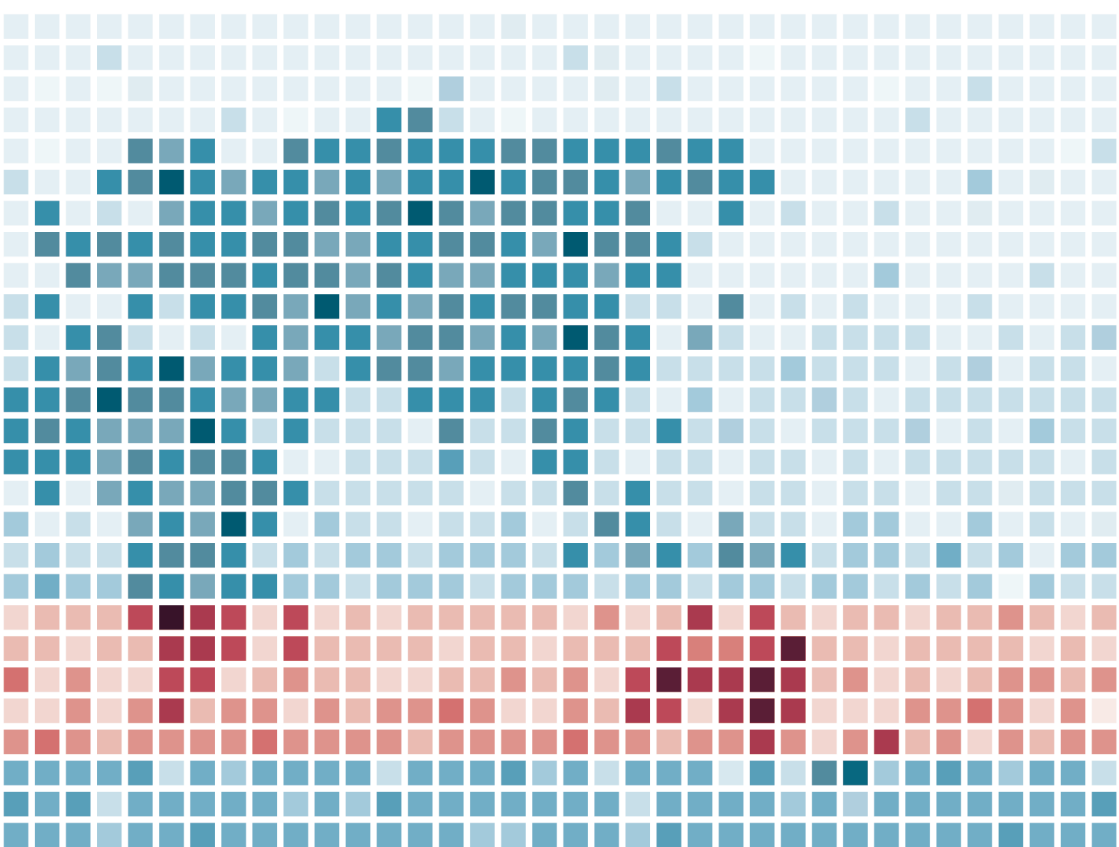


MEDICINES AUSTRALIA
→ FactsBook 1 FIRST EDITION



MEDICINES
Australia

MEDICINES AUSTRALIA → FactsBook ① FIRST EDITION

INTRODUCTION

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

This edition, published in December 2009, includes the most recent available data on aspects of the Australian and international pharmaceutical industry.

Its purpose is to provide a handy statistical guide to the industry for government, media, researchers, students and anyone interested in the pharmaceutical industry in Australia. The publication is also available on the Medicines Australia (MA) website at www.medicinesaustralia.com.au

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

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ABOUT MEDICINES AUSTRALIA

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Our member companies comprise more than 80 percent of the prescription pharmaceuticals 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 pharmaceutical industry provides benefits to both Australians' health and the health of the economy. It is a high technology, knowledge-intensive sector which invests around \$860 million in research and development each year. The innovative arm of the industry directly employs over 14,000 people in Australia. In 2007–08, Australian pharmaceutical manufacturing 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 Pharmaceuticals Benefits Scheme) and ensuring the continuation of a viable pharmaceutical industry
- administering the Medicines Australia Code of Conduct which sets the standard for the ethical marketing and promotion of prescription medicines
- working along with other health professional and consumer organisations to address issues of mutual concern.

AUSTRALIA: THE DEMOGRAPHICS

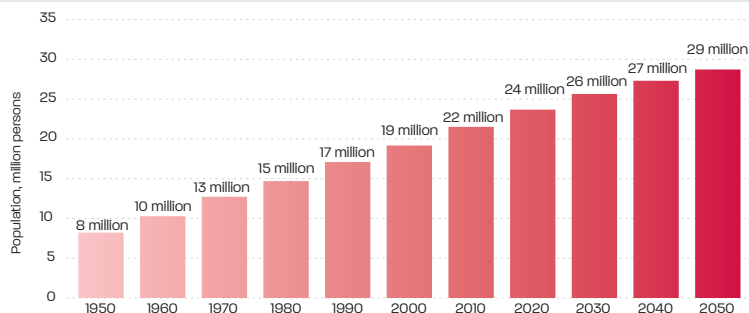
- By 2050, Australia's population is expected to grow by 5 million (an increase of nearly 25% on current numbers) and the proportion aged 75 years or older will have more than doubled (constituting 13.6% of the total population).

Ageing populations place considerable strain on health systems. Improvements in medicines, along with life-style improvements, will do much to ease that strain.

01

FIGURE 1 Australia: total projected population growth

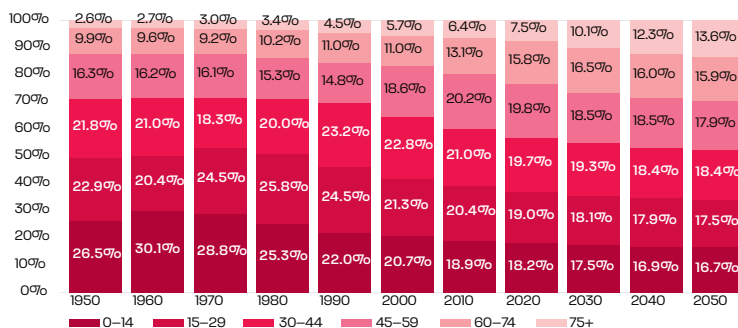
SOURCE: Department of Economic and Social Affairs of the United Nations Secretariat, *World Population Prospects: The 2008 Revision*. Available at: <http://www.un.org/esa/population/unpop.htm>



02

FIGURE 2 Australia: projected population growth by age group

SOURCE: Department of Economic and Social Affairs of the United Nations Secretariat, *World Population Prospects: The 2008 Revision*. Available at: <http://www.un.org/esa/population/unpop.htm>



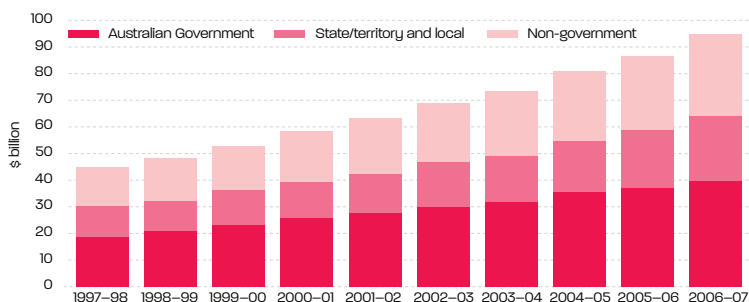
HEALTH EXPENDITURE

- In 2006–07, Australia's total health expenditure was \$94 billion and Australia ranked close to the OECD average on health expenditure as a proportion of GDP.

03

FIGURE 3 **Total health expenditure: 1997–2007**

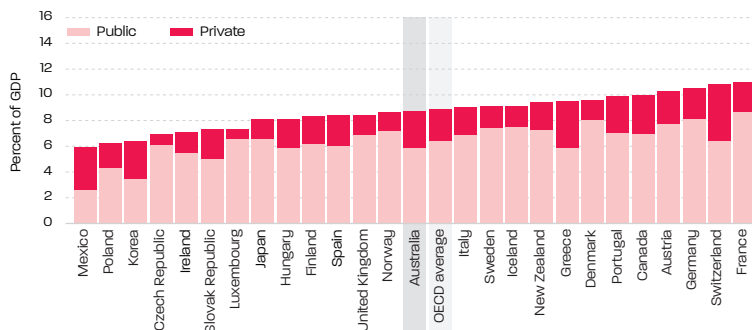
SOURCE: Australian Institute of Health and Welfare, *Health expenditure Australia 2007–08*, Table 3.1 2009



04

FIGURE 4 **Total health expenditure as proportion of GDP (%) in 2006**

SOURCE: OECD Health data 2009, OECD 2009



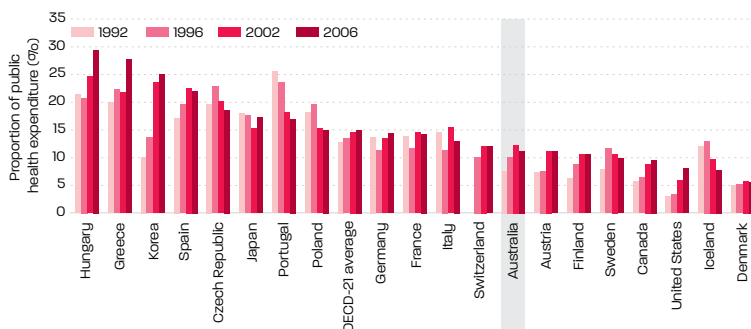
HEALTH EXPENDITURE

- Australian Government pharmaceutical expenditure as a proportion of its health expenditure is below the OECD average and Government expenditure on the Pharmaceutical Benefits Scheme in the decade to 2008 remained between 0.5 % and 0.7 % of GDP.

05

FIGURE 5 Public pharmaceutical expenditure as a proportion of public expenditure on health

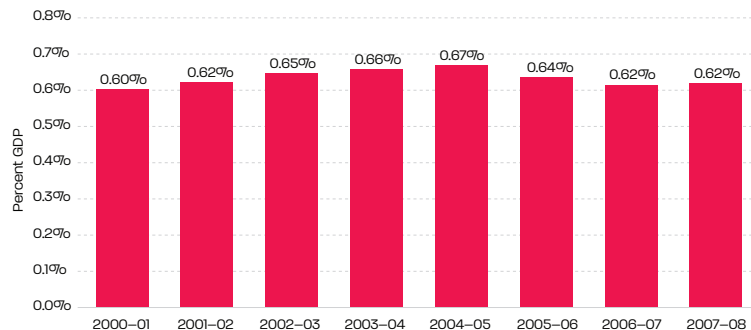
SOURCE: OECD HEALTH DATA 2009, June 09



06

FIGURE 6 Pharmaceutical Benefits Scheme as a proportion of Australian GDP (%), 1998–2008

SOURCE: Australian Bureau of Statistics, Australian National Accounts, Series 5206, PBS Expenditure data, Department of Health and Ageing Annual Reports 1998–99 to 2007–08



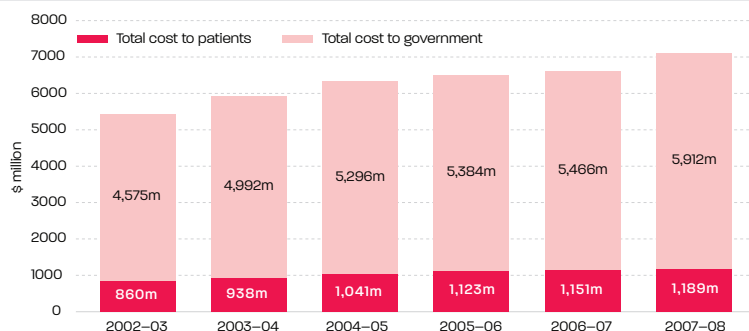
HEALTH EXPENDITURE

- The Australian Government contributed 83% of the cost of the Pharmaceutical Benefits Scheme listed medicines in 2007–08.

07

FIGURE 7 Pharmaceutical Benefits Scheme: Australian Government and patients' contributions, current prices, 2002–03 to 2007–08

SOURCE: Australian Institute of Health and Welfare, *Health expenditure Australia 2007–08*, Table 4.18, 2009



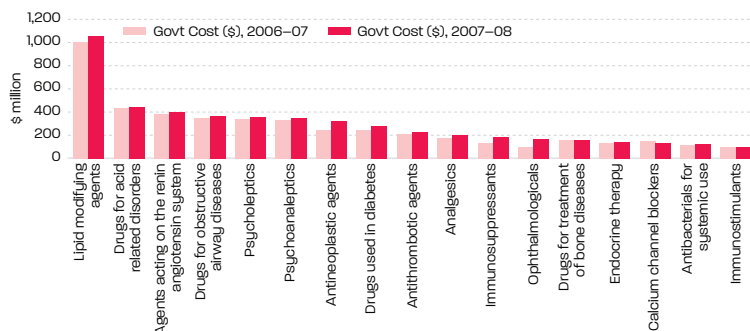
HEALTH EXPENDITURE

- In comparison to 2006–07, there was a rise in both the cost and the number of scripts issued across most significant Pharmaceutical Benefits Scheme listed drug groups in 2007–08.

08

FIGURE 8 Significant drug groups on the Pharmaceutical Benefits Scheme a. By Government cost

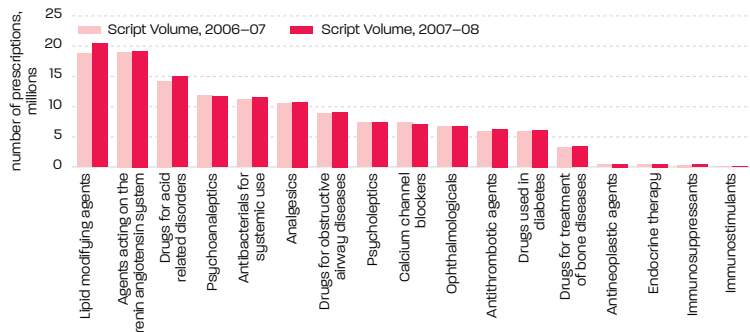
SOURCE: Department of Health and Ageing, *Pharmaceutical Benefits Pricing Authority Annual Report, 2007–08*



09

FIGURE 9 Significant drug groups on the Pharmaceutical Benefits Scheme b. By script volume

SOURCE: Department of Health and Ageing, *Pharmaceutical Benefits Pricing Authority Annual Report, 2007–08*



HEALTH EXPENDITURE

→ Millions of Australians rely on the Pharmaceutical Benefits Scheme listed medicines for their health and wellbeing.

10

TABLE 10 **Significant drug groups on the Pharmaceutical Benefits Scheme: Top 10 dispensed medicines, 2007–08**

SOURCE: Department of Health and Ageing, *Expenditure and prescriptions, twelve months to 30 June 2008*

RANK	DRUG	NUMBER OF PRESCRIPTIONS	USE
1	ATORVASTATIN CALCIUM	9,866,405	Lipid modifying agent
2	ESOMEPRAZOLE MAGNESIUM TRIHYDRATE	4,780,929	Drugs for acid related disorders
3	SIMVASTATIN	5,354,876	Lipid modifying agent
4	ATENOLOL	2,969,778	Antihypertensive
5	PANTOPRAZOLE SODIUM SESQUIHYDRATE	2,868,405	Drugs for acid related disorders
6	CLOPIDOGREL HYDROGEN SULFATE	2,309,279	Antithrombotic agent
7	SALBUTAMOL SULFATE	2,608,019	Drug for obstructive airway diseases
8	TEMAZEPAM	1,834,417	Hypnotic and sedative
9	CEPHALEXIN	2,113,671	Antibacterial for systemic use
10	IRBESARTAN with HYDROCHLOROTHIAZIDE	2,245,601	Antihypertensive and diuretic

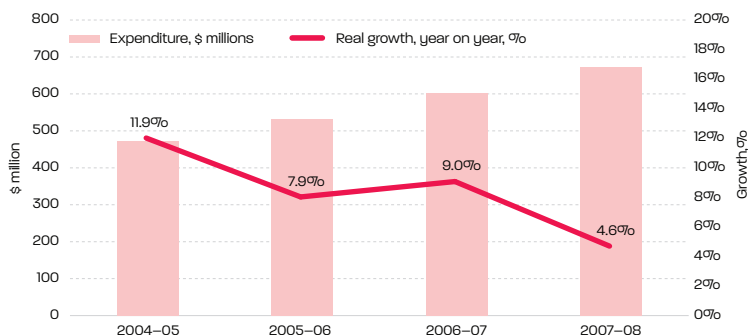
HEALTH EXPENDITURE

- A Highly Specialised Drug (HSD) is a medicine for the treatment of chronic conditions that, due to its clinical use or other special features, is restricted to supply through public and private hospitals with access to appropriate specialist facilities.
- In 2007–08, Australia's pharmaceutical expenditure on highly specialised drugs grew by 4.6% in real terms.

11

FIGURE 11 Significant drug groups on the Pharmaceutical Benefits Scheme: Government expenditure on Highly Specialised Drugs Program

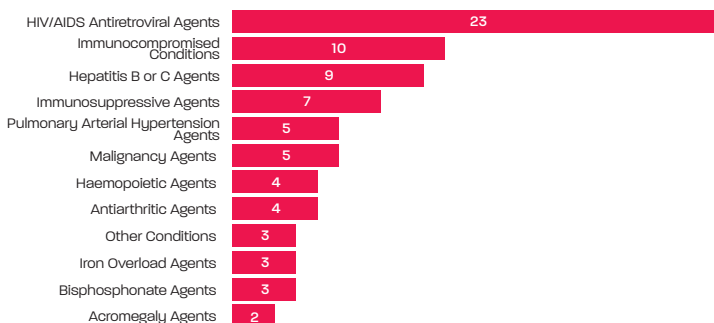
SOURCE: Department of Health and Ageing, *Annual Reports various years*



12

FIGURE 12 Number of drugs on Highly Specialised Drugs Program in 2007–08: categorised by indication

SOURCE: Department of Health and Ageing, *Pharmaceutical Benefits Pricing Authority Annual Report, 2007–08*



HEALTH EXPENDITURE

- In 2007–08, at least nine new molecules were made available to patients in Australia through the Pharmaceutical Benefits Scheme and a further eight were approved for treatment of new medical conditions (extended listings).

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TABLE 13 Key Pharmaceutical Benefits Scheme listings in 2007–08

NEW MOLECULES

<i>Strattera®</i>	(Atomoxetine, Eli Lilly, ADHD)
<i>Lucentis®</i>	(Ranibizumab, Novartis, Macular degeneration)
<i>Sprycel®</i>	(Dasatinib, Bristol-Myers Squibb, Chronic myeloid leukaemia)
<i>Aptivus®</i>	(Tiplranavir, Boehringer Ingelheim, HIV)
<i>Apidra®</i>	(Insulin analogue, Aventis Pharma, Diabetes)
<i>Mabthera®</i>	(Rituximab, Roche, Rheumatoid arthritis)
<i>Renagel®</i>	(Sevelamer, Genzyme, Chronic kidney disease)
<i>Champix®</i>	(Varenicline, Pfizer, Smoking cessation)
<i>Tykerb®</i>	(Lapatinib, GlaxoSmithKline, Breast cancer)

NEW EXTENDED LISTINGS

<i>Ezetrol®</i>	(Ezetimibe, Merck Sharp & Dohme, Lipid lowering drug)
<i>Mirena®</i>	(Levonorgestral, Schering Plough, Contraceptive)
<i>Arava®</i>	(Leflunomide, Aventis Pharma, Arthritis)
<i>Femara®</i>	(Letrozole, Novartis, Breast cancer)
<i>Taxotere®</i>	(Docetaxel, Sanofi-Aventis, Anti-cancer)
<i>Remicade®</i>	(Infliximab, Schering Plough, Crohn's disease)
<i>Alimta®</i>	(Pemetrexed disodium, Eli Lilly, Non-small cell lung cancer)
<i>Actos®</i>	(Pioglitazone, Eli Lilly, Type 2 Diabetes)

HEALTH EXPENDITURE

→ 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.

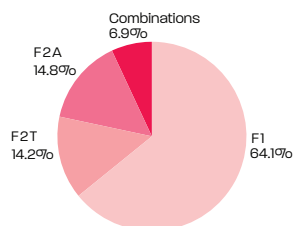
14

FIGURE 14 Pharmaceutical Benefits Scheme formularies 2007–08 (post Pharmaceutical Benefits Scheme reforms implementation)

SOURCE: Centre for Strategic Economic Studies, Victoria University

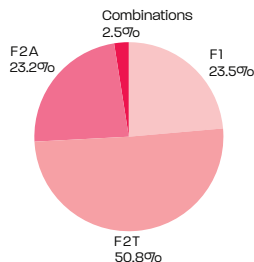
Number of molecules

Total molecules: 696



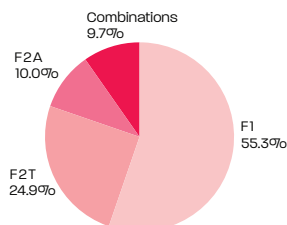
Number of brands

Total brands: 1907



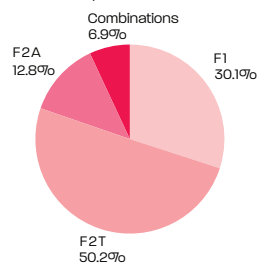
Government Expenditure

Total Expenditure: \$7 billion



Number of prescriptions

Total Prescriptions: 170.96 million



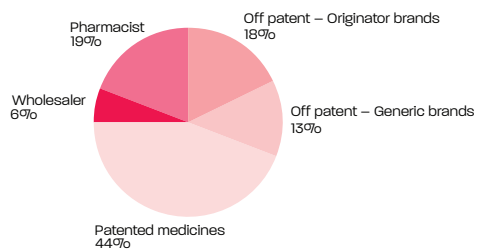
HEALTH EXPENDITURE

- In 2007–08 innovative medicines under patent consisted 44% of Pharmaceutical Benefits Scheme expenditure, while off-patent medicines accounted for 31% of expenditure.

15

FIGURE 15 Share of Pharmaceutical Benefits Scheme expenditure by supplier groups, 2007–08

SOURCE: Unpublished data, Centre for Strategic Economic Studies, Victoria University, 2008



NOTE: estimates based on 2007–08 expenditure and prescription data from the Department of Health and Ageing. Includes highly specialised drugs (HSD) dispensed through hospitals and patient contributions.

HEALTH EXPENDITURE

- In 2008, 68% of all multi branded and therapeutically interchangeable brands on the Pharmaceutical Benefits Scheme were sold at benchmark prices.

16

TABLE 16 Brand premium on the Pharmaceutical Benefits Scheme

SOURCE: Department of Health and Ageing, *Pharmaceutical Benefits Pricing Authority Annual Reports, various years*

	2000	2001	2002	2003	2004	2005	2006	2007	2008
Number of products with a premium	253	297	293	303	323	335	345	360	353
Average brand premium	\$2.12	\$2.20	\$2.83	\$2.94	\$2.85	\$2.78	\$2.76	\$2.88	\$3.03
Weighted average brand premium	\$1.45	\$1.68	\$1.57	\$1.57	\$1.89	\$1.77	\$1.76	\$1.83	\$2.17
Brand premium range	\$0.23 to \$43.28	\$0.01 to \$45.33	\$0.01 to \$79.48	\$0.06 to \$79.48	\$0.06 to \$79.48	\$0.06 to \$79.48	\$0.06 to \$79.48	\$0.09 to \$76.86	\$0.08 to \$76.86
Prescriptions dispensed with a brand premium during the year (million)	33.4m	33.4m	33.3m	32.6m	28.5m	30m	30.1m	27.9m	25.2m
Prescriptions dispensed at the benchmark level during the year (million)	26.3m	29.4m	22.6m	37.8m	43.1m	50.5m	51.9m	52.7m	53m
Percentage at the benchmark level	44%	47%	49%	54%	60%	63%	63%	65%	68%
Products at the benchmark price	434	766	854	943	979	996	1014	1089	1183

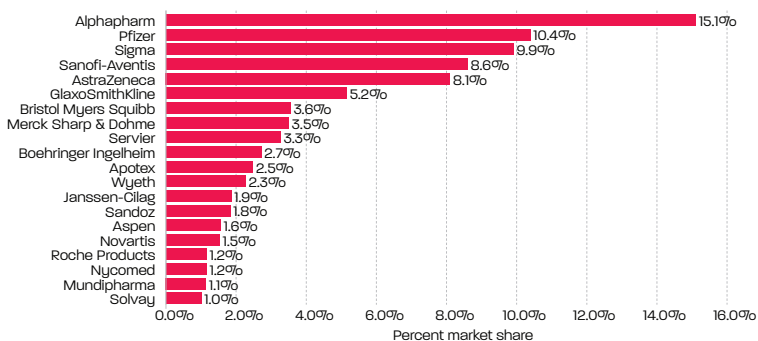
HEALTH EXPENDITURE

- In 2007–08, the generics manufacturer Alphapharm was the biggest supplier to the Pharmaceutical Benefits Scheme by script volume.

17

**FIGURE 17 Top 20 companies on Pharmaceutical Benefit Scheme: 2007–08
a. By script volume**

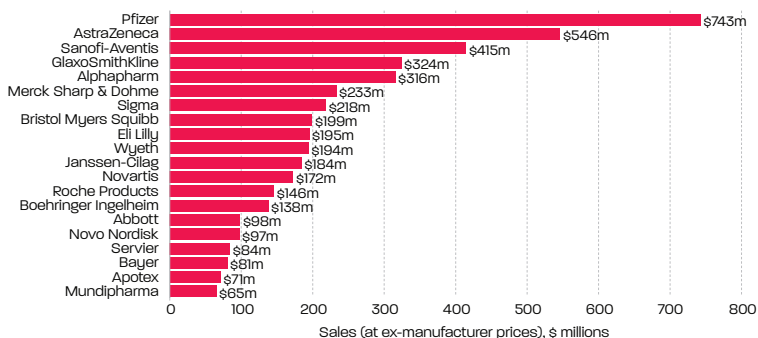
SOURCE: Department of Health and Ageing, *Pharmaceutical Benefits Pricing Authority Annual Report, 2007–08*



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**FIGURE 18 Top 20 companies on Pharmaceutical Benefit Scheme: 2007–08
b. By sales (at ex-manufacture prices)**

SOURCE: Department of Health and Ageing, *Pharmaceutical Benefits Pricing Authority Annual Report, 2007–08*



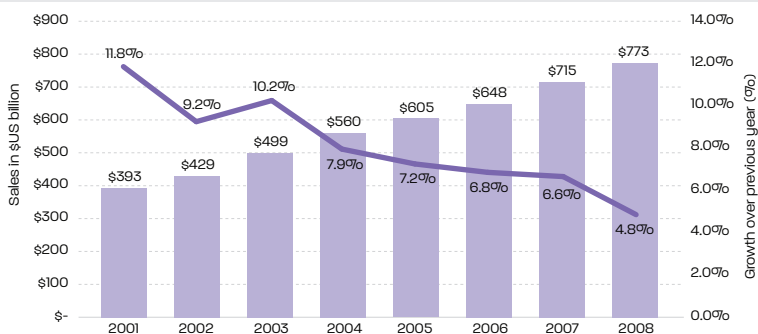
INDUSTRY STATISTICS: GLOBAL

→ In 2008, US\$773 billion worth of medicines were sold globally.

19

FIGURE 19 Global sales and growth, 2001–2008

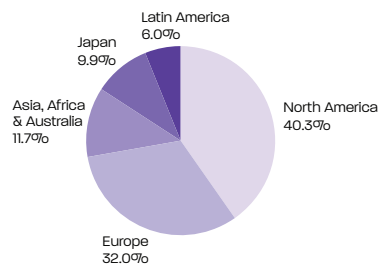
SOURCE: IMS Health, *IMS Health Market Prognosis March 2009* (includes IMS audited and unaudited markets)



20

FIGURE 20 Global market by region in 2008

SOURCE: IMS Health, *Market Prognosis March 2009* (includes IMS audited and unaudited markets)



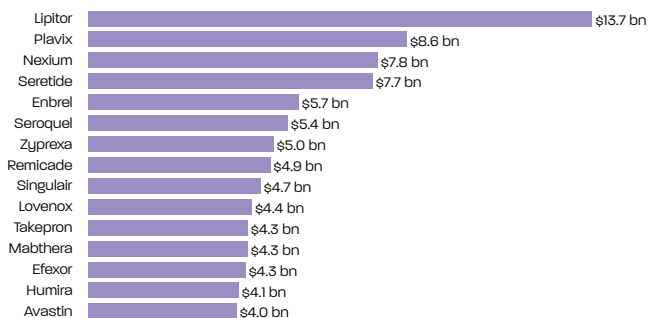
INDUSTRY STATISTICS: GLOBAL

- The top four selling medicines in the world in 2008 were a cholesterol-lowering medication (Lipitor), a blood clot inhibitor (Plavix), a medicine to treat gastric reflux (Nexium) and a medicine to treat asthma (Seretide).

21

FIGURE 21 Top 15 global products (by sales value, US\$, billions)

SOURCE: IMS Health, *IMS Health Market Prognosis, March 2009* (includes IMS audited and unaudited markets)



INDUSTRY STATISTICS: GLOBAL

→ In 2008, an estimated US\$65 billion was spent on research and development (R&D) worldwide.

22

FIGURE 22 Global industry expenditure on research & development

SOURCE: Pharmaceutical Research and Manufacturers of America (PhRMA), *Pharmaceutical Industry Profile 2009*
Available at: www.phrma.org



NOTE: 2008 global R&D figures are estimates

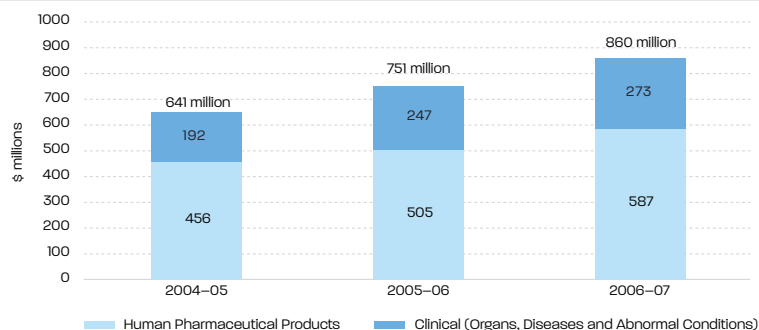
AUSTRALIAN PHARMACEUTICALS INDUSTRY

→ In 2006–07, the Australian pharmaceuticals industry invested \$860 million in research and development.

23

FIGURE 23 Pharmaceutical research & development in Australia

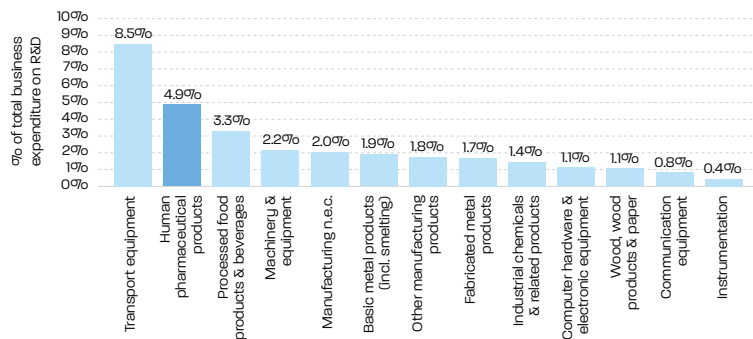
SOURCE: Australian Bureau of Statistics, *Business Expenditure on Research and Development*, Catalogue 8104, unpublished data, 2008



24

FIGURE 24 Manufacturing industry's contribution to Australian business expenditure on research & development in 2006–07

SOURCE: Australian Bureau of Statistics, *Business Expenditure on Research and Development*, Catalogue 8104, 2008



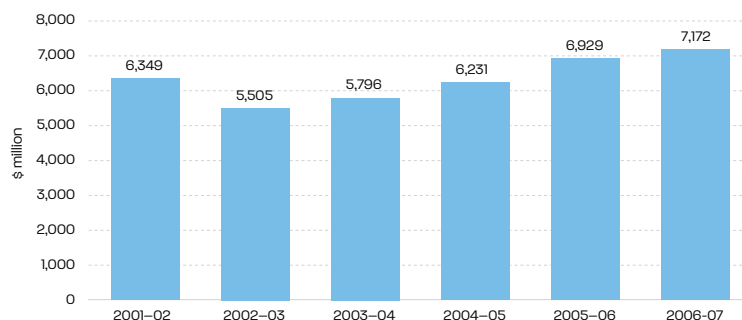
AUSTRALIAN PHARMACEUTICALS INDUSTRY

→ In 2006–07, Australian pharmaceutical manufacturing contributed over \$7 billion to the economy and more than 14,000 jobs.

25

FIGURE 25 Pharmaceuticals sales and service income

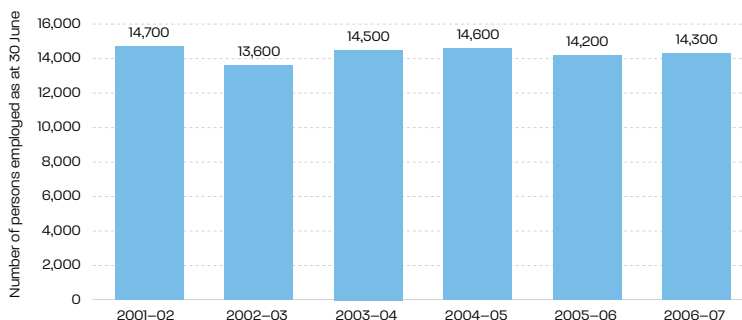
SOURCE: Australian Bureau of Statistics, Catalogue 8221, *Manufacturing Industry, Australia, 2006–07*, August 2008



26

FIGURE 26 Employment in pharmaceuticals manufacturing

SOURCE: Australian Bureau of Statistics, Catalogue 8221, *Manufacturing Industry, Australia, 2006–07*, August 2008



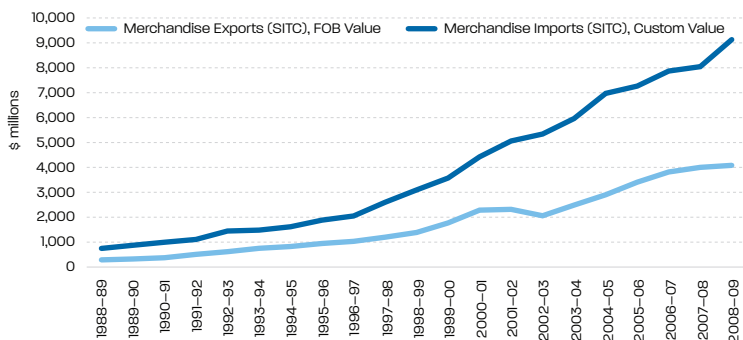
AUSTRALIAN PHARMACEUTICALS INDUSTRY

→ In 2008–09, the Australian medicinal and pharmaceuticals sector contributed over \$4 billion in exports earnings and overtook road vehicles as the largest manufactured export sector.

27

FIGURE 27 Medicinal and pharmaceuticals trade, by financial years: 1988–89 to 2008–09

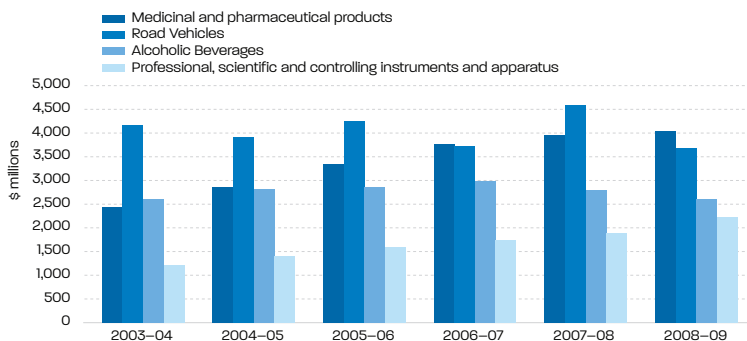
SOURCE: Australian Bureau of Statistics, Catalogue 5388.0, *International Trade in Goods and Services, Australia 2008–09*, July 2009; SITC: Standard International Trade Classification



28

FIGURE 28 Medicinal and pharmaceuticals exports vs other manufactured exports

SOURCE: Australian Bureau of Statistics, Catalogue 5388.0, *International Trade in Goods and Services, Australia 2007–08*, September 2009



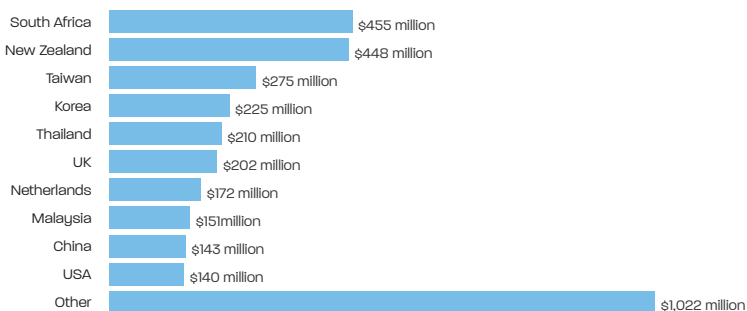
AUSTRALIAN PHARMACEUTICALS INDUSTRY

→ In 2007, South Africa and New Zealand were the two key markets for Australian pharmaceuticals exports.

29

FIGURE 29 Key markets for Australian exports in 2007

SOURCE: Australian Bureau of Statistics, Catalogue 5368.0, *International Trade in Goods and Services*, unpublished data, 2007



AUSTRALIAN PHARMACEUTICALS INDUSTRY

→ In 2007, the market cap of listed Australian biotechs was \$25 billion.

30

TABLE 30 Biotechnology Industry in Australia: At a glance

SOURCE: Australian Biotechnology Sector Fact Sheet, available at <http://www.innovation.gov.au/Section/AboutDIISR/FactSheets/Pages/AustralianBiotechnologySectorFactSheet.aspx>

	2006	2007
Number of biotechs	449	470
Number of ASX listed biotechs	72	75
Market Cap of listed biotechs (including CSL) (A\$bn)	16.7	24.9
Employment in listed biotechs	8,350	8,820
Overall employment in Biotech sector	14,189	N/A
Major exports	Intellectual Property, through licensing deals with large, international pharmaceutical and biotechnology companies.	
Australia's largest biotechnology company in 2008	CSL (market cap A\$ 19.3bn)	

AUSTRALIAN PHARMACEUTICALS INDUSTRY

→ In 2007, the generics medicines industry provided nearly 5,000 jobs and the top eight companies made \$928 million in sales.

31

TABLE 31 Generics medicines industry in Australia, 2007: At a glance

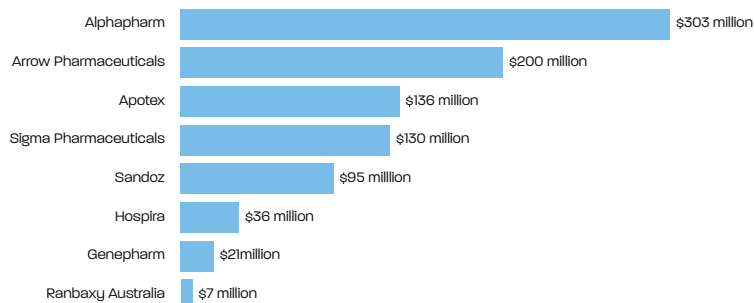
SOURCE: Generic Medicines Industry Association (GMIA). Available at: <http://www.gmia.com.au/>

Employment in Generics manufacturing	1,700
Overall employment in Generics Medicines Industry	5,000
Key export destinations	Asia, Europe, Canada, USA and New Zealand

32

FIGURE 32 Leading generics medicines companies' sales: 2008

SOURCE: IMS Health, *Australian Pharmaceuticals Index*, Ethical sales—12 months to Dec 2008 (MAT)



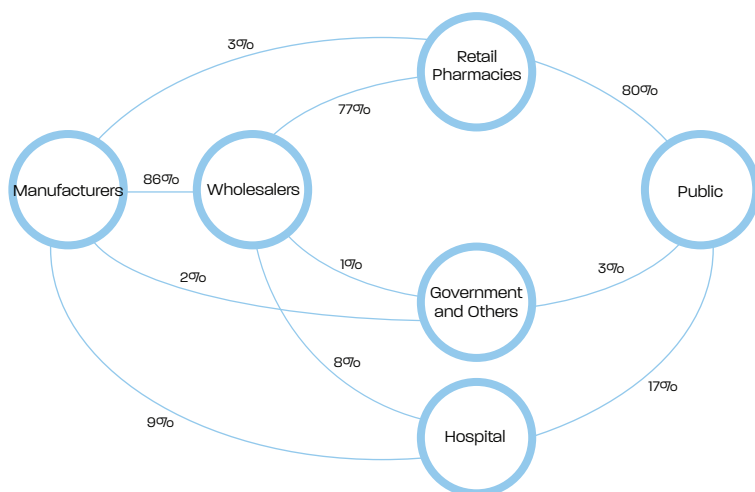
AUSTRALIAN PHARMACEUTICALS INDUSTRY

- Full line wholesalers are required to supply all medicines listed on the Pharmaceutical Benefits Scheme within a reasonable timeframe. Short line wholesalers carry a more selective range of medicines.
- The three full line wholesalers dominate nearly 90% distribution to point of sale. The remainder is split between short line wholesalers and direct manufacturer supply. With respect to hospitals, direct supply from manufacturers accounts for a little over a half of hospital pharmaceutical purchases.

33

FIGURE 33 Distribution of pharmaceuticals in Australia

SOURCE: IMS Health, *Australian Pharmaceutical Index, 2008*



NOTE: This schematic illustrates the distribution of pharmaceutical products in Australia. Variations will occur by individual manufacturers and therapy groups.

AUSTRALIAN PHARMACEUTICALS INDUSTRY

- In 2008–09, the community pharmacy sector had an annual turnover of \$12 billion.

34

TABLE 34 **Wholesalers in Australia**

CURRENT FULL LINE WHOLESALERS IN AUSTRALIA:

- Australian Pharmaceutical Industries
- Sigma Pharmaceuticals limited
- Symbion Pharmacy services

NON FULL LINE WHOLESALERS/SHORT LINE WHOLESALERS:

- Central Hospital supplies
- Barretts wholesale distributors
- Clifford Hallam Healthcare
- Strategic Western Australia Pharmacy Supplies
- National Pharmacies
- DHL Pharmacy Supply

35

TABLE 35 **Community pharmacy: At a glance**

SOURCE: Pharmacy Guild of Australia, Kos Sclavos, National President of the Pharmacy Guild of Australia, National Press Club address, 29 July 2009

	2008–09
Number of community pharmacies	5,000
Total employment	73,000
Annual turnover	\$12 billion

MEDICINES AUSTRALIA MEMBERSHIP IN 2009

Abbott Australasia Pty Ltd	KPMG
Actelion Pharmaceuticals Australasia Pty Ltd	Lundbeck Australia Pty Ltd
Alcon Laboratories (Australia) Pty Ltd	Merck Serono Australia Pty Ltd
Allergan Australia Pty Ltd	Merck Sharp & Dohme (Australia) Pty Ltd
Amgen Australia Pty Ltd	Mundipharma Pty Ltd
AstraZeneca Pty Ltd	Norgine Pty Ltd
Baxter Healthcare Pty Ltd	Novartis Pharmaceuticals Australia Pty Ltd
Bayer Schering Pharma	Novo Nordisk Pharmaceuticals Pty Ltd
Biogen Idec Australia Pty Ltd	Nycomed Pty Ltd
Boehringer Ingelheim Pty Ltd	Pfizer Australia Pty Ltd
Bristol-Myers Squibb Australia Pty Ltd	PharmaLink Pty Ltd (Innovex)
Celgene Pty Ltd	Pretium Pty Ltd
Commercial Eyes Pty Ltd	PricewaterhouseCoopers
Covance Pty Ltd	Princeton Publishing Pty Ltd
CSL Limited	Quintiles Pty Ltd
Eli Lilly Australia Pty Ltd	Roche Products Pty Ltd
Genzyme Australasia Pty Ltd	sanofi-aventis
Gilead Sciences Pty Ltd	Schering-Plough Pty Ltd
GlaxoSmithKline Australia Pty Ltd	Servier Laboratories (Australia) Pty Ltd
IMS Health Australia Pty Ltd	Shire Australia Pty Ltd
iNova Pharmaceuticals Pty Ltd	Smith & Nephew Pty Ltd
Institute of Drug Technology (IDT) Australia Ltd	Solvay Pharmaceuticals Pty Ltd
Ipsen Pty Ltd	Stiefel Laboratories Pty Ltd
Janssen-Cilag Pty Ltd	UCB Pharma
Kendle Pty Ltd	Wyeth Australia Pty Ltd
KMC Health Care	

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FIGURE 2 Australia: projected population growth by age group

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