

MEDICINES AUSTRALIA
→ FactsBook 2 SECOND EDITION
UPDATE



MEDICINES
Australia

MEDICINES AUSTRALIA → FactsBook SECOND EDITION UPDATE

INTRODUCTION

Welcome to the **updated** second 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 December 2011, includes the most recent available data on aspects of the Australian and international medicines industry, and where possible compares it to the 2010 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

For further information on the medicines industry, or additional copies of the Facts Book, please contact:

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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 Australian's 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 close to 14,000 people in Australia. In 2010-11, Australian medicines exports totalled over \$3.8 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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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 emerged as a leading exporter of high-technology goods and services from Australia and a keen investor in research.

Currently the medicines industry is:

- the largest high-technology exporter from Australia—\$3.8 billion in 2010-11;
- the highest manufacturing industry investor in R&D—\$1.0 billion in 2009-10; and
- one of the largest employers of science graduates in Australia.

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

MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

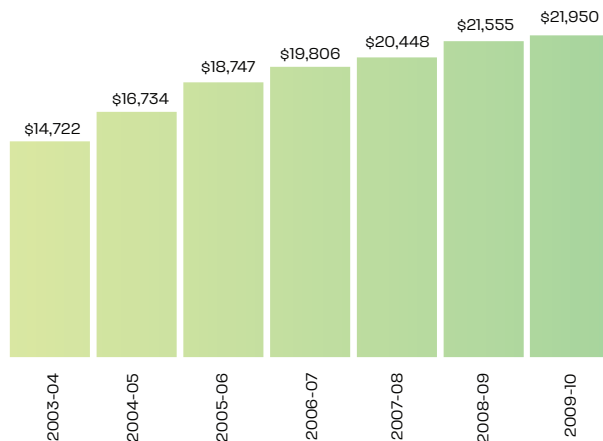
- In 2009-10, the Australian medicines industry had a turnover close to \$22 billion.

01

FIGURE 1 Australian Medicines Industry Turnover

Source: Australian Pharmaceuticals Industry Data Card, Key Statistics: Pharmaceuticals Manufacturing in Australia, accessed on 15 November 2011, available at <http://www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/Pharmaceuticals/Pages/PharmaceuticalsIndustryDataCard.aspx>

Australian Pharmaceuticals Industry Turnover, \$ millions



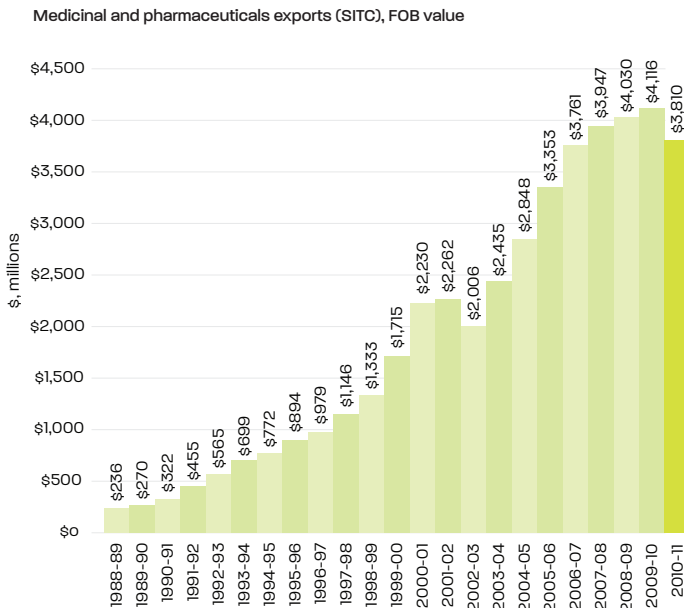
MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- In 2010-11, the Australian medicines industry contributed close to \$4 billion in export earnings to the Australian economy and led the high-technology exports sector for the third year running.

02

FIGURE 2 Medicines export by financial years 1988-2011

Source: Australian Bureau of Statistics, Catalogue 5368.0, International Trade in Goods and Services, Australia 2010-11, September 2011



MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

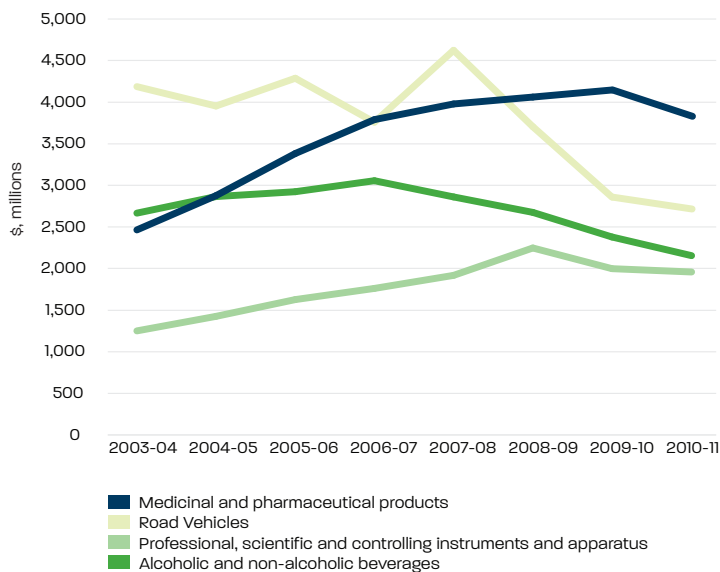
→ In 2010-11, medicines were the top hi-tech Australian export.

03

FIGURE 3 Medicines exports vs. other manufactured exports, by financial year

Source: Australian Bureau of Statistics, Catalogue 5368.0, International Trade in Goods and Services, Australia 2010-11, September 2011

Medicinal and pharmaceutical exports vs other manufactured Australian exports



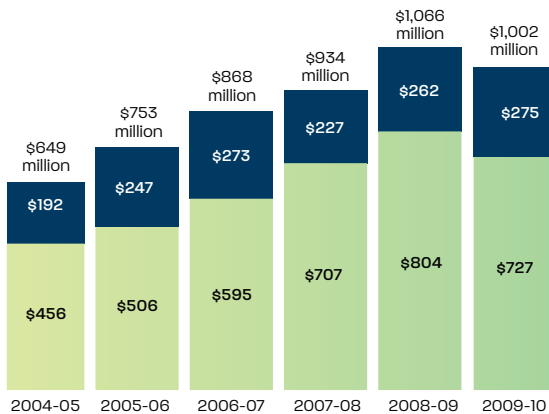
MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- In 2009-10, the Australian medicines industry invested over \$1 billion in research and development.

04

FIGURE 4 Medicines R&D in Australia

Source: Australian Bureau of Statistics, Catalogue 8104, Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2009-10



■ Clinical Health (organs, diseases and abnormal conditions)
■ Human Pharmaceutical Products

MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- Medicines remain amongst the top areas of business investment in Australian R&D.

05

TABLE 5 **Top 5 areas of business R&D investments**

Source: Australian Bureau of Statistics, Catalogue 8104, Research and Experimental Development by Socio-Economic Objectives, Businesses, Australia, 2009-10

| | | | 2007-08 | 2008-09 | 2009-10 |
|------------------------------------|---|--|-------------------------------------|-------------------------------------|-------------------------------------|
| Sector | Area of R&D expenditure | | Business Expenditure (\$,000) | Business Expenditure (\$,000) | Business Expenditure (\$,000) |
| 1 Financial and insurance services | Financial services | | \$1,376,067 | \$1,981,541 | \$2,617,817 |
| 2 Mining | Mining and extraction of energy resources | | \$1,168,740 | \$1,464,320 | \$1,541,939 |
| 3 Mining | Primary mining and extraction of mineral resources | | \$1,195,695 | \$1,498,998 | \$1,020,714 |
| 4 Manufacturing | Medicines R&D (human pharmaceutical products and clinical health) | | \$933,776 | \$1,066,090 | \$1,001,857 |
| 5 Services | Computer software and services | | \$903,052 | \$911,798 | \$952,763 |

MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

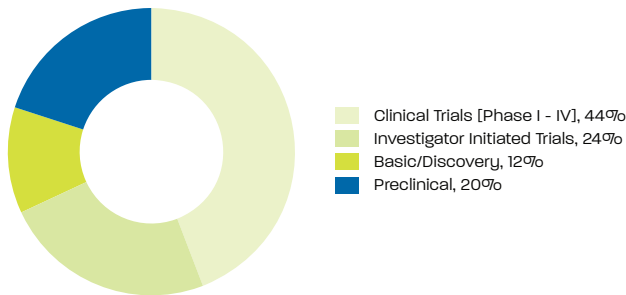
CLINICAL TRIALS IN AUSTRALIA: A SNAPSHOT

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

06

FIGURE 6 Types of Industry Sponsored Clinical Research conducted in Australia

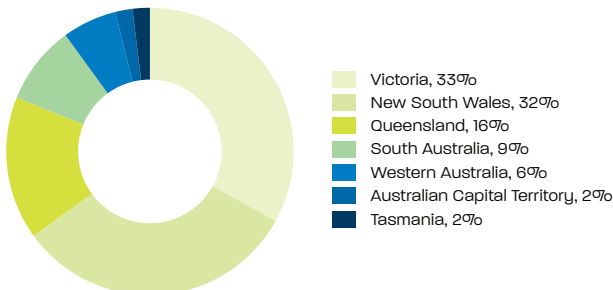
Source: Pharmaceuticals Industry Council, Benchmarking Survey of Clinical Research in Australia (2010)



07

FIGURE 7 Geographic Location of Clinical Trials Conducted in Australia

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



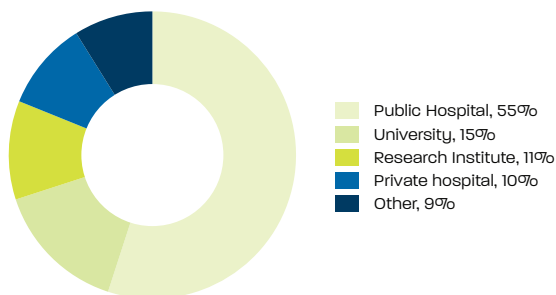
MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

CLINICAL TRIALS IN AUSTRALIA: A SNAPSHOT

08

FIGURE 8 Types of Institutions Involved in Conducting Industry Sponsored Clinical Research in Australia

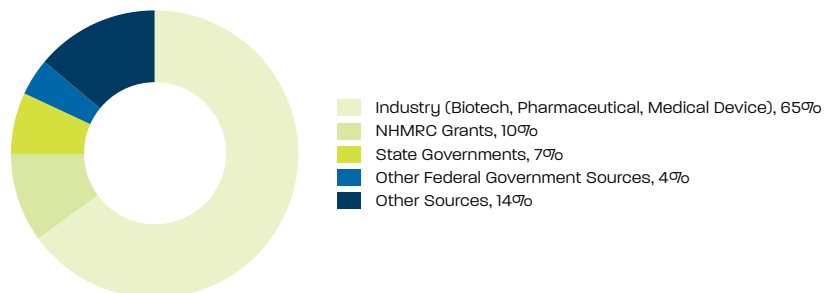
Source: NSW Clinical Trials Business Development Centre, Inaugural Survey of Investigator Perceptions on the Value of Industry Funded Clinical Research (2009)



09

FIGURE 9 Sources of Funding for Clinical Trials Conducted in Australia

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



MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- Clinical trial are costly and can take years to complete. A number of factors are considered by global medicines companies before a location is decided.

10

TABLE 10 **Key factors in deciding the location of a clinical trial**

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

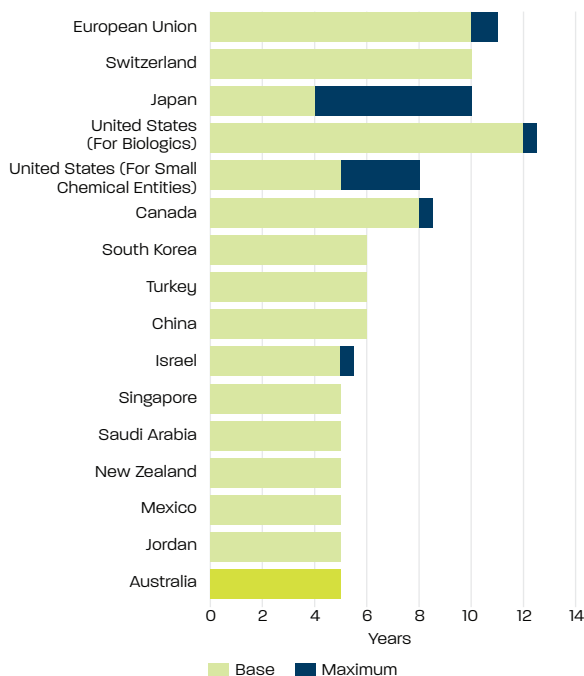
| Rank | Key factors in deciding location of a clinical trial |
|------|--|
| 1 | Ability to meet patient recruitment targets |
| 2 | Cost of conducting a clinical trial |
| 3 | Time taken to initiate a clinical trial |
| 4 | Quality of data produced in a clinical trial |
| 5 | Productivity of a clinical trial |

MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- Data exclusivity is an independent form of intellectual property protection. It is used by the medicines industry to protect proprietary product safety and efficacy data against unauthorised use by a third party 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



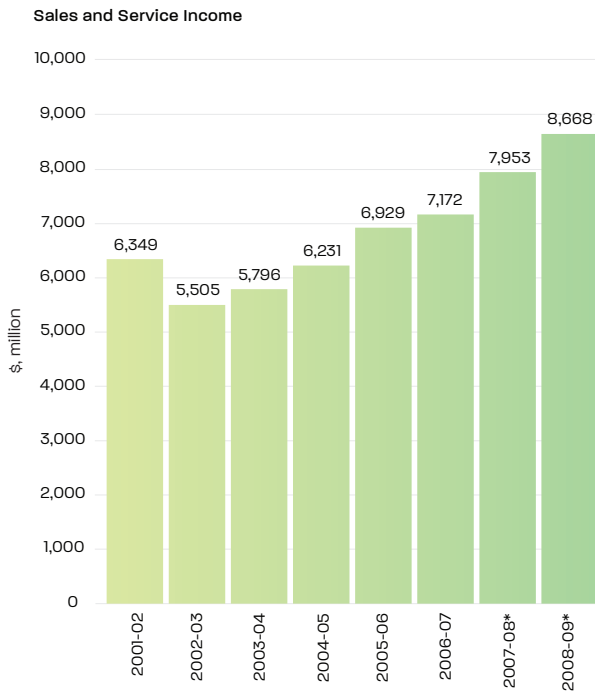
MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- In 2008-09, Australian medicines manufacturing contributed close to \$8.7 billion to the economy.

12

FIGURE 12 Medicines sales and service income—2008-09

Source: Australian Bureau of Statistics, Catalogue 8221, Manufacturing Industry, Australia, 2006-07, August 2008 and Catalogue 8159, Experimental Estimates for the Manufacturing Industry, 2008-09, December 2010



* Estimates only

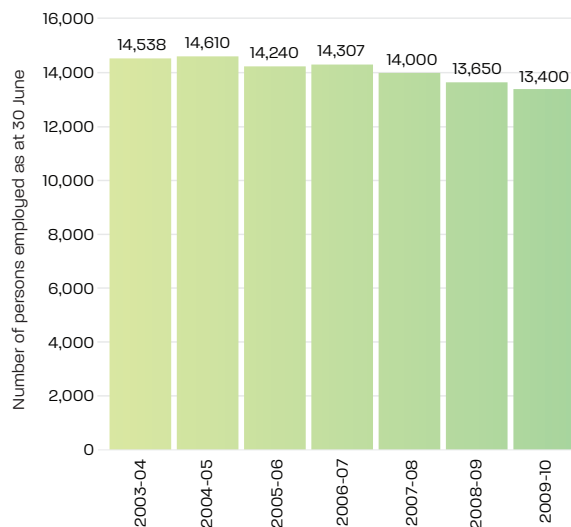
MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- In 2008-09, the medicines manufacturing sector employed 13,400 people. Between 2003 and 2011, over 1300 manufacturing jobs were lost due to factory closures.

13

FIGURE 13 Employment in pharmaceutical manufacturing

Source: Australian Pharmaceuticals Industry Fact Sheet, Key Statistics: Pharmaceuticals manufacturing, accessed on 15 November 2011, available at <http://www.innovation.gov.au/Industry/PharmaceuticalsandHealthTechnologies/Pharmaceuticals/Pages/PharmaceuticalsIndustryDataCard.aspx>



MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- In the first quarter of 2011, the market capitalisation of listed Australian biotechs was over \$23 billion. Biotechnology holds potential for new breakthrough therapies and cures in the future.

14

TABLE 14 **Biotechnology industry in Australia at a glance**

Source: Australian Biotechnology Sector Fact Sheet, Department of Innovation, Industry, Science and Research, Accessed on 12 December 2011, available at <http://www.innovation.gov.au/AboutUs/KeyPublications/Documents/InnovationPortfolioFactSheets.pdf>

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

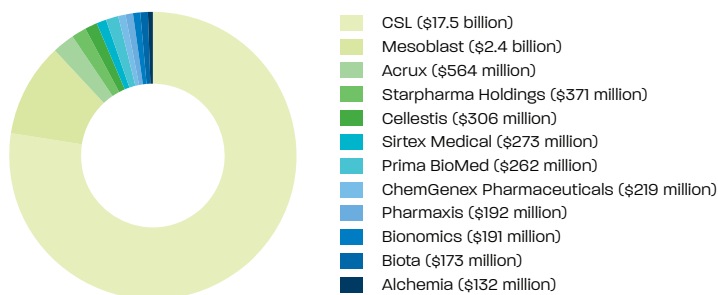
MEDICINES INDUSTRY AND THE AUSTRALIAN ECONOMY

- There were at least 12 biotechnology companies listed on the Australian Securities Exchange (ASX) with market capitalisation in excess of \$100 million in 2011.

15

FIGURE 15 Leading biotechnology companies in Australia

Source: Department of Innovation, Industry, Science and Research, THE AUSTRALIAN BIOTECHNOLOGY SECTOR, Pg 66, Accessed on 15 November 2011, available at <http://www.innovation.gov.au/AboutUs/KeyPublications/Documents/InnovationPortfolioFactSheets.pdf>



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.

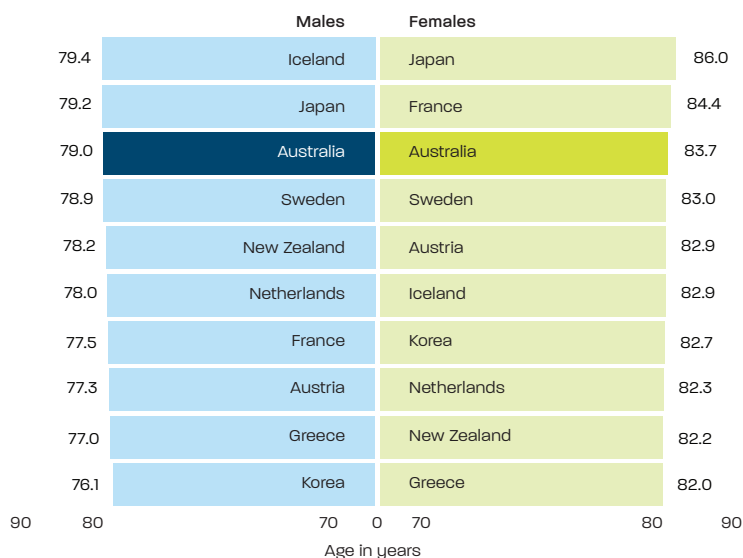
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- Australians enjoy one of the longest life expectancies in the world, at 81.4 years. Only the Japanese have longer life expectancies.

16

FIGURE 16 **Australian life expectancy**

Source: Australian Institute of Health and Welfare, Australia's Health 2010, Table 2.3, 2010



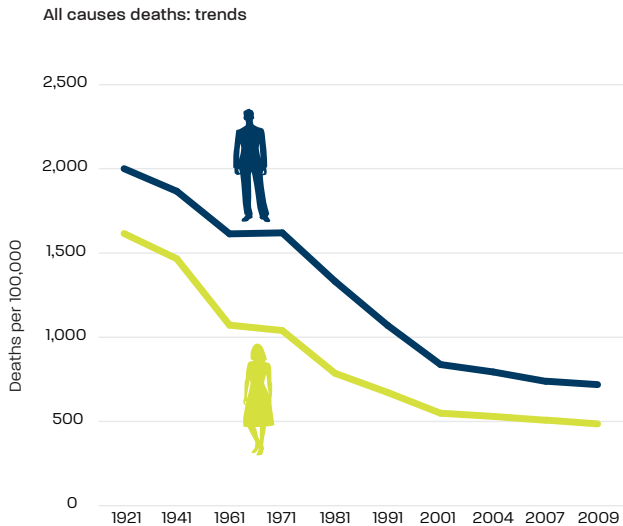
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- 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, 2009



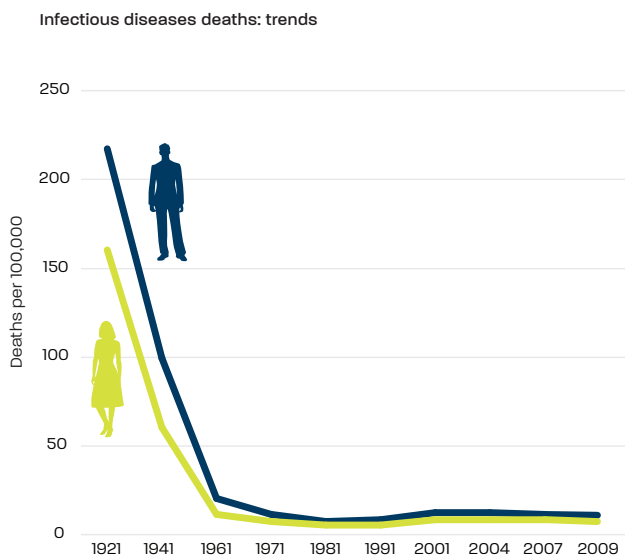
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- Advances in medicines and vaccines have contributed to the dramatic decline in infectious disease deaths rates—a 96% fall. Once considered a death sentence, HIV/AIDS is now a chronic disease managed with medications.

18

FIGURE 18 Age-standardised death rates (infectious diseases), by sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2009



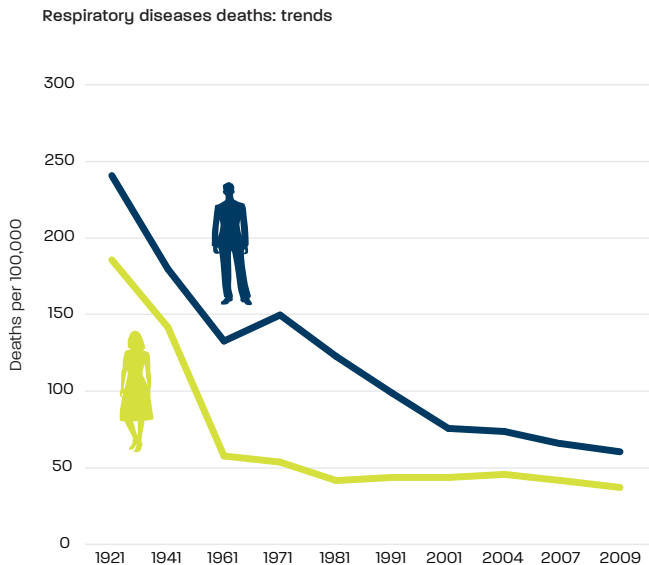
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- 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, 2009



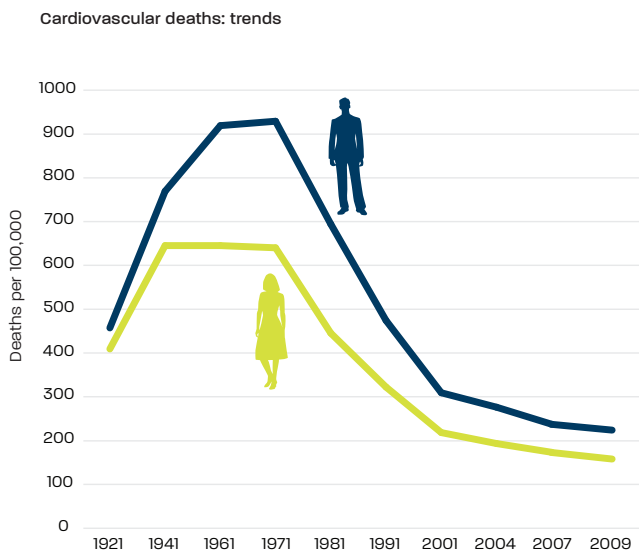
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- Over the past few decades Australia has achieved major gains in the fight against cardiovascular disease (CVD). From 831 deaths per 100,000 of population in 1968 to 183 deaths per 100,000 in 2009—a 78% fall.

20

FIGURE 20 Age-standardised death rates (cardiovascular diseases), by sex

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2009



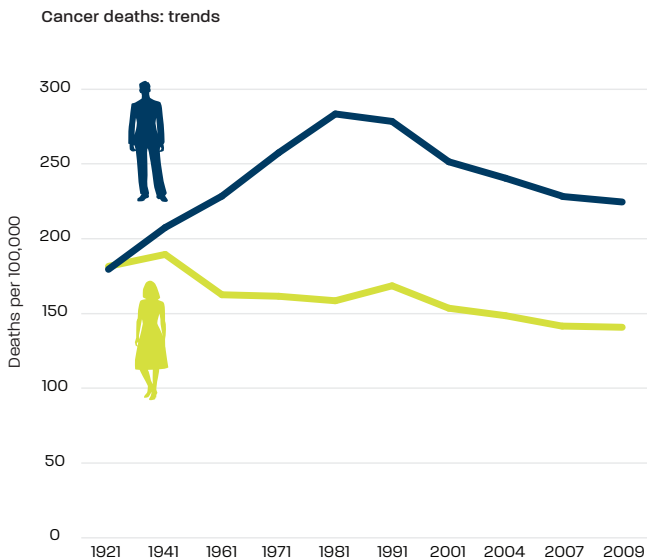
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- 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 2009—this represents a 16% fall. The medicines industry has committed billions of dollars globally in the fight against cancers. Currently over 800 medicines are under development to treat cancers.

21

FIGURE 21 **Age-standardised death rates (Cancers), by sex**

Source: Australian Bureau of Statistics, Catalogue 3303.0 Causes of Death, Australia, 2009



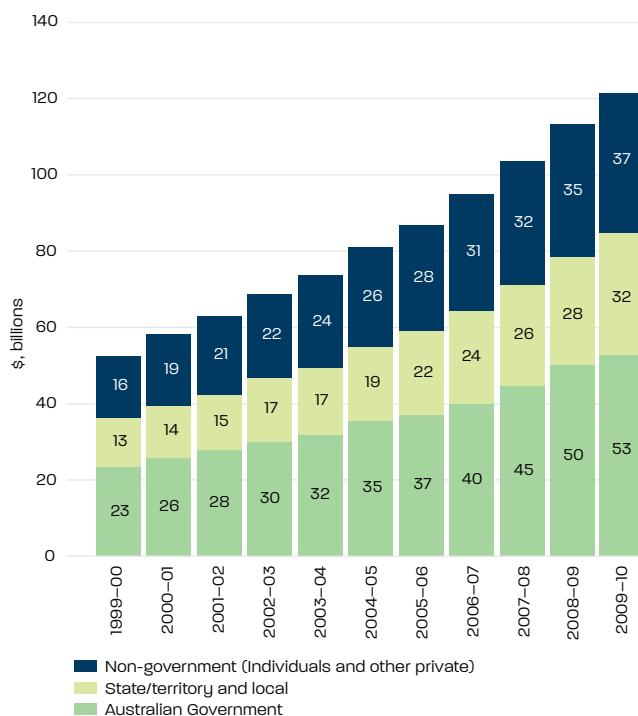
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- In 2009-10 Australia's total health expenditure was \$121 billion. The majority of this expenditure (70%) was government funded.

22

FIGURE 22 Health expenditure in Australia

Source: Australian Institute of Health and Welfare, Health expenditure Australia 2009-10, at current prices, Table 3.1, 2011



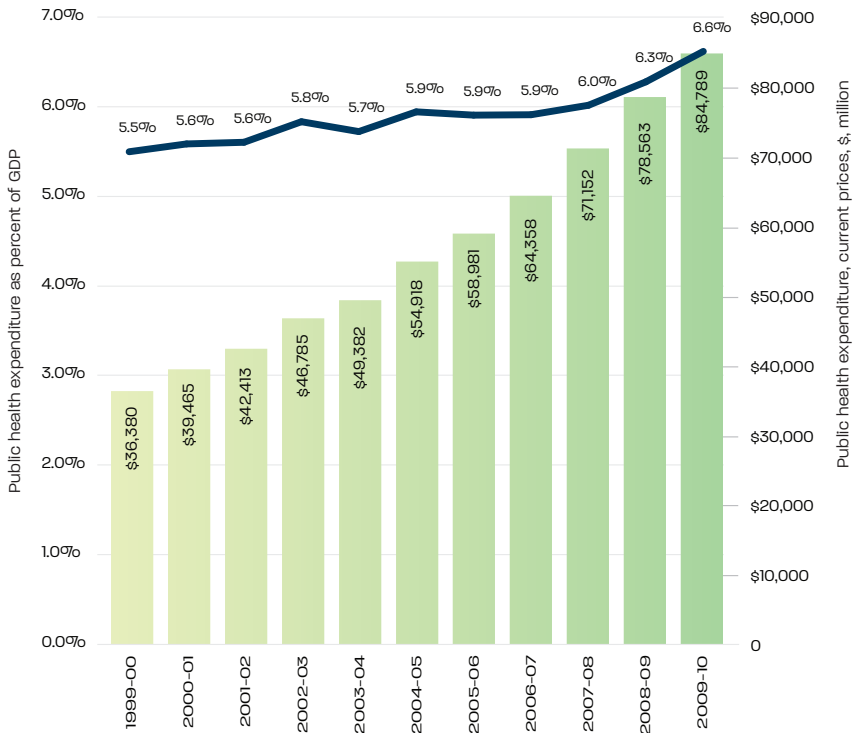
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- In 2009-10 the total public health expenditure was \$85 billion or 6.6% of Australian GDP.

23

FIGURE 23 **Public health expenditure in Australia**

Source: Australian Institute of Health and Welfare, Health expenditure Australia 2009-10, at current prices, Table 3.1, 2011 and Australian Bureau of Statistics, Catalogue 5206.0 Australian National Accounts: National Income, Expenditure and Product, GDP at current prices, June 2011



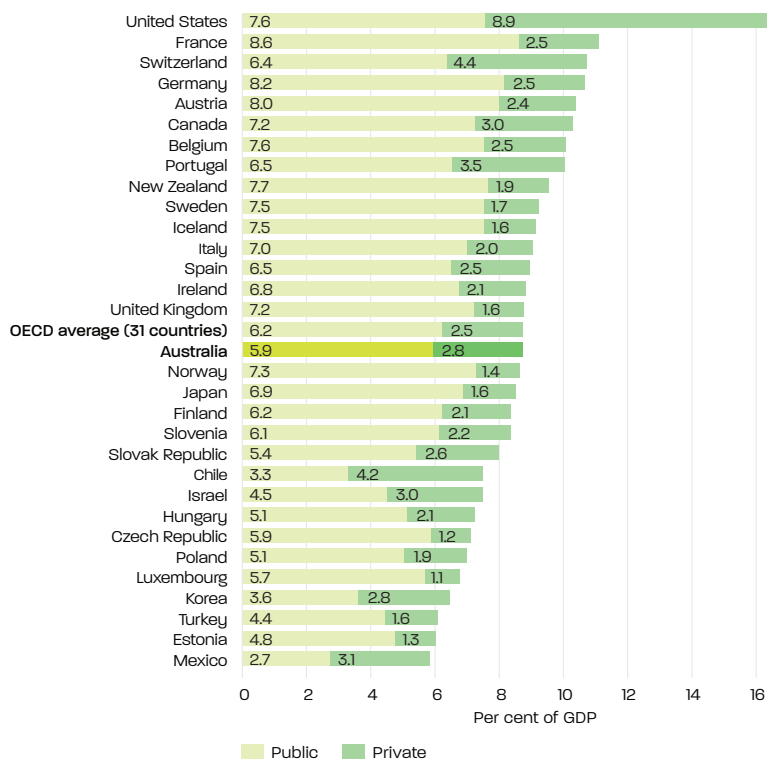
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- 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 in OECD countries (2008)**

Source: OECD HEALTH DATA November 2011



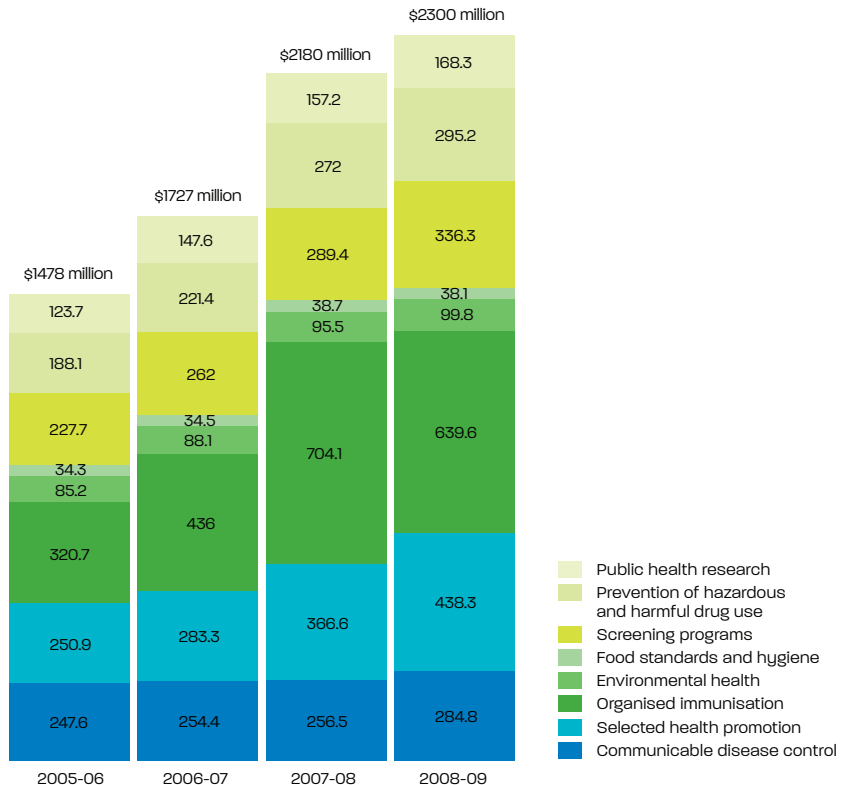
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- 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, \$ million**

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



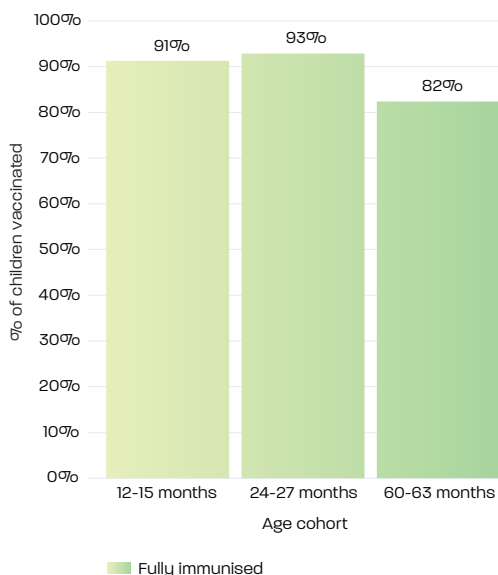
MEDICINES INDUSTRY AND AUSTRALIA'S HEALTH

- In 2008-09, over 4 million vaccinations were administered to children nationally. Ninety-three percent of all Australian children were fully immunised by the age of two.

26

FIGURE 26 Percentage of children fully immunised by age group

Source: Australian Institute of Health and Welfare, Australia's Health 2010, Table 3.17, 2010



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 890 medicines listed on the PBS.

Listing of medicines on the PBS involves a rigorous 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 the growth, key suppliers, most prescribed medicines and how Australia's investment in medicines compares with its OECD peers.

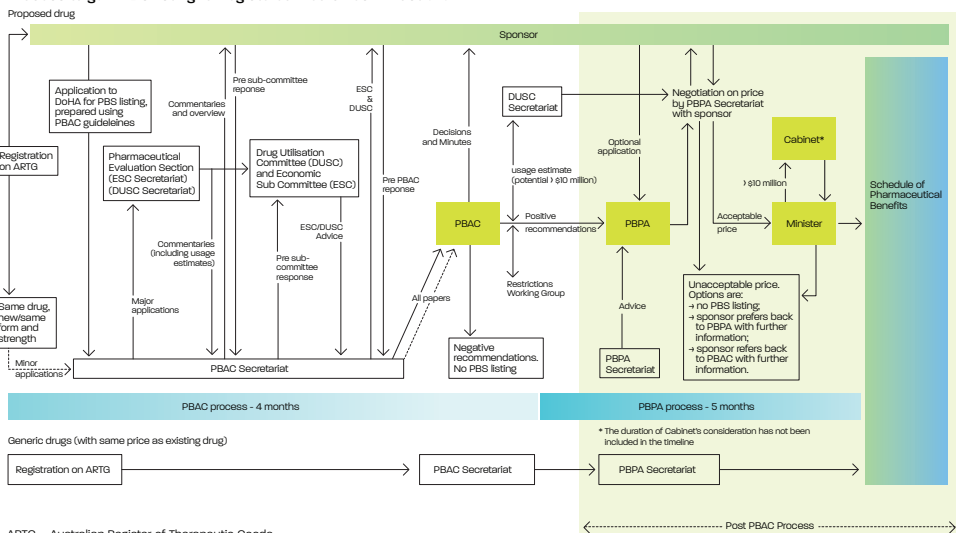
THE PHARMACEUTICAL BENEFITS SCHEME

- New medicines listed on the PBS are assessed for clinical benefit and cost-effectiveness against already listed medicines for the same indication.

27 FIGURE 27 Process to gain PBS listing for registered medicines

Source: Department of Health and Ageing, PBPA Policies, Procedures and Methods, Attachment D, viewed on 9 December 2011, available at [http://www.health.gov.au/internet/publications/publishing.nsf/Content/CA25774C001B57CACA2575DE001A573B/\\$File/AttachmentD.pdf](http://www.health.gov.au/internet/publications/publishing.nsf/Content/CA25774C001B57CACA2575DE001A573B/$File/AttachmentD.pdf)

Process to gain PBS listing for registered medicines in Australia



THE PHARMACEUTICAL BENEFITS SCHEME

- In 2010-11, 21 new medicines were made available to Australians through the PBS.

28

TABLE 28 New listings on the PBS in 2010-11

Source: New Listings and Changes fact sheets, pbs.gov.au, Department of Health and Ageing 2010-11.
Does not include medicines for which indications were extended

| | Brand name | Composition | Company | Indication |
|----|------------|---|------------------------------------|--|
| 1 | Actemra | Tocilizumab | Roche | Rheumatoid Arthritis |
| 2 | Aloxi | Palonosetron | Specialised Therapeutics Australia | Management of nausea and vomiting associated with cytotoxic chemotherapy |
| 3 | Avodart | Dutasteride | GSK | Enlarged prostate |
| 4 | Azarga | Brinzolamide with timolol maleate | Alcon | Open angle glaucoma or ocular hypertension |
| 5 | Byetta | Exenatide | Eli Lilly | Type 2 diabetes |
| 6 | Cetrotide | Cetrorelix | Merck Serono | Infertility |
| 7 | Cimzia | Certolizumab | UCB | Rheumatoid Arthritis |
| 8 | Epiduo | Adapalene with benzoyl peroxide | Galderma | Severe Acne |
| 9 | Exforge | Amlodipine with valsartan and hydrochlorothiazide | Novartis | Hypertension |
| 10 | Firmagon | Degarelix | Ferring Pharmaceuticals | Prostate Cancer |
| 11 | Galvumet | Vildagliptin and Metformin | Novartis | Type 2 Diabetes |
| 12 | Galvus | Vildagliptin | Novartis | Type 2 diabetes |
| 13 | Nplate | Romiplostim | Amgen | Blood Disorder |
| 14 | Onglyza | Saxagliptin | AstraZeneca/BMS | Type 2 diabetes |
| 15 | Orgalutran | Ganirelix | MSD | Infertility |
| 16 | Prolia | Denosumab | Amgen | Osteoporosis |
| 17 | Relpax | Eletriptan | Pfizer | Acute treatment of migraine headache |
| 18 | Sevikar | Olmesartan with amlodipine | MSD | Hypertension |
| 19 | Simponi | Golimumab | Janssen-Cilag | Rheumatoid arthritis |
| 20 | Twynsta | Telmisartan with Amlodipine | Boehringer-Ingelheim | Hypertension |
| 21 | Vidaza | Azacitidine | Celgene Pty Ltd | Treatment of myelodysplastic syndrome |

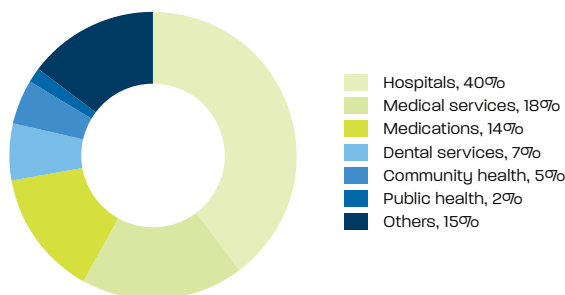
THE PHARMACEUTICAL BENEFITS SCHEME

- Australia's total recurrent health expenditure in 2009-10 was just over \$116 billion at current prices. Hospitals were by far the biggest area of health expenditure (40%).
- Medicines make up 14% of the total recurrent expenditure comprising benefit-paid medicines (8.0%) and all other medications* (6%).

29

FIGURE 29 Recurrent health expenditure, current prices, by area of expenditure, 2009-10

Source: Australian Institute of Health and Welfare, Health Expenditure Australia 2009-10, Table 4.1 pg 44



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

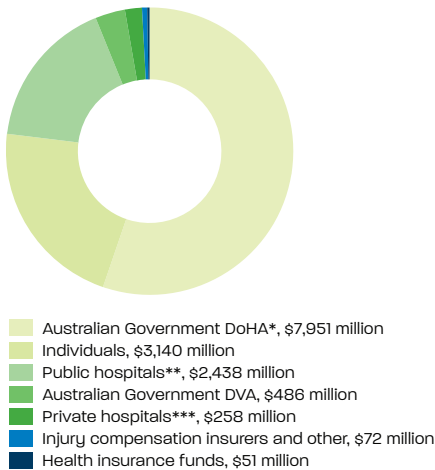
THE PHARMACEUTICAL BENEFITS SCHEME

- In 2009-10 the overall expenditure on prescription medicines was in excess of \$14 billion.

30

FIGURE 30 Expenditure on prescription medicines dispensed in community and hospitals (2009-10), by providers and funders

Source: Australian Institute of Health and Welfare, Health Expenditure Australia 2009-10, Table 4.16 pg 72



* 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. Non hospital medications includes private prescriptions and under co-payment prescriptions

** 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.

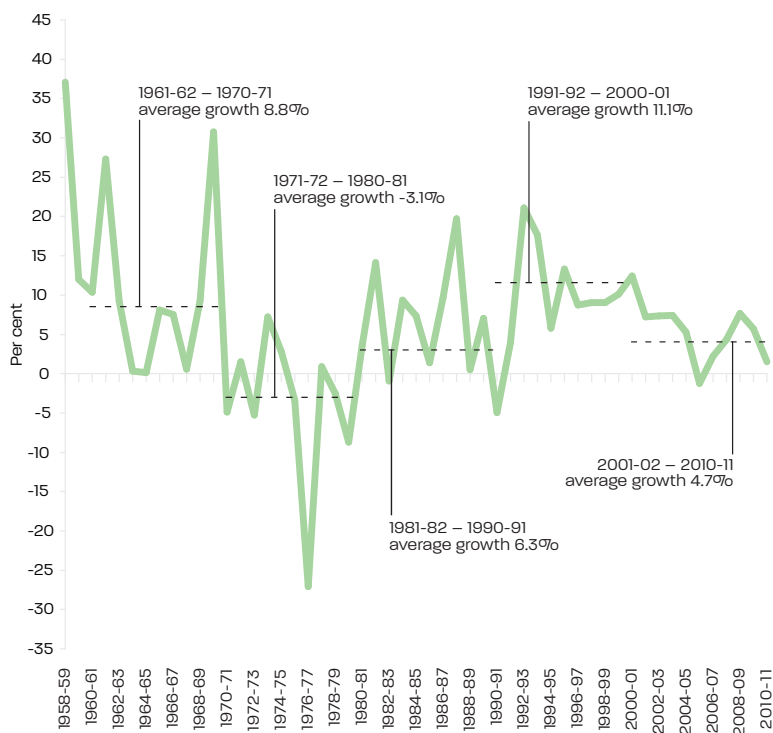
THE PHARMACEUTICAL BENEFITS SCHEME

- The long-term average real growth in the PBS has slowed down considerably in the last decade and continues to trend downward.

31

FIGURE 31 Long-term view of real growth in PBS

Source: Department of Health and Ageing 2009, 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



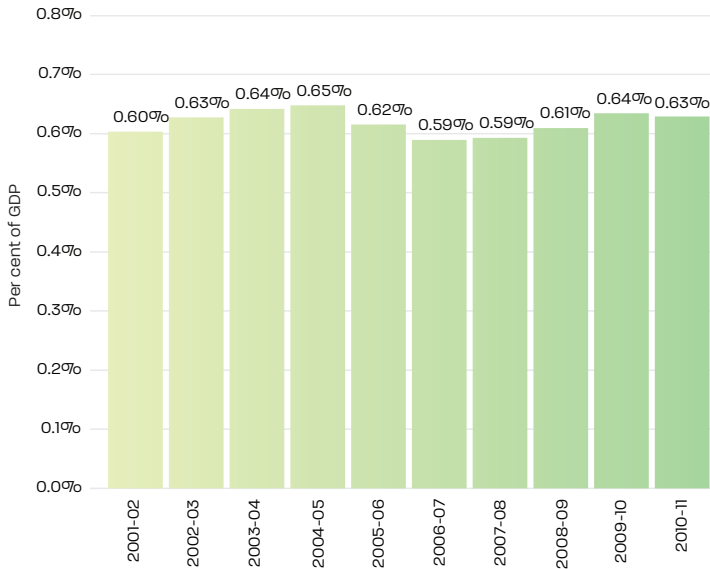
THE PHARMACEUTICAL BENEFITS SCHEME

- 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 2011



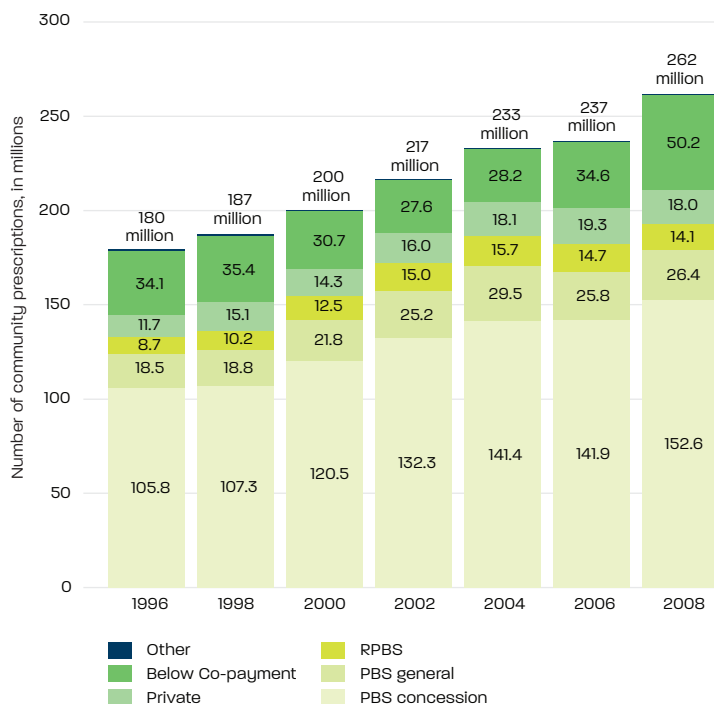
THE PHARMACEUTICAL BENEFITS SCHEME

- Trends show a steady increase in the total number of community prescriptions, from 180 million in 1996 to 262 million prescriptions in 2008.

33

FIGURE 33 Trends in prescribed medicines, number of prescriptions dispensed in community pharmacies

Source: Australian Institute of Health and Welfare, Australia's Health 2010, Table 7.19, 2010



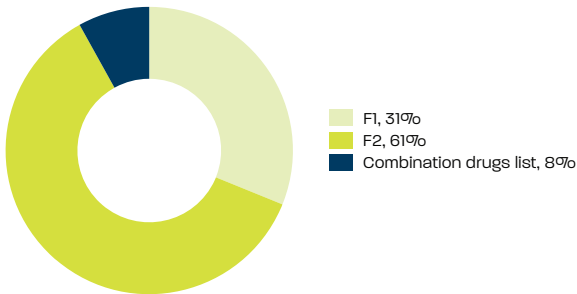
THE PHARMACEUTICAL BENEFITS SCHEME

- 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

FIGURE 34 Percent of benefit paid scripts on the PBS in 2010-11, by formulary

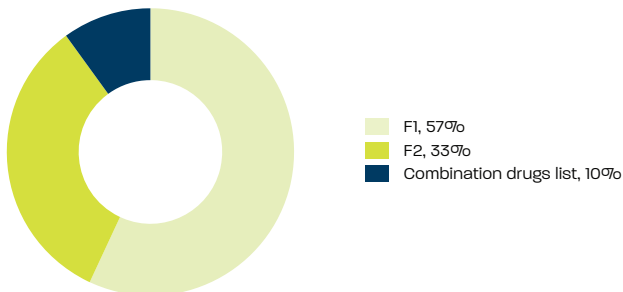
Source: Medicines Australia analysis, includes only Section 85 benefits paid scripts



35

FIGURE 35 Percent of Government expenditure on the PBS in 2010-11, by formulary

Source: Medicines Australia analysis includes only Section 85 expenditure



THE PHARMACEUTICAL BENEFITS SCHEME

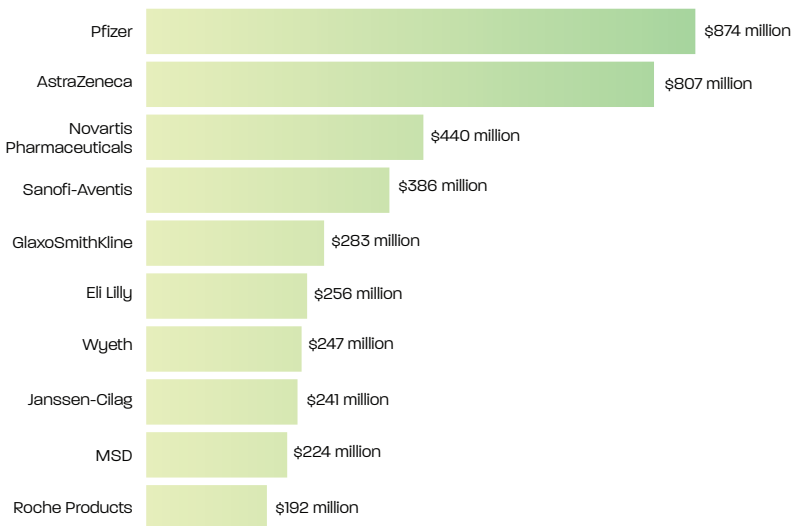
- In 2010-11, the top 10 suppliers (by value) to the PBS were Medicines Australia members companies.

36

FIGURE 36 Top 10 suppliers to the Pharmaceutical Benefits Scheme (PBS) in 2010-11, \$ millions

Source: Department of Health and Ageing, Expenditure and prescription twelve months to 30 June 2011, Top 10 responsible persons by derived ex-manufacturer sales (Section 85 only)

PBS Sales (at ex-manufacturer prices)



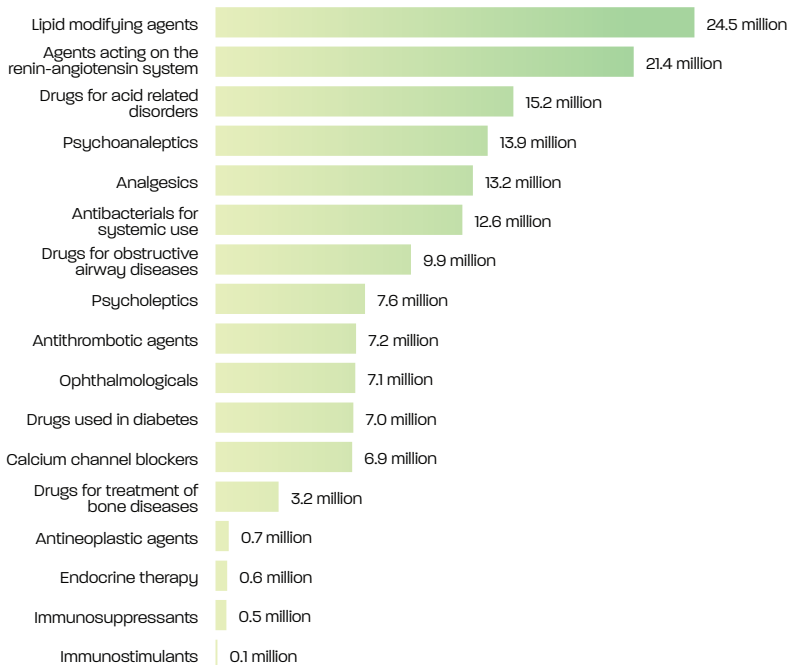
THE PHARMACEUTICAL BENEFITS SCHEME

- Blood pressure and lipid lowering medicines were among the most prescribed medicines on the PBS in 2010-11

37

FIGURE 37 Significant drug groups by highest Government cost, Script volume (Section 85 only)

Source: Department of Health and Ageing, Expenditure and prescription twelve months to 30 June 2011



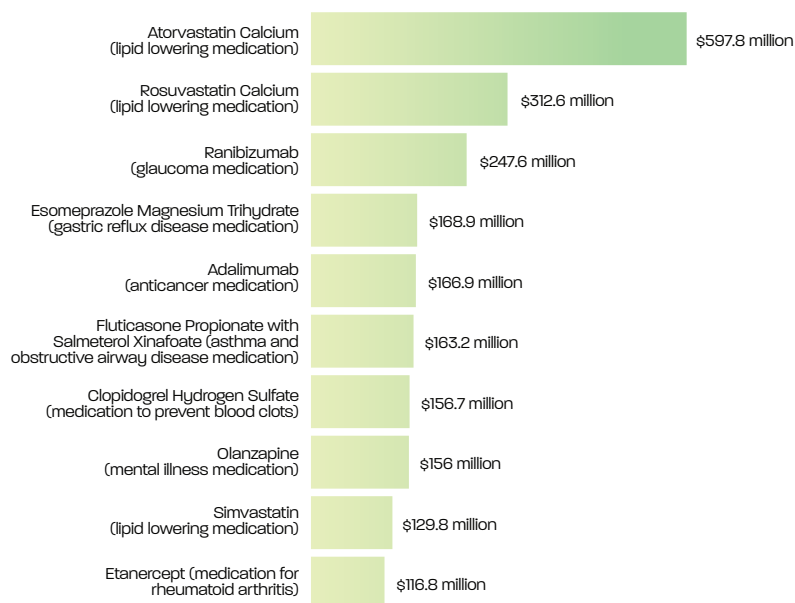
THE PHARMACEUTICAL BENEFITS SCHEME

- The drug utilisation reflects the burden of disease in Australia. Cardiovascular, glaucoma, gastric ulcers, anti-cancer, asthma and medication to prevent blood clots are among the most prescribed drugs in Australia.

38

FIGURE 38 Top 10 PBS medicines by Government cost (section 85)

Source: Department of Health and Ageing, Expenditure and prescriptions twelve months to 30 June, 2011



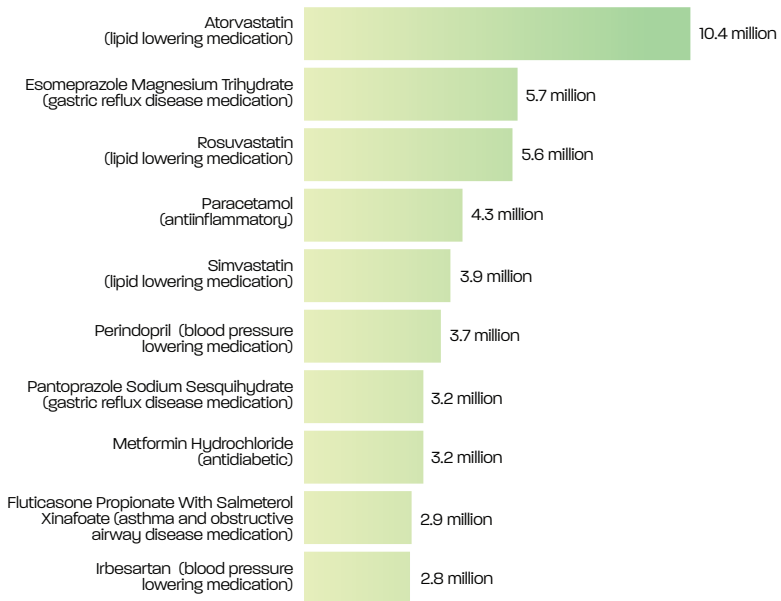
THE PHARMACEUTICAL BENEFITS SCHEME

- Blood pressure and lipid lowering medicines were among the most used medicines in Australia.

39

FIGURE 39 Highest volume PBS medications (section 85 only), number of benefits paid scripts

Source: Department of Health and Ageing, Expenditure and prescriptions twelve months to 30 June, 2011



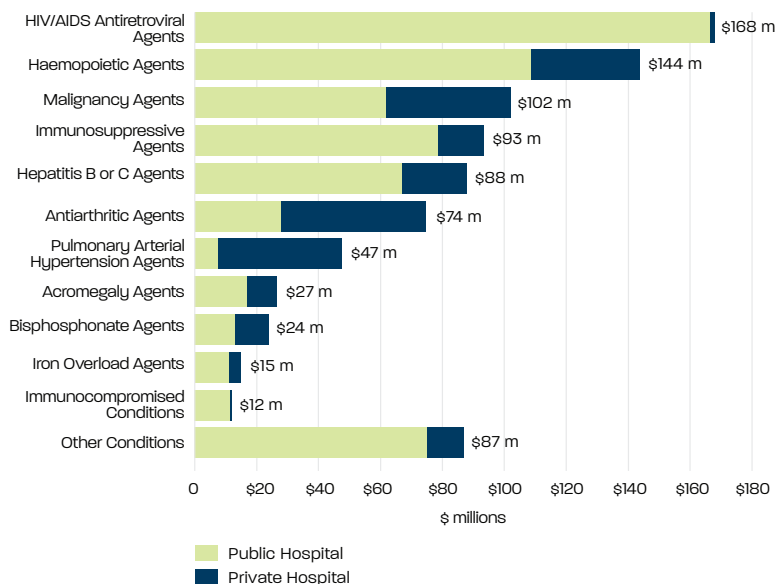
THE PHARMACEUTICAL BENEFITS SCHEME

- In the year to June 30, 2010 the Highly Specialised Drugs program grew by \$105 million or 14% to \$880 million. Five new medicines were added to the existing 83 drugs in 2009-10.

40

FIGURE 40 Expenditure on highly specialised medicines in 2009-10

Source: Pharmaceutical Benefits Pricing Authority, Annual report 2009-10, Government expenditure on highly specialised drugs program



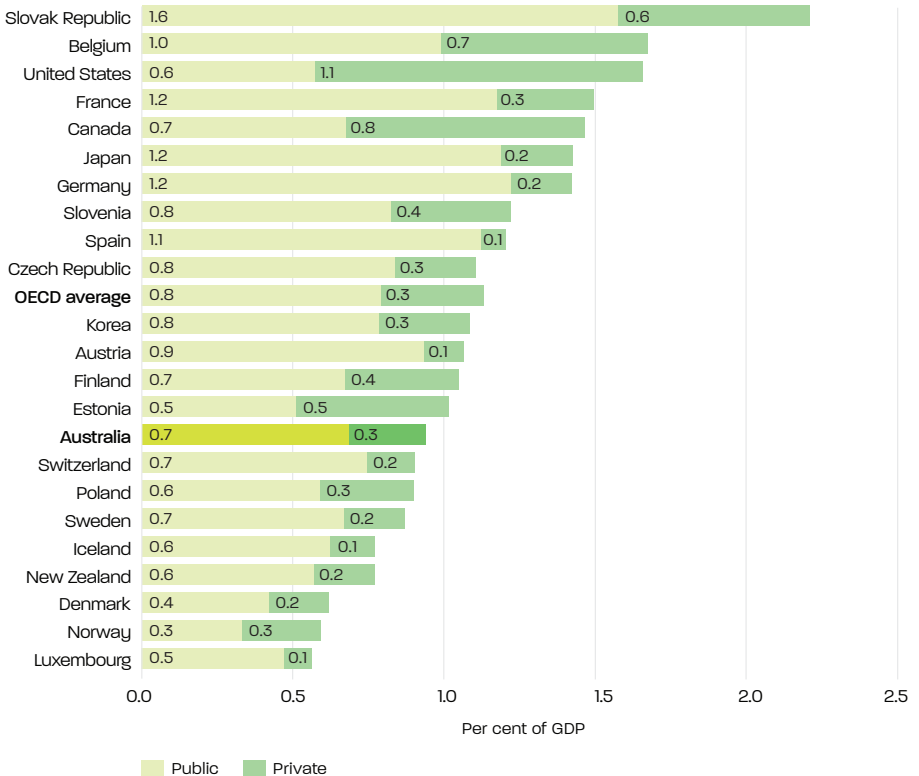
THE PHARMACEUTICAL BENEFITS SCHEME

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

41

FIGURE 41 **Total pharmaceutical expenditure as a proportion of GDP in 2008**

Source OECD Health Statistics 2011, 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 diseases 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.

MEDICINES INDUSTRY GLOBALLY

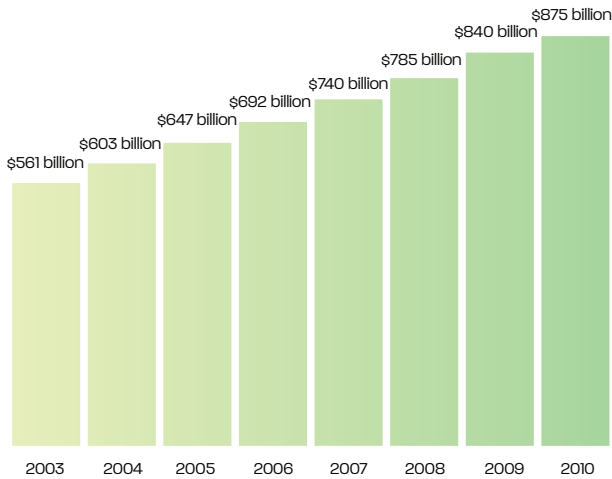
- In 2010, the overall world medicines market was worth USD \$875 billion.

42

FIGURE 4.2 World medicines market (2003-2010)

Source: IMS Health Market Prognosis, March 2011.

Includes IMS Audited and Unaudited markets, constant US\$ uses Qtr 4, 2010 average exchange rates



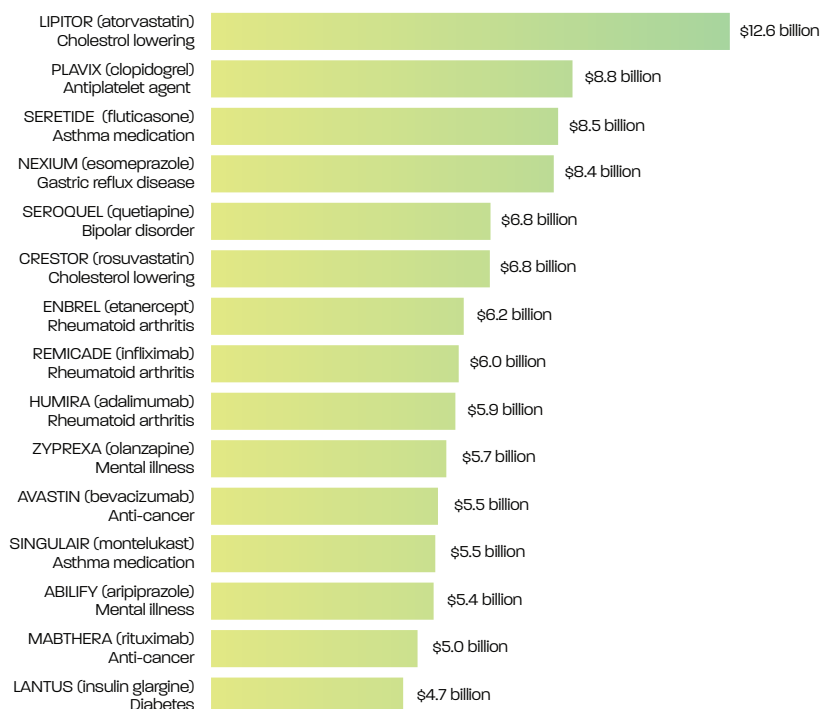
MEDICINES INDUSTRY GLOBALLY

- The top four selling medicines in the world in 2010 were a cholesterol-lowering medication (Lipitor), a blood clot inhibitor (Plavix), a medicine to treat asthma (Seretide) and a medicine to treat gastric reflux (Nexium).

43

FIGURE 4.3 Top 15 medicines by sales globally

Source: IMS Health Market Prognosis, March 2011. Includes IMS Audited and Unaudited markets, figures are in US dollars



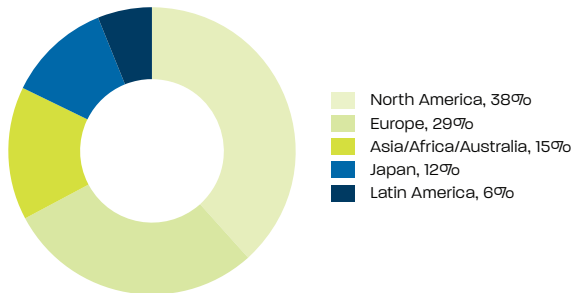
MEDICINES INDUSTRY GLOBALLY

- North America and Europe together make up 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 1.3 per cent of the total world market for medicines.

44

FIGURE 44 **World medicines market by regions**

Source: IMS Health Market Prognosis, March 2011. Includes IMS Audited and Unaudited markets



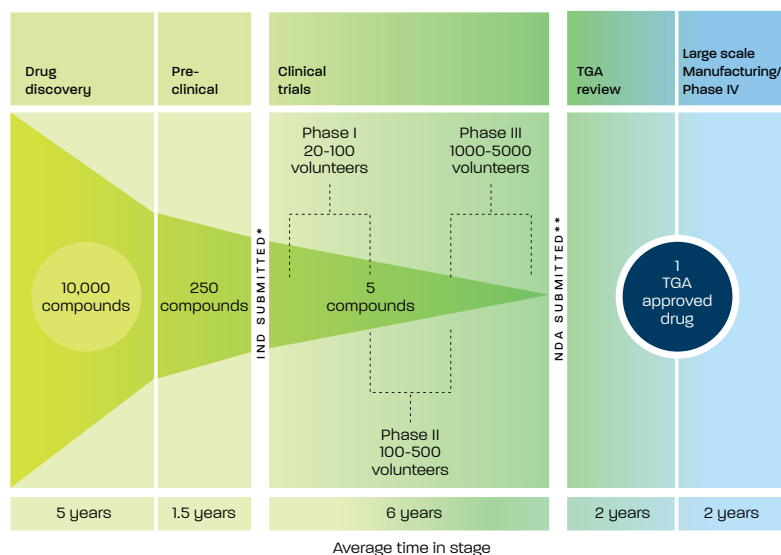
MEDICINES INDUSTRY GLOBALLY

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

45

FIGURE 45 Journey of medicines—from discovery to market

Source: Pharmaceutical Research and Manufacturers of America, 2011 profile, Research and Development Process, Figure 4, pg 12



*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)

MEDICINES INDUSTRY GLOBALLY

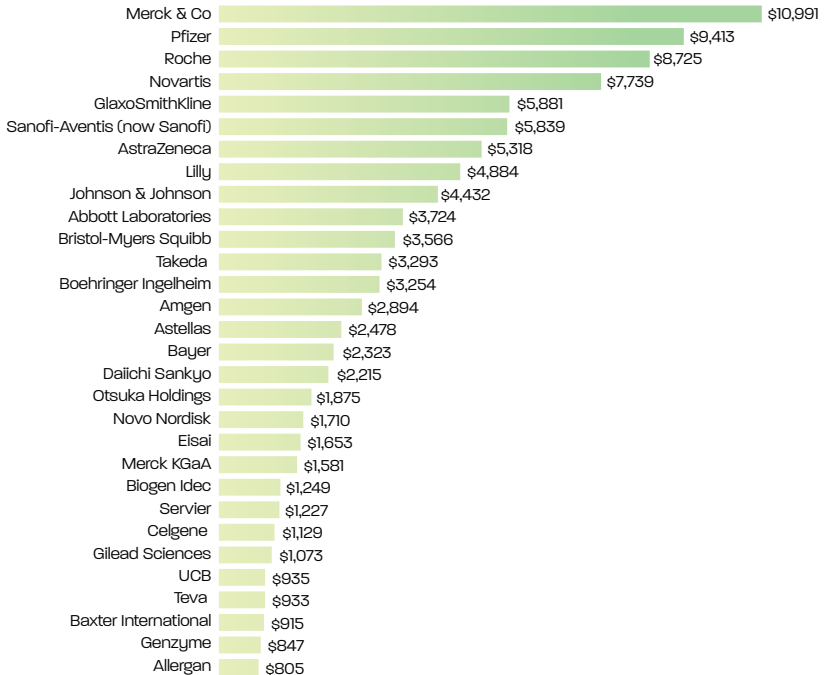
- In 2010 the global industry invested in excess of US\$100 billion in medicines R&D.

46

FIGURE 46 **Top 30 global investors in medicines R&D in 2010, in US\$ millions**

Source: Scrip's Pharmaceutical Company League Tables 2010

2010 Pharma R&D Spend (\$m)



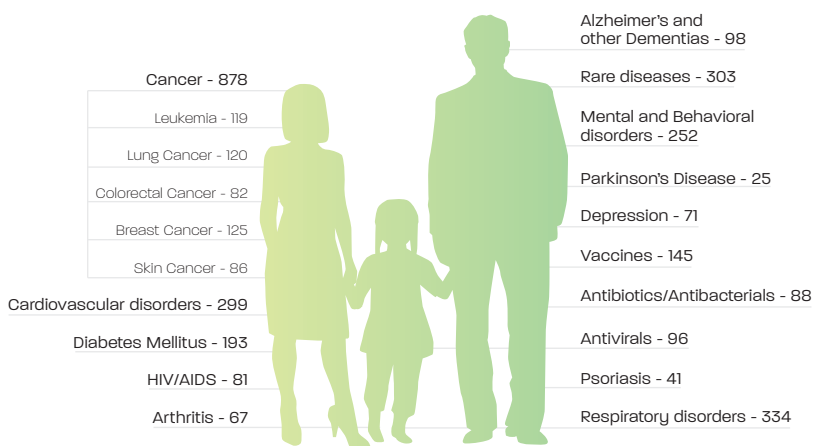
MEDICINES INDUSTRY GLOBALLY

- In 2011, there were over 3,050 medicines under development for various illnesses.

47

FIGURE 47 Medicines in development

Source: Pharmaceutical research and manufacturers of America, Medicines in Development, available at <http://www.phrma.org/research/new-medicines>



MEDICINES AUSTRALIA MEMBERSHIP IN 2011

| | |
|--|--|
| Abbott Australasia Pty Ltd | IQnovate Ltd |
| Actelion Pharmaceuticals Australia Pty Ltd | Iris Interactive Pty Ltd |
| Allergan Australia Pty Ltd | Janssen Pty Ltd |
| Amgen Australia Pty Ltd | Kendle Pty Ltd |
| Andrew's Refrigerated Transport | KMC Health Care |
| Astellas Pharma Australia | Leo Pharma |
| AstraZeneca Pty Ltd | Lundbeck Australia Pty Ltd |
| Baxter Healthcare Pty Ltd | Merck Serono Australia Pty Ltd |
| Bayer Australia Limited | MSD (Australia) Pty Ltd |
| Biogen Idec Australia Pty Ltd | Mundipharma Pty Ltd |
| Boehringer Ingelheim Pty Ltd | Norgine Pty Ltd |
| Bristol-Myers Squibb Australia Pty Ltd | Novartis Pharmaceuticals |
| Celgene Pty Limited | Novo Nordisk Pharmaceuticals Pty Ltd- Australia |
| Commercial Eyes Pty Ltd | Nycomed Pty Ltd |
| Covance Pty Ltd | Pfizer Australia Pty Ltd |
| CSL Limited | Pretium Pty Ltd |
| Eli Lilly Australia Pty Ltd | PriceWaterhouseCoopers |
| FIT-BioCeuticals Ltd | Princeton Publishing Pty Ltd |
| Fresenius Kabi Australia Pty Ltd | Quintiles Pty Ltd |
| Genzyme Australasia Pty Ltd | Roche |
| Gilead Sciences Pty Ltd | Sanofi |
| GlaxoSmithKline Australia Pty Ltd | Servier Laboratories (Aust) Pty Ltd |
| IDT Australia Limited | Shire Australia Pty Limited |
| IMS Health Australia Pty Ltd | Smith & Nephew Pty Ltd |
| iNova Pharmaceuticals Pty Ltd | UCB Australia Pty Ltd |
| Invida | Vifor Pharma Pty Ltd |
| Ipsen Pty Ltd | |

