

compare

COMPARISON OF ACCESS AND REIMBURSEMENT ENVIRONMENTS

> A report benchmarking Australia's access to new medicines

> > Edition 1

compare

Welcome to the first COMPARE report. This report provides information on the current state of access to prescription medicines in Australia and how we compare to 19 similar OECD countries¹.

For very good public health reasons, the Australian Government provides a public insurance scheme that offers universal health care coverage to its citizens. This is underpinned by the availability of prescription medicines provided in a timely manner and at a cost that the Government and the community can afford through the Pharmaceutical Benefits Scheme (PBS).

To understand Australia's access and reimbursement environment in a global context, Medicines Australia commissioned IMS Consulting Group to undertake an independent analysis and report on how Australian patients fare compared to 19 other OECD countries. The countries examined were selected because they have comparable nominal and per capita GDP values to Australia. The analysis also included New Zealand as a regional partner and to respond to recent suggestions that Australia could model its system on that of New Zealand.

The analysis reviewed 247 new medicines² that were first registered in the 20 OECD countries between 1 January 2009 and 30 November 2014. Each successive COMPARE report will add another year's data to develop a longitudinal comparison. We will benchmark Australia's access to new and innovative medicines from this inaugural edition.

We hope you find this a valuable resource and we would welcome your feedback on it.

Dr Martin Cross

Medicines Australia Chairman

Tun James

Tim James

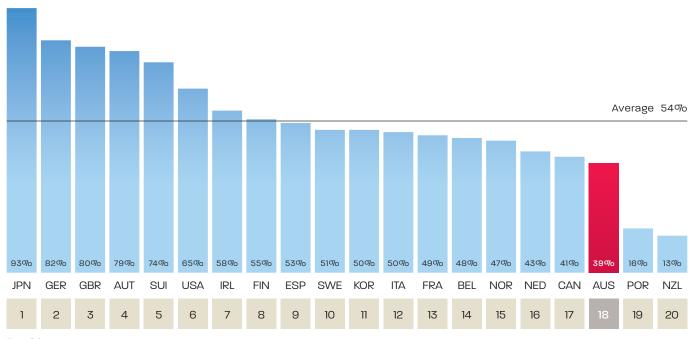
Medicines Australia CFO

¹ Countries included in the report are Australia (AUS), Austria (AUT), Belgium (BEL), Canada (CAN), Finland (FIN), France (FRA), Germany (GER), Ireland (IRL), Italy (ITA), Japan (JPN), Netherlands (NED), New Zealand (NZL), Norway (NOR), Portugal (POR), South Korea (KOR), Spain (ESP), Sweden (SWE), Switzerland (SUI), United Kingdom (GBR), USA (USA).

² New medicines are defined as New Molecular Entities (NMEs). These are innovative pharmaceutical medicines (including biological medicines) that contain a molecule first registered in any of the assessed countries between 1 January 2009 and 30 November 2014.

Australia ranks
18th out of 20
OECD countries
for access to
new medicines

Australians are missing out on reimbursed access to many new registered medicines.



Ranking

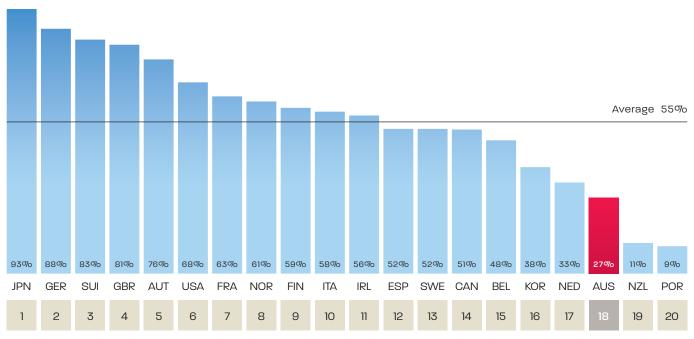
FIGURE 1 Proportion of new medicines reimbursed of those registered in each country, 2009-2014

Only 39 per cent of medicines registered during this period in Australia have been subsequently listed on the PBS.

In Australia, this is all new medicines listed on the PBS as a proportion of those registered and included on the Australian Register of Therapeutic Goods (ARTG).

Australia falls even further behind when it comes to the most innovative medicines

Australia has listed only a quarter of all the possible first-in-class medicines that could be listed on the PBS.



Ranking

FIGURE 2 Proportion of first-in-class medicines reimbursed of those registered in each country, 2009-2014

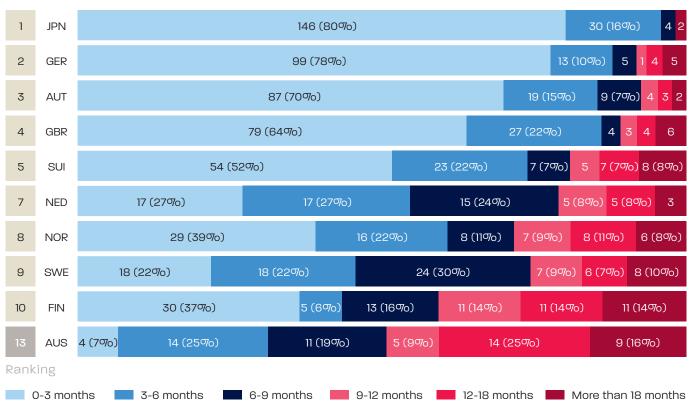
Australia's poor access compared to other countries is even more startling when we confine the examination to include only first-in-class medicines³. The term 'first-in-class', in this instance, refers to innovative products considered important enough to have expedited, breakthrough or priority assessments.

We rank third last on this measure.

³ First-in-class is defined according to the USA and UK designations and are therefore defined as more innovative relative to new molecules generally.



More than half of the 247 medicines analysed in the report are still not registered in Australia. Of those that were eventually reimbursed, 23 had a delay of more than a year, and 16 took between 6 and 12 months. Only 18 took less than 6 months.



Note: USA takes on average 180 days to reimburse all products. Not represented here

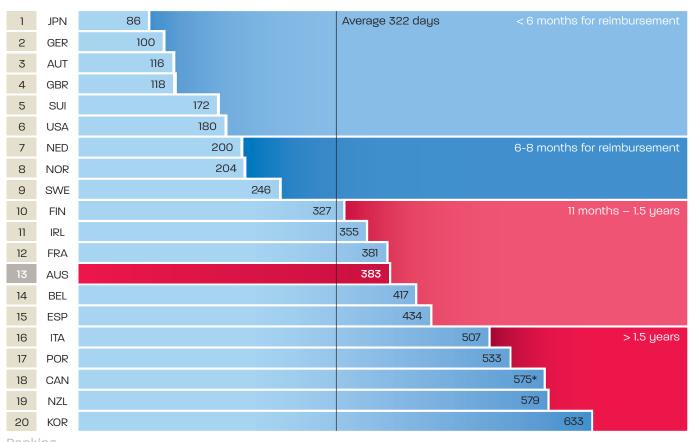
FIGURE 3 Number and proportion of new medicines reimbursed in Australia compared to top OECD countries based on time from registration to reimbursement, 2009-2014

Consider this: Australia listed only 18 new medicines for reimbursement within a six month timeframe. Japan, Germany, Austria and the UK reimbursed at least 100 medicines each within the same time. Japan and Germany are the fastest, achieving these results within three months.

Many OECD countries reimburse a new medicine at the same time it is registered, while the fastest a new medicine was PBS listed in Australia during 2009-2014 was 2.5 months after registration.

Australia has longer delays in access compared to other nations

On average, it takes more than a year (383 days) for Australia to list a new medicine on the PBS following its registration.



Ranking * The time to reimbursement for Canada varies greatly depending on methodology applied, as reimbursement is at provincial level.

The average of all provinces reimbursed is used for this chart.

 $\hbox{FIGURE 4} \quad \hbox{Average time from registration to reimbur sement (days) for new medicines, 2009-2014 } \\$

Australia's average time to reimbursement is at least three times longer than countries such as Japan, Germany, Austria and the UK. Moreover, we are still two months behind the OECD average time to reimbursement.

New medicines for National Health Priorities face significant delays

No single disease area is immune. Even National Health Priority areas are facing significant delays in access to new medicines.

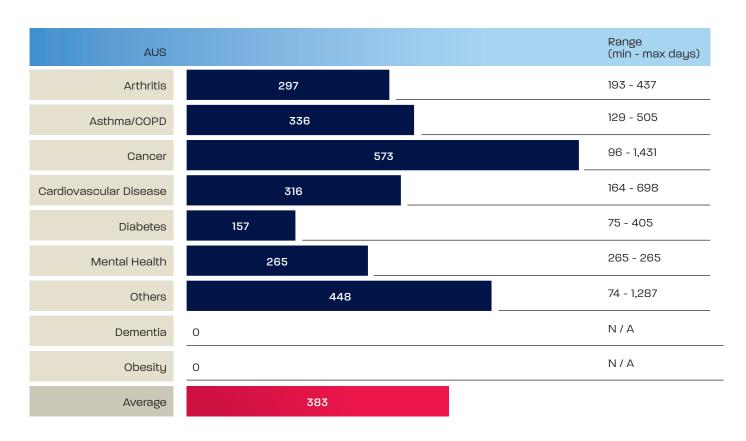


FIGURE 5 Average time from registration to reimbursement (days) for new medicines by National Health Priority, 2009-2014

The chart above shows the range and average times for Australia's reimbursement of new medicines according to the Government's National Health Priority areas.

Cancer patients wait the longest, with new cancer medicines delayed by half a year more than the average new medicine in Australia.

What new medicines are Australians missing out on?

Australian patients are missing out on 33 new medicines that are reimbursed in at least 10 other OECD countries.

TABLE 1

NATIONAL HEALTH PRIORITY AREA	Number of products not reimbursed in Australia	Average months behind OECD average reimbursement date	Average months behind first reimbursement in OECD
Arthritis	4	2 years 9 months	3 years 5 months
Asthma/COPD	2	2 years	2 years 9 months
Cancer	13	1 year 7 months	2 years 5 months
Cardiovascular Disease	2	2 years 5 months	3 years
Diabetes	3	2 years 6 months	3 years 3 months
Other Disease Areas	9	1 year 11 months	3 years 1 month
TOTAL	34		

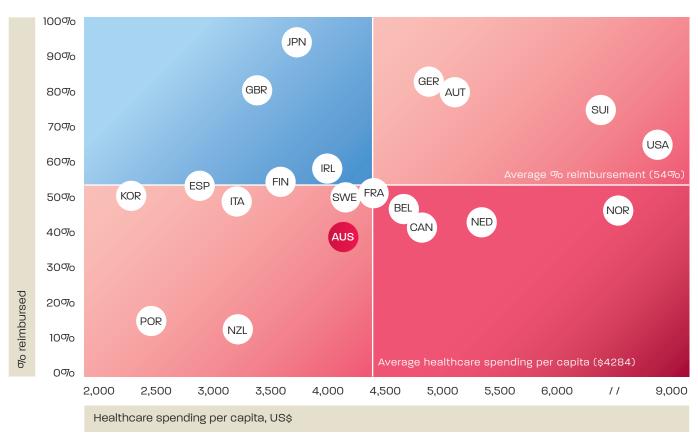
Note: as of 30 November 2014

The table above shows the number of new medicines by National Health Priority area that are still not reimbursed in Australia, but are reimbursed in at least 10 other OECD countries. The table also identifies the average time since the OECD reimbursement date for each priority area, and the average time since the first reimbursement date in any of the OECD countries analysed.

Some of these new medicines will never be reimbursed on the PBS in Australia. Others may take longer to achieve reimbursement. Nevertheless, Australian patients are waiting notably longer than their OECD counterparts.

Australia's per capita healthcare spend and access to medicines are well below the OECD average

Relative to other OECD countries, Australia is falling behind.



Source: The percentage of healthcare spending and GDP per capita (2013) information are sourced from the OECD statistics website http://stats.oecd.org/

FIGURE 6 Proportion of new medicines reimbursed, 2009-2014 vs. healthcare spending per capita (2013)

Japan and the UK outperform other countries when comparing the value gained by publicly funding medicines. The chart above shows that Japan and the UK reimburse a high percentage of new medicines while keeping their healthcare spending per capita below the OECD average.

What new medicines are we still waiting for?

The following new medicines are reimbursed in at least 10 OECD countries but were still awaiting reimbursement on the PBS as of 30 November 2014. Some of these new medicines may have been listed on the PBS since.

TABLE 2

HEALTH PRIORITY AREA	Product name	Molecule name	Time behind average reimbursement date in the OECD	Time behind first reimbursement date in the OECD
ARTHRITIS 3 years 5 months behind first, 2 years 9 months behind average	Nulojix	Belatacept	2 years 9 months	3 years 5 months
	Benlysta	Belimumab	2 years 10 months	3 years 4 months
	Ilaris	Canakinumab	4 years 4 months	5 years
	Pomalyst	Pomalidomide	11 months	1 year 9 months
ASTHMA/COPD 2 years 9 months behind first, 2 years behind average	Breo Ellipta	Fluticasone Furoate and Vilanterol	8 months	1 year 1 month
	Daliresp	Roflumilast	3 years 3 months	4 years 4 months
CANCER	Arzerra	Ofatumumab	3 years 10 months	4 years 8 months
2 years 6 months behind first,	Kadcyla	Trastuzumab Emtansine	10 months	1 year 4 months
1 year 8 months behind average	Giotrif	Afatinib	9 months	1 year 2 months
	Inlyta	Axitinib	1 year 8 months	2 years 6 months
	Bosulif	Bosutinib	1 year 3 months	1 year 9 months
	Xalkori	Crizotinib	1 year 8 months	2 years 10 months
	Stivarga	Regorafenib	1 year 2 months	1 year 8 months
	Jakavi	Ruxolitinib	1 year 6 months	2 years 7 months
	Caprelsa	Vandetanib	2 years 2 months	3 years 2 months
	Zelboraf	Vemurafenib	2 years	2 years 10 months
	Adcetris	Brentuximab Vedotin	1 year 6 months	2 years 10 months
	Erivedge	Vismodegib	1 year 1 month	2 year 5 months
	Xtandi	Enzalutamide	1 year	1 year 9 months
CARDIOVASCULAR DISEASE	Multaq	Dronedarone	4 years 3 months	5 years
3 years behind first, 2 years 5 months behind average	Adempas	Riociguat	7 months	11 months
DIABETES	Jentadueto	Linagliptin and Metformin	1 year 10 months	2 years 5 months
3 years 3 months behind first,	Victoza	Liraglutide	4 years 5 months	5 years 6 months
2 years 6 months behind average	Lyxumia	Lixisenatide	1 year 2 months	1 year 10 months
OTHERS 3 years 1 month behind first, 1 year 11 months behind average	Dificid	Fidaxomicin	1 year 7 months	3 years 10 months
	Xiaflex	Collagenase Clostridium Histolyticum	3 years 3 months	4 years 2 months
	Picato	Ingenol Mebutate	1 year 5 months	2 years 5 months
	Betanis	Mirabegron	1 year 6 months	3 years 3 months
	Teflaro	Ceftaroline Fosamil	1 year 10 months	3 years 8 months
	Sovriad	Simeprevir	5 months	1 year
	Sovaldi	Sofosbuvir	6 months	11 months
	Zebinix	Eslicarbazepine Acetate	3 years 7 months	5 years 2 months
	Trobalt	Retigabine	3 years	3 years 8 months

What was new in 2014?

The following new medicines were listed on the PBS in 2014. This list will be updated each year to highlight the new innovative medicines made available for patients since the previous COMPARE report.

TABLE 3

NATIONAL HEALTH PRIORITY AREA	Product name	Molecule name	PBS Reimbursement date
Diabetes	Nesina Met	Alogliptin and Metformin	1 / 02 / 2014
Diabetes	Kombiglyze	Metformin and Saxagliptin	1 / 03 / 2014
Other	Clobex	Clobetasol	1 / 04 / 2014
Other	Tivicay	Dolutegravir	1 / 04 / 2014
Asthma / COPD	Seebri Breezhaler	Glycopyrronium	1 / 04 / 2014
Other	Stribild	Cobicistat, Elvitegravir, Emtricitabine, Tenofovir and Disoproxil	1 / 05 / 2014
Cancer	Mozobil	Plerixafor	1 / 05 / 2014
Other	Kuvan	Sapropterin	1 / 05 / 2014
Other	Ferinject	Ferric carboxymaltose	1 / 06 / 2014
Other	Palexia	Tapentadol	1 / 06 / 2014
Asthma / COPD	Bretaris Genuair	Aclidinium Bromide	1 / 08 / 2014
Cardiovascular	Opsumit	Macitentan	1 / 09 / 2014
Asthma / COPD	Ultibro Breezhaler	Glycopyrronium and Indacaterol	1 / 11 / 2014
Other	Fycompa	Perampanel	1 / 11 / 2014

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