June 2011



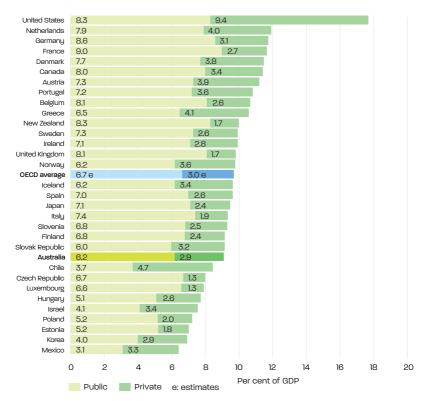


In comparison to other OECD countries, Australia is an average spender on health. However, its public expenditure is lower than its OECD peers.

24

FIGURE 24 Total Expenditure on Health as a Proportion of GDP —OECD comparison (2009*)

Source: OECD HEALTH DATA, October 2012



^{*} latest available data

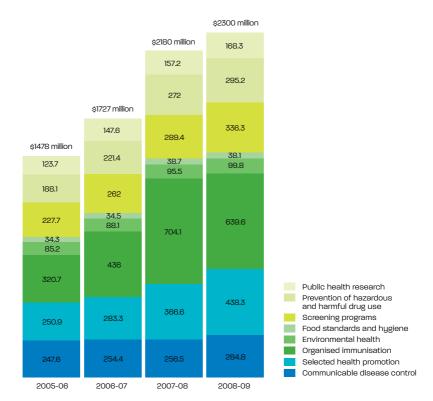


→ In 2008-09, the Australian Government invested \$2.3 billion in public health activities, including over \$640 million in organised immunisation.

25

FIGURE 25 Government Expenditure, on Public Health Activities

Source: Australian Institute of Health and Welfare, Public health expenditure by area of expenditure, 2008-09*



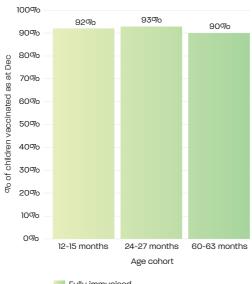
^{*} latest available data



As at December 2011, the proportion of Australian children assessed as fully Immunised was 90% or higher for each of the age groups.

FIGURE 26 Percentage of Australian Children Fully Immunised in 2011, by Age Group

Source: AIHW, Australia Health 2012, Chapter 4, Table 4.3, pg. 158





Part 3

THE PHARMACEUTICAL BENEFITS SCHEME

The Pharmaceutical Benefits Scheme (PBS) has long been a centrepiece of Australian health since its introduction in 1948. The PBS subsidises access to medicines for millions of Australians every year. Currently there are close to 894 medicines listed on the PBS.

Listing of medicines on the PBS involves a rigorous clinical and cost-effectiveness evaluation against already available alternatives, ensuring that Australians get the best value for money.

This section illustrates the listing process, new listings and government expenditure on the PBS. It also shows expenditure growth, key suppliers, and most-prescribed medicines and how Australia's investment in medicines compares with its OECD peers.



→ New medicines listed on the PBS are assessed for clinical benefit and cost-effectiveness against already listed medicines for the same indication. Since 1 January 2011, the registration and reimbursement evaluation processes for a new medicine can be undertaken concurrently, rather than sequentially.*

27

PRS

Pharmaceutical Benefits Scheme

FIGURE 27 Process to gain PBS Listing for Registered Medicines

Source: Historical diagram from the Department of Health and Ageing, PBPA Policies, Procedures and Methods, Attachment B: PBS listing process

Process to gain PBS listing for registered medicines in Australia Proposed drug Sponsor Application to DoHA for PBS listing prepared using PBAC guideleines Negotiation on price by PBPA Secretariat ESC DUSC and Minute Drug Utilisation Committee (DUSC) harmaceutical Evaluation Section and Economic Sub Committee (ESC) (ESC Secretariat) ntial > \$10 m (DUSC Secretariat) ESC/DUS (including usage Unacceptable price. Options are: → no PBS listing; Same drug → sponsor prefers bac to PBPA with further form and Negative recommendations No PBS listing sponsor refers back to PBAC with further information. PBPA PBAC Secretariat PBAC process - 4 months PBPA process - 5 months * The duration of Cabinet's consideration has not bee Generic drugs (with same price as existing drug) Registration on ARTG PBAC Secretaria PBPA Secretariat Post PBAC Process ARTG Australian Register of Therapeutic Goods DoHA Department of Health and Ageing DUSC Drug Utilisation Sub-Committee ESC Economic Sub-Committee PBAC Pharmaceutical Benefits Advisory Committee PBPA Pharmaceutical Benefits Pricing Authority

* Details available from http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-parallel-TGA-and-PBAC-processes



→ In 2011-12, 15 new medicines were made available to Australians through the PBS.

TABLE 28 New Listings on the PBS In 2011-12
Source: Centre for Strategic Economic Studies, Victoria University. Does not include were extended Source: Centre for Strategic Economic Studies, Victoria University. Does not include medicines for which indications

	Brand name	Composition	Company	Indication
1	Eliquis	apixaban	Bristol-Myers Squibb	Antithrombotic agent used to prevent blood clots
2	Saphris	asenapine	Lundbeck	Treatment for mental illness
3	Elonva	corifollitropin alfa	MSD	Hormone therapy
4	Duodart	dutasteride plus tamsulosin	GlaxoSmithKline	Treatment of benign prostatic hypertrophy
5	Revolade	eltrombopag	GlaxoSmithKline	Haemostatic to prevent excessive bleeding
6	Ferro tab	ferrous fumarate	AFT Pharmaceuticals	Treatment for anaemia
7	Gilenya	fingolimod	Novartis Pharmaceuticals	Immunosuppressant used in the treatment of multiple sclerosis
8	Onbrez	indacaterol	Novartis Pharmaceuticals	Treatment for obstructive airway diseases
9	Mag-Sup	magnesium	Petrus Pharmaceuticals	Treatment for magnesium deficiency in Aboriginal and Torres Straits Islander people
10	Xolair	omalizumab	Novartis Pharmaceuticals	Treatment for obstructive airway diseases
11	Targin	oxycodone plus naloxone	Mundipharma	Treatment for chronic severe pain
12	Trajenta	linagliptin	Boehringer Ingelheim	Treatment for diabetes
13	Edurant	rilpivirine	Janssen-Cilag	Antiviral used in the treatment of HIV
14	Adcirca	tadalafil	Eli Lily	Blood pressure medication
15	Eviplera	tenofovir with emtricitabine and rilpivirine	Gilead Sciences	Antiviral used in the treatment of HIV

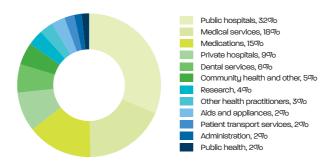


- → Australia's total recurrent health expenditure in 2010-11 was just under \$124 billion at current prices. Hospitals were by far the biggest area of health expenditure (40%).
- → Medicines make up 15% of the total recurrent expenditure comprising benefit-paid medicines (8.0%) and all other medications* (7%).

29

FIGURE 29 Recurrent Health Expenditure, in current prices, by Area of Expenditure in 2010-11

Source: Australian Institute of Health and Welfare, Health Expenditure Australia 2010-11, Supplementary tables, Table 4.3



* includes patient contributions and out-of-pocket expenditure on medicines

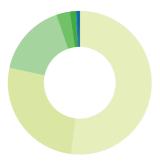


→ In 2010-11 overall expenditure on prescription medicines was close to \$16 billion.

30

FIGURE 30 Expenditure on Prescription Medicines Dispensed in Community and Hospitals (2010-11), by Providers and Funders

Source: Australian Institute of Health and Welfare, Health Expenditure Australia 2010-11, Supplementary tables Table 4.19



- Australian Government DoHA*, \$8248 million
- Individuals, \$4159 million
- Public hospitals**, \$2619 million
- Australian Government DVA, \$473 million
- Private hospitals***, \$249 million
- Injury compensation insurers and other, \$70 million
- Health insurance funds, \$48 million
- Includes Benefit paid pharmaceuticals and all other (non-hospital) medications. Includes \$365 million in Section 100 payments for human growth hormones, in-vitro fertilisation and other subsidised pharmaceuticals.
- ** Includes \$642 million in Australian Government payments to states and territories for highly specialised drugs.
- *** Comprises Australian Government payments for highly specialised drugs only.

DoHA Department of Health and Ageing

DVA Department of Veterans Affairs

Note: Components may not add to totals due to rounding.



→ Long term average real growth in the PBS has slowed down considerably in the last decade and continues to trend downward.

FIGURE 31 Long-Term View of Real PBS Growth

Source: Department of Health and Ageing, Annual report various years, Canberra; ABS cat 6401.0 Consumer price index. Note: includes expenditure on highly specialised drugs program. Growth figures adjusted for inflation using ABS consumer price index as at June 2012



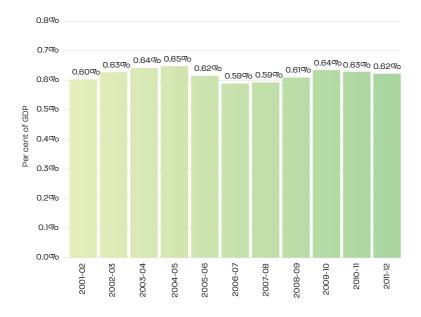


→ The PBS as a percentage of Australian GDP has remained relatively stable in the last decade.

32

FIGURE 32 PBS and Australian GDP

Source: Department of Health and Ageing, Annual reports various years. Australian Bureau of Statistics, catalogue 5206.0, Australian National Accounts: National Income, Expenditure and Product, June 2012



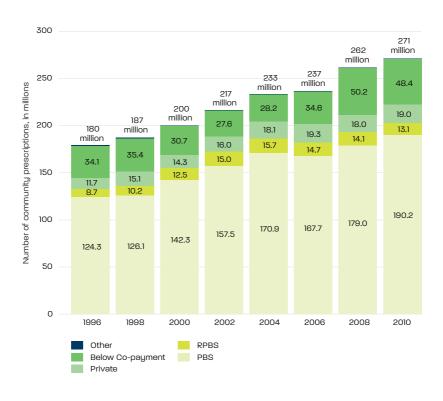


→ Trends show a steady increase in the total number of community prescriptions, from 180 million in 1996 to 271 million prescriptions in 2010.

33

$\begin{tabular}{ll} F \ I \ G \ U \ R \ E & 3 \ 3 \ & Trends in Prescribed Medicines—Number of Prescriptions \\ Dispensed in Community Pharmacies \\ \end{tabular}$

Source: Australian Institute of Health and Welfare, Australia's Health 2012, Table 7.8, pg. 406, 2012



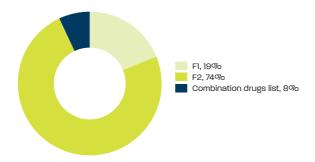


- → From 1 August 2007, PBS medicines were listed on two separate formularies which determine the approach to pricing:
 - Formulary 1 (F1) comprises single brand medicines not interchangeable at the patient level.
 - Formulary 2 (F2) comprises multiple brand medicines and single brand medicines which are interchangeable with multiple brand medicines at the patient level.

34

$\begin{tabular}{ll} F \ I \ G \ U \ R \ E & 3 \ 4 & \begin{tabular}{ll} \textbf{Per Cent of Benefits Paid Scripts Dispensed in 2011-12,} \\ \textbf{By PBS Formularies} \\ \end{tabular}$

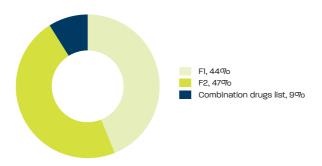
Source: Centre for Strategic Economic Studies, Victoria University, 2012. Includes expenditure on Highly Specialised Drugs (HSD) program. Formulary allocations are as at November 2012



35

<code>FIGURE 35</code> Per Cent of Benefits Paid In 2011-12, By PBS Formulary

Source: Centre for Strategic Economic Studies, Victoria University, 2012. includes expenditure on Highly Specialised Drugs (HSD) program. Formulary allocations are as at November 2012





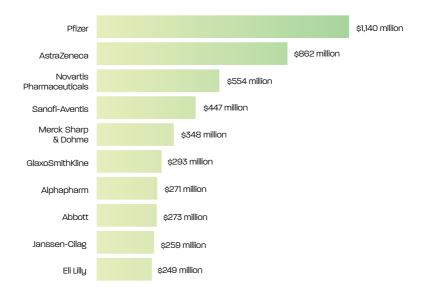
→ In 2011-12, 9 out of 10 top suppliers (by value) to the PBS were Medicines Australia members companies.



FIGURE 36 Top 10 Suppliers to the PBS in 2011-12

Source: Department of Health and Ageing, Expenditure and prescription twelve months to 30 June 2012, Top 10 responsible persons by derived ex-manufacturer sales (Section 85only)

PBS Sales (at ex-manufacturer prices)



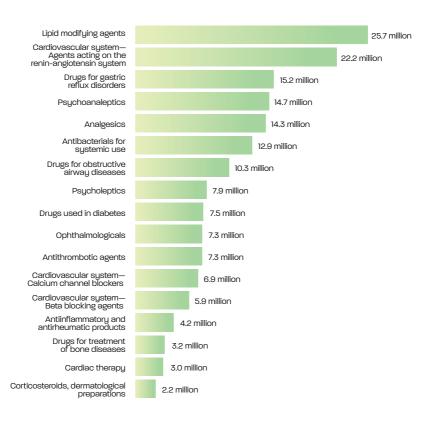


→ Blood pressure and lipid lowering medicines were among the most prescribed medicines on the PBS in 2011-12.

37

FIGURE 37 Script Volumes of Significant Drug Groups (by Highest Cost) to Government in 2011-12

Source: Department of Health and Ageing, Expenditure and prescription twelve months to 30 June 2012. The script volume relates to Section 85 drugs only



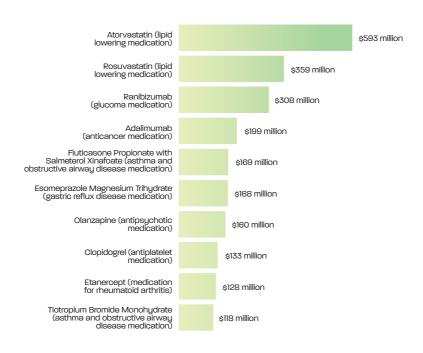


→ Drug spending broadly reflects the burden of disease in Australia. Cardiovascular, glaucoma, Cancer, respiratory disorders, mental illness and auto immune disorders medications are among the top PBS medicines by cost.

38

FIGURE 38 Top 10 PBS Medicines by Government Cost in 2011-12

Source: Department of Health and Ageing, Expenditure and prescriptions twelve months to 30 June, 2012. Government cost relates to Section 85 drugs only



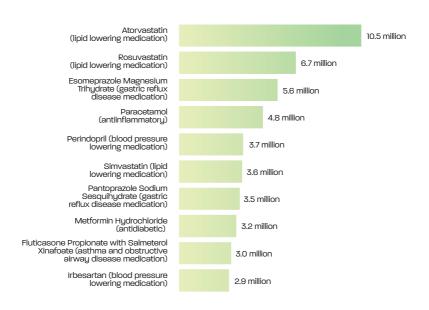


→ Medicines that prevent high blood pressure and lower cholesterol were among the most prescribed medicines on the PBS.

39

FIGURE 39 Most Prescribed PBS Medications in 2011-12

Source: Department of Health and Ageing, Expenditure and prescriptions twelve months to 30 June, 2012



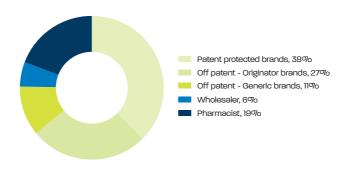


→ Expenditure on the PBS is split between various members of the supply chain. Depending on their role in the supply of medicines, each member receives a per cent of the total spend.

40

FIGURE 40 Share of PBS Expenditure by Suppliers in 2011-12

Source: Centre for Strategic Economic Studies, Victoria University, 2012. Includes government expenditure and patient contributions



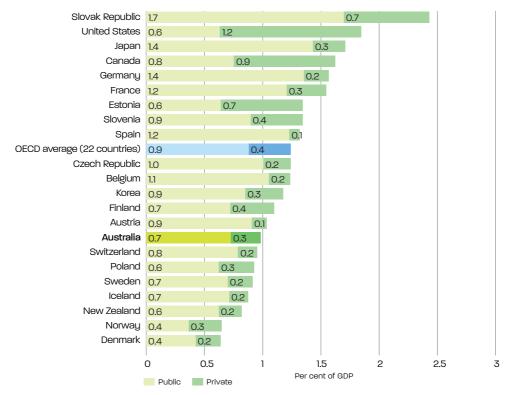


→ Australia's total expenditure on medicines as a proportion of its GDP is below the OECD average.

4

FIGURE 41 Total pharmaceutical expenditure as a proportion of GDP in 2009*—OECD comparison

Source OECD Health Statistics 2012, available at http://stats.oecd.org





Part 4

MEDICINES INDUSTRY GLOBALLY

The global medicines industry provides both economic and social benefits to individual countries and their citizens.

Worldwide, the industry is committed to fighting disease and improving patient outcomes. Top-selling medicines internationally combat cholesterol, arthritis, asthma and cancer.

This section examines the key statistics for the global medicines industry, looks at the rigorous journey a medicine undertakes—from discovery to market—as well as the type and number of new medicines that are currently being developed.

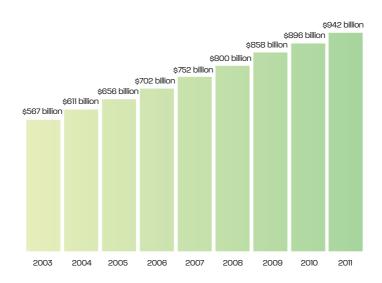


→ In 2011, the overall world medicines market was worth USD \$942 billion.

42

FIGURE 42 World Medicines Market (2003-2011)

Source: IMS Health Market Prognosis, May 2012. Includes IMS Audited and Unaudited markets, constant US\$ uses Q411 average exchange rates. All information current as of May 2012



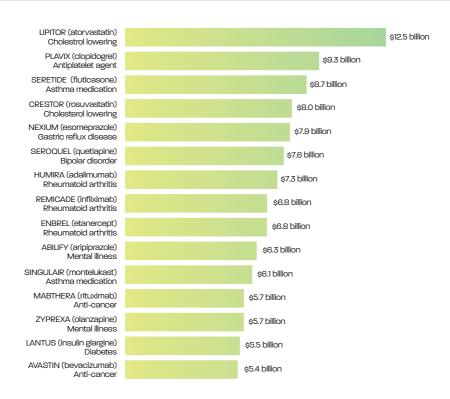


→ Of the top selling brands in the world, a number of the medicines are used in the prevention of high cholesterol, blood clots, gastric ulcer and damage due to auto-immune disorders.

43

FIGURE 43 Top 15 Medicines by Sales Globally

Source: IMS Health MIDAS, December 2011. Includes IMS Audited and Unaudited markets, Sales are in US\$ with quarterly exchange rates



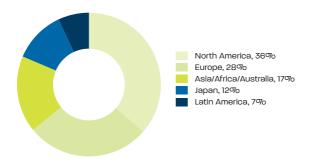


→ North America and Europe together make up nearly two-thirds of the world pharmaceutical market. However, Asia as a proportion of the total world market is increasing in size. Australia currently accounts for around one per cent of the total world market for medicines.

44

FIGURE 44 World Medicines Market by Regions

Source: IMS Health Market Prognosis, Total Unaudited and Audited Global Pharmaceutical Market By Region, Market Prognosis, May 2012



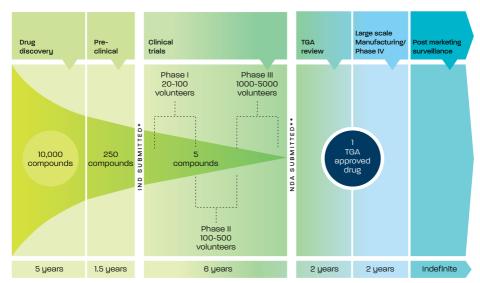


→ Out of the 10,000 compounds tested for potential medical benefits, only five ever reach clinical trials and only one reaches the market. Developing a new medicine takes an average 10-15 years.

45

FIGURE 45 Journey of Medicines—From Discovery to Market

Source: Adapted from Pharmaceutical Research and Manufacturers of America, Industry profile 2012, The Research and Development Process



Average time in stage

^{*}IND submitted: Investigational new drug application submitted to the US Food and Drug Administration

^{**}NDA submitted: New drug application submitted to the Australian Therapeutic Goods Administration (TGA)



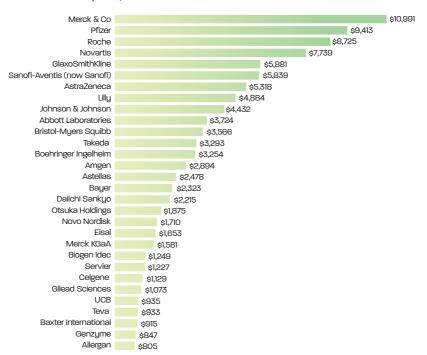
→ In 2010 the global industry invested in excess of US\$100 billion in medicines R&D.



FIGURE 46 Top 30 Global Investors in Medicines R&D in 2010

Source: Scrip's Pharmaceutical Company League Tables 2010

2010 Pharma R&D Spend (\$m)



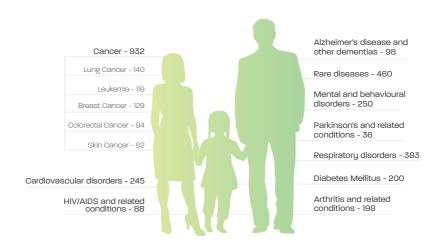


→ In 2011, there were 3091 medicines under development for various illnesses worldwide.

47

FIGURE 47 Medicines in Development Worldwide

Source: Pharmaceutical Research and Manufacturers of America, Industry profile 2012





MEDICINES AUSTRALIA MEMBERSHIP IN 2012-13

A. Menarini Australia Pty Ltd

Abbott Australasia Pty Ltd

AbbVie Pty Ltd

Actelion Pharmaceuticals Australia Pty Limited

Allergan Australia Pty Ltd Amgen Australia Pty Ltd

Andrew's Refrigerated Transport

Astellas Pharma Australia AstraZeneca Pty Ltd

Baxter Healthcare Pty Ltd
Bayer Australia Pty Ltd

Biogen Idec Australia Pty Ltd Boehringer Ingelheim Pty Limited

Bristol-Myers Squibb Australia Pty Ltd

Celgene Pty Ltd

Commercial Eyes Pty Ltd

Covance Pty Ltd

CSL Limited

Eli Lilly Australia Pty Ltd

FIT-BioCeuticals Ltd

Fresenius-Kabi Australia Pty Ltd Genzyme Australasia Pty Ltd

Gilead Sciences Pty Ltd

GlaxoSmithKline Australia Pty Ltd

IDT Australia Ltd

IMS HealthAustralia Pty Ltd
INCResearch Australia Pty Ltd

iNova Pharmaceuticals Pty Ltd

Ipsen Pty Ltd

IQnovate Ltd

Iris Interactive Pty Ltd

Janssen Pty Ltd

KMC Health Care Leo Pharma

Lundbeck Australia Pty Ltd

Medlab Pty Ltd

Merck Serono Australia Pty Ltd

MSD Australia Pty Ltd Mundipharma Pty Ltd Norgine Pty Limited

Novartis Pharmaceuticals Australia Pty Ltd

Novo Nordisk Pharmaceuticals Pty Ltd - Australia

Pfizer Australia Pty Ltd

Pretium Pty Ltd

PricewaterhouseCoopers
Princeton Publishing Pty Ltd
Quintiles Australia Pty Ltd
Roche Products Pty Ltd

Sanofi Pty Ltd

Servier Laboratories (Aust) Pty Ltd

Shire Australia Pty Ltd

Takeda Pharmaceuticals Australia Pty Ltd

UCB Australia Pty Ltd Vifor Pharma Ltd