

MEDICINES
Australia

compare

COMPARISON OF
ACCESS AND
REIMBURSEMENT
ENVIRONMENTS

A report benchmarking
Australia's access to
new medicines

Edition 2
2016

compare

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2016



Welcome to the second edition of the 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 countries.

The Australian Government provides a public health insurance scheme, the Pharmaceutical Benefits Scheme (PBS), as part of the National Medicines Policy (NMP). This policy espouse four objectives:

1. Timely access to medicines that Australians need, at a cost individuals and the community can afford;
2. Medicines meeting appropriate standards of quality, safety and efficacy;
3. Quality use of medicines; and
4. Maintaining a responsible and viable medicines industry.

To understand Australia's access and reimbursement environment in a global context, Medicines Australia commissioned IMS Consulting Group to update their independent analysis and report on how Australian patients fare compared to 19 other OECD countries. The countries examined were selected because they have comparable GDP values, and health expenditure as a proportion of GDP to Australia. The analysis also included New Zealand as a regional partner.

Similarly to COMPARE 1, the analysis reviewed 249 new medicines¹ that were first registered in the 20 OECD countries. The time period has been expanded to include new medicines registered between 1 January 2010 and 31 December 2015. This rolling time period will allow longitudinal comparison between each successive COMPARE report and provide an opportunity to show the impact of Government policy reforms aimed at streamlining efficiencies, reducing red-tape and eliminating duplication.

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

¹ 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 2010 and 31 December 2015.

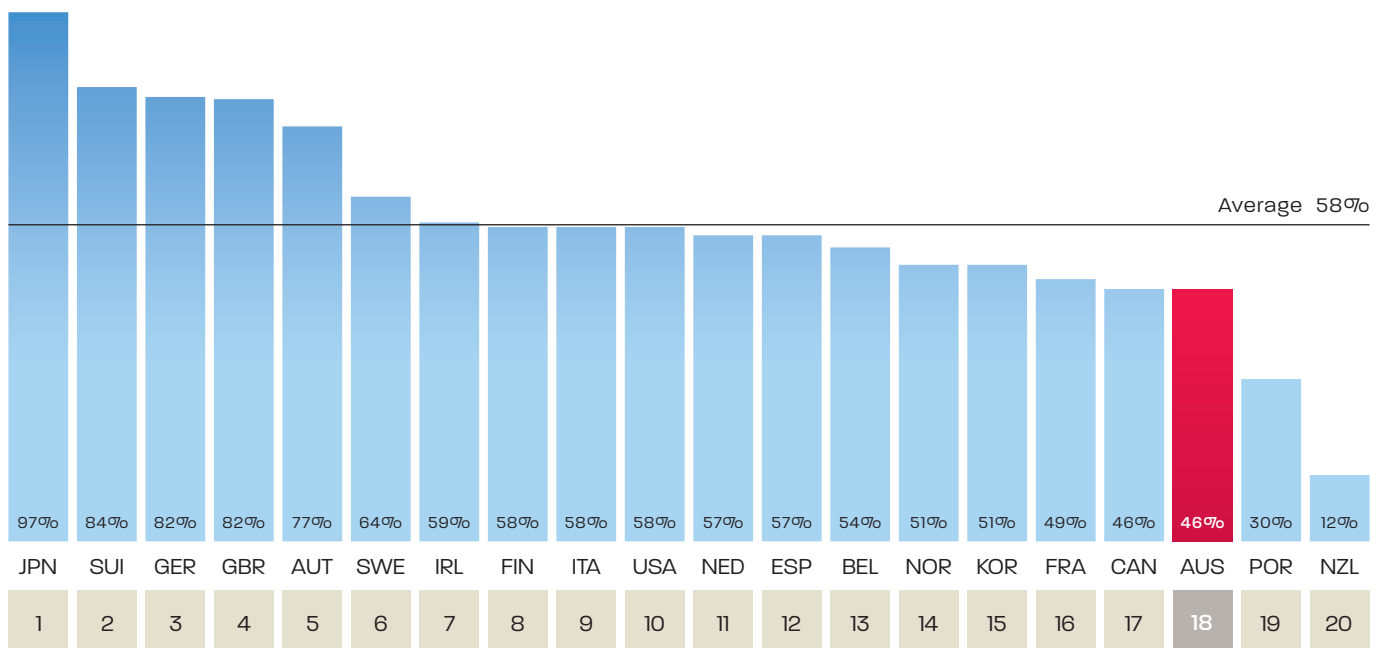
In Australia most NMEs achieved reimbursement more than one year after registration

Key Outcomes

- Australia ranks 18th by proportion of reimbursed New Molecular Entities (NMEs).
- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed NMEs; unchanged from COMPARE 1.
- It takes up to three times longer for NMEs to achieve reimbursement in Australia (397 days) than the world leaders Japan (98 days), Germany (117 days) and the UK (123 days).
- The top 10 countries reimburse NMEs on an average time to reimbursement from registration of 185 days with Australia ranking 13th for average time to reimbursement from registration of 397 days.
- Australia compares favourably to top 10 OECD countries for the proportion of reimbursed NMEs due to the 21 reimbursement approvals in 2015.
- Although the number of reimbursed NMEs increased, the time to reimbursement from registration still varies considerably between the areas of national health priorities: Cancer (597 days), mental health (547 days), arthritis (344 days) Diabetes (180 days) and Asthma (281 days).
- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed First-in-Class (FIC) and NMEs with expedited designation.
- Most countries have a higher proportion of FIC and/or Expedited reimbursed than the country overall percentage of reimbursed NMEs.
- 59 NMEs were registered but not reimbursed in Australia (figures current at end of December 2015).

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

46% of medicines registered between 2010 and 2015 in Australia have subsequently been reimbursed in Australia.



Ranking

FIGURE 1 Proportion of new medicines reimbursed of those registered in each country, 2010-2015

This is a slight improvement from 39% of new medicines reimbursed after registration, reported in COMPARE 1.

In Australia this refers to new medicines that have been listed on the PBS as a proportion of those registered on the Australia Register of Therapeutic Goods (ARTG).²

62% of NMEs are launched in Australia versus over 68% for the average launch rate amongst the 20 countries.

² As this data was to December 2015 this does not capture any of the recently announced reforms from the Medicines and Medical Devices Review

Australia lists around half of all possible first-in-class medicines on the PBS

Australia has listed just under half of all the possible first-in-class medicines that could be listed on the PBS.

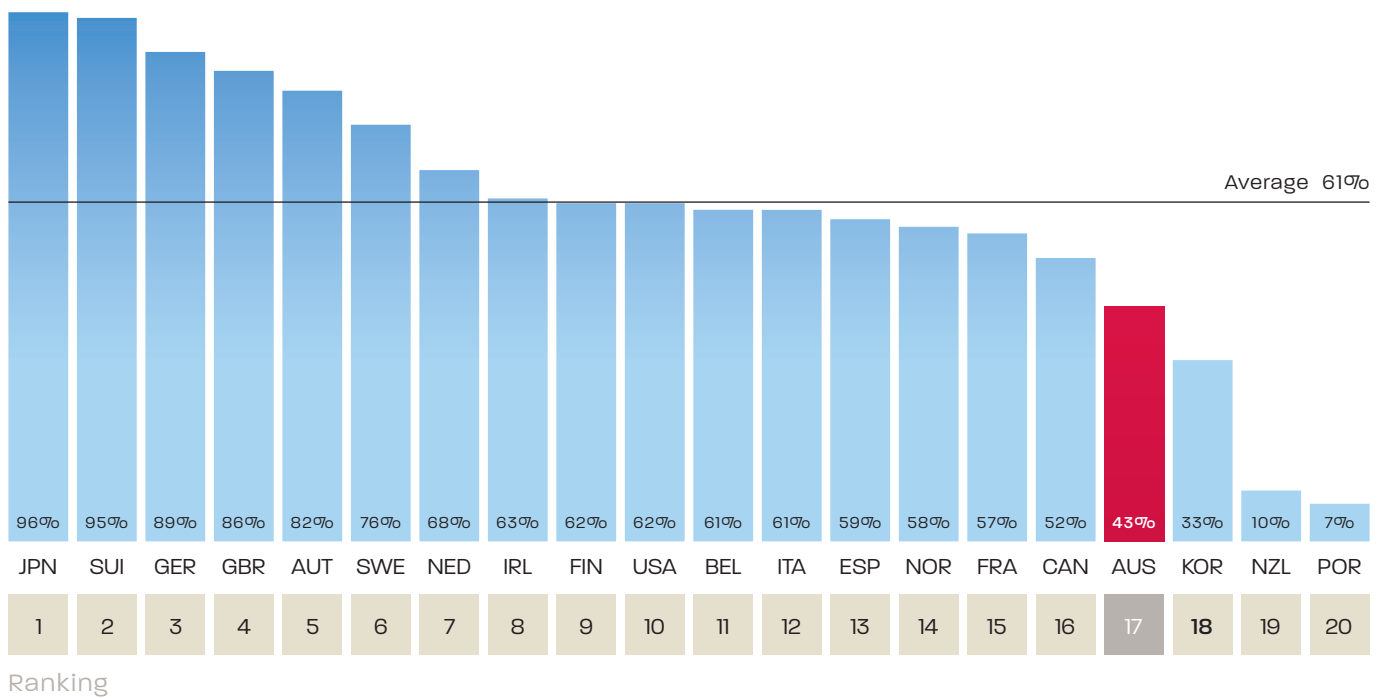
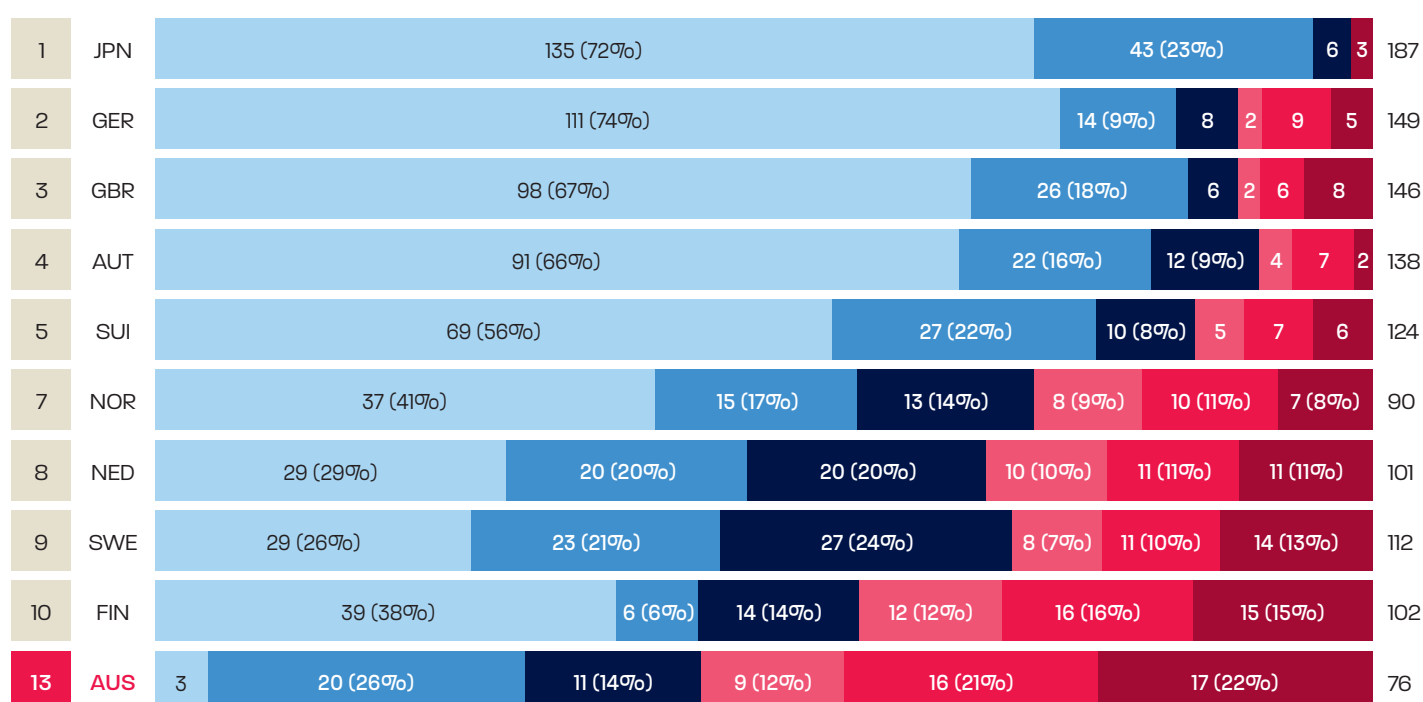


FIGURE 2 Proportion of first-in-class medicines reimbursed of those registered in each country, 2010-2015

While access to first-in-class medicines in Australia has improved from 27% in COMPARE 1 we rank fourth last on this measure, indicating that there is still further work to be done if we are to catch up with the world leading countries in this area.

Australia compared to the top OECD countries – new medicines reimbursed

Approximately a quarter of the 249 medicines analysed in the report are not registered in Australia. Of those that were reimbursed, 33 took more than a year, and 20 took between 6 and 12 months.



Ranking

0-3 months 3-6 months 6-9 months 9-12 months 12-18 months More than 18 months

In Australia, the three MNEs that got reimbursement in under three months are Nesina[®], Onglyza[®] and Triumeq[®]
 Note: USA not represented in the above as it takes on average 180 days to reimburse all products

FIGURE 3 Number (proportion) of NMEs reimbursed for Australia compared to top OECD countries – time between registration to reimbursement

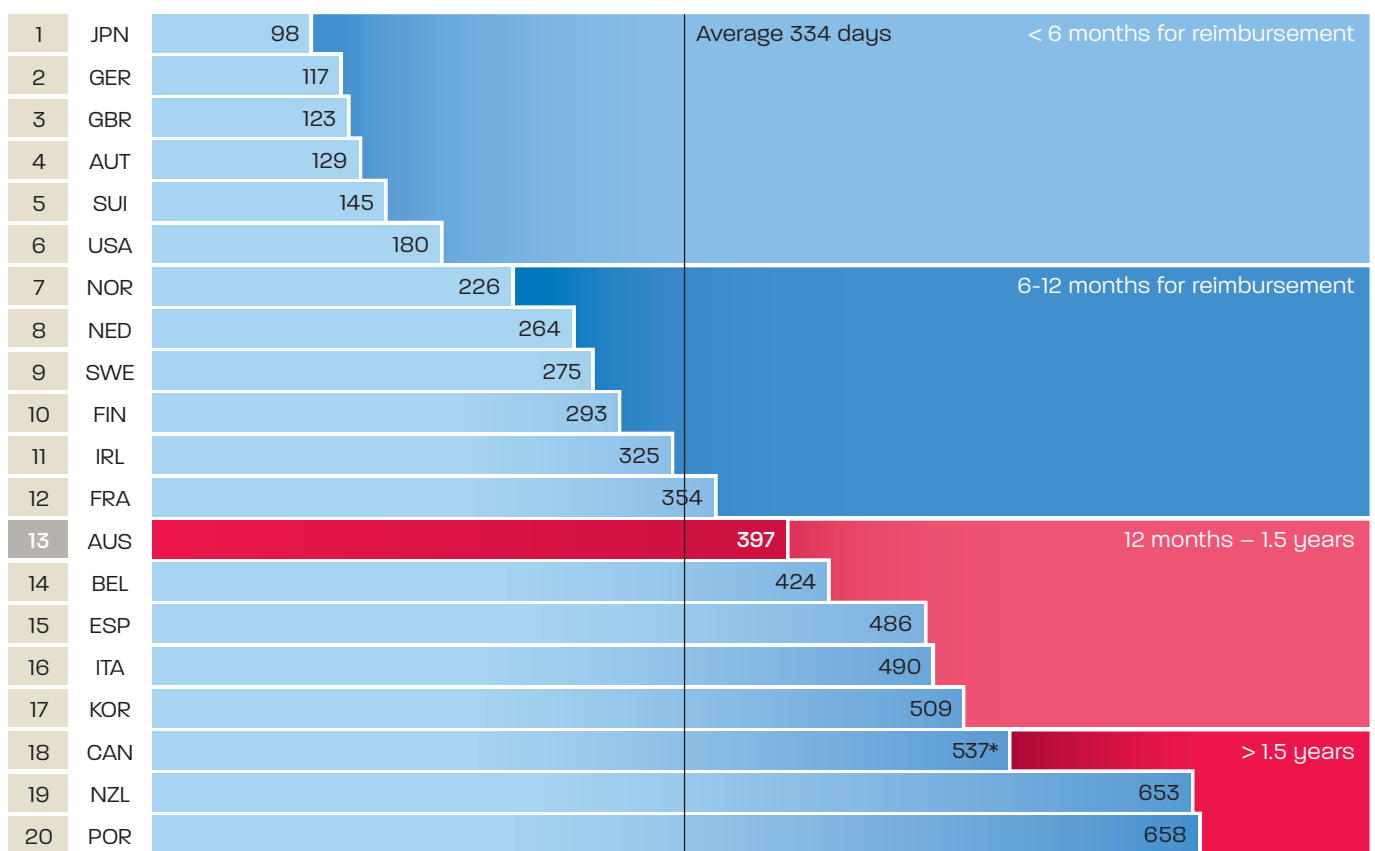
Australia listed 23 new medicines for reimbursement within a six month timeframe. The fastest a new medicine was PBS listed in Australia during 2010-2015 was 2.5 months after registration.

The top OECD countries include Japan, Germany, Austria and the UK which reimbursed at least 100 medicines each within the same time. Japan and Germany are the fastest, achieving these results within three months.

In contrast to Australia, many OECD countries reimburse a new medicine at the same time it is registered, due to differences in the systems for access to medicines.

Australia falls slightly short of the OECD average for reimbursement of new medicines

On average, it takes more than a year (397 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.

FIGURE 4 Average time to reimbursement from registration (days), NMEs registered 2010-2015

Australia is two months behind the OECD average time to reimbursement. Our average is longer than the world leading countries such as Japan, Germany, Austria and the UK.

National Health Priorities – results of average reimbursement timelines

Some national health priority areas are behind the average time it takes to list a new medicine whilst other areas achieve rapid listing times.

AUS	Days	Range (min–max days)
Arthritis	344	207 - 414
Asthma/COPD	281	143 - 519
Cancer	597	110 - 1,445
Cardiovascular Disease	383	178 - 712
Dementia	0	N / A
Diabetes	180	89 - 419
Hepatitis C	339	150 - 462
Mental health	547	279 - 785
Obesity	0	N / A
Others	365	88 - 1,301
Average	397	

FIGURE 5 **Average time from registration to reimbursement (days) for new medicines by National Health Priority 2010-2015**

Figure 5 shows the range and average times for Australia's reimbursement of new medicines according to the Government's National Health Priority areas.

Diabetes and Asthma medicines were made available more quickly than the average time of 397 days, at 180 and 281 days respectively.

New cancer medicines and medicines became available on average six months later than the average new medicine in Australia.

New medicines by National Health priority

There are 34 new medicines that are reimbursed in at least 10 other OECD countries, but are not currently available in Australia for a range of reasons.

TABLE 1 Number of new medicines by National Health Priority area not reimbursed in Australia

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 6 months	3 years 3 months
Asthma/COPD	1	1 years 2 months	1 year 2 months
Cancer	21	1 year 7 months	2 years 4 months
Cardiovascular Disease	9	0 years 10 months	1 year 2 months
Diabetes	5	1 year 3 months	1 year 11 months
Hepatitis C	6	0 years 9 months	1 year 2 months
Other disease areas	42	1 year 8 months	2 years 6 months
TOTAL	88		

Table 1 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 due to a range of reasons. Others may take more time.

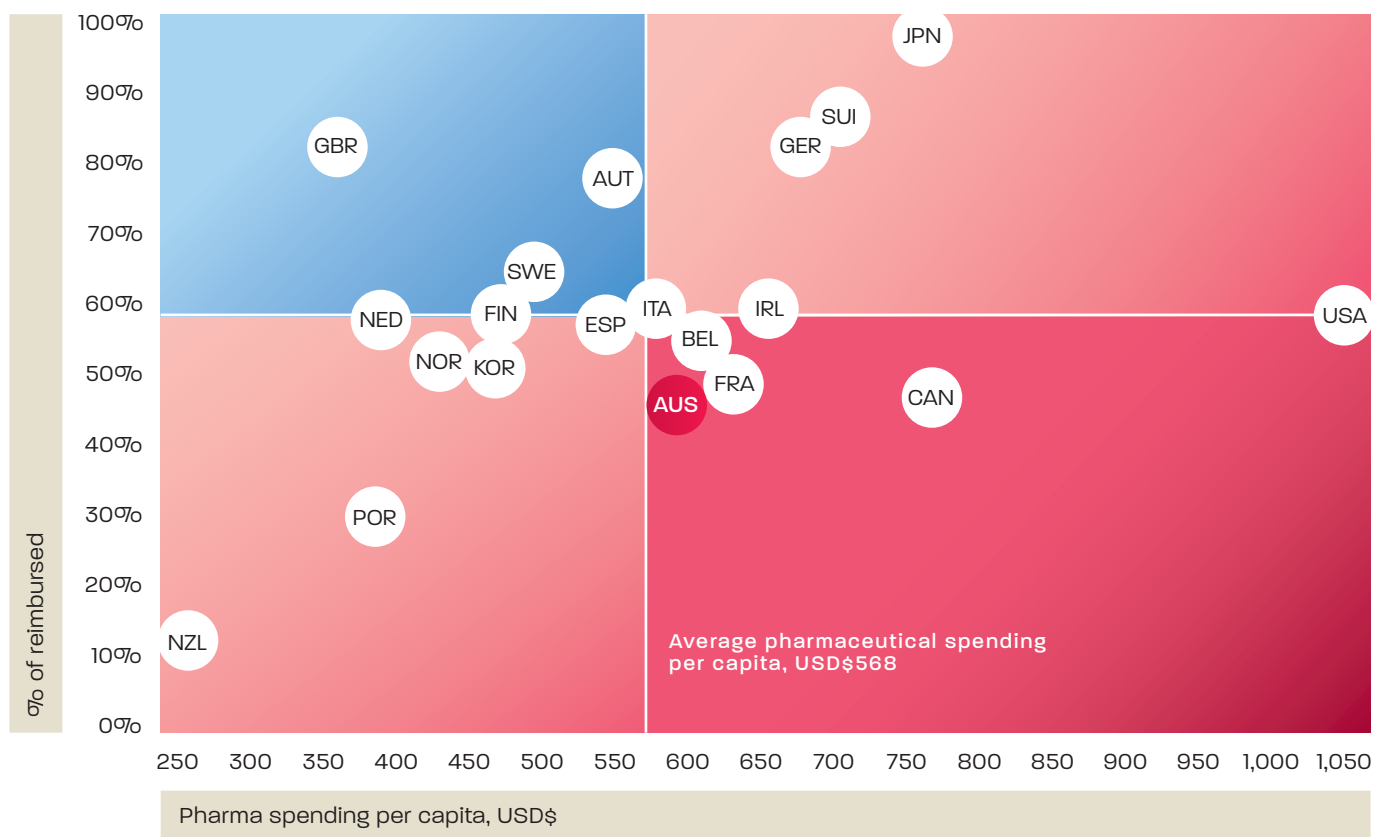
59 NMEs are registered but not reimbursed in Australia (reimbursed by the end of December 2015), of which 36 NMEs registered before January 2015 are still waiting for reimbursement (allowing for on average one year reimbursement).

Although there are six Hepatitis C medicines not reimbursed in Australia, seven new Hepatitis C medicines were newly PBS listed in Australia in 2016:

- Jakavi was PBS listed on 1 February 2016
- Jadamet, Sovaldi, Harvoni and Daklinza were PBS listed on 1 March 2016
- Akynzeo and Evotaz were listed on 1 April 2016.

Australia is slightly above the OECD average for spending on medicines per capita

Australia's pharmaceutical spending per capita is slightly above the OECD average.



Source: The total pharmaceutical spending per capita and pharma spending as percentage of healthcare spending (2013) information is sourced from the OECD statistics website, <http://stats.oecd.org/>

FIGURE 6 Proportion of NMEs reimbursed (2010-2015) vs. pharma spending per capita

The percentage of new medicines reimbursed by the Government is lower than the OECD average.

Japan and the UK outperform other countries when comparing the value gained by publicly funding medicines. The chart 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 10 OECD countries but were still awaiting reimbursement on the PBS in Australia as of 31 December 2015. Some of these new medicines will have been listed on the PBS since this time. For further information on what is currently available on the PBS, please refer to the Department of Health's website: www.pbs.gov.au

TABLE 2

NATIONAL HEALTH PRIORITIES (NHP)	Product name	Molecule name	Months behind average reimbursement date of all countries of OECD countries in analysis	Months behind first reimbursement date in OECD countries in analysis
ARTHRITIS 41 months behind first, 33 months behind average	Nulojix [®]	Belatacept	33	41
	Benlysta [®]	Belimumab	34	40
	Ilaris [®]	Canakinumab	52	60
	Pomalyst [®]	Pomalidomide	11	21
ASTHMA/COPD 33 months behind first, 24 months behind average	Breo Ellipta [®]	Fluticasone Furoate and Vilanterol	8	13
	Daliresp [®]	Roflumilast	39	52
CANCER 30 months behind first, 20 months behind average	Arzerra [®]	Ofatumumab	46	58
	Kadcyla [®]	Trastuzumab Emtansine	10	16
	Giotrif [®]	Afatinib	9	14
	Inlyta [®]	Axitinib	20	30
	Bosulif [®]	Bosutinib	15	21
	Xalkori [®]	Crizotinib	20	34
	Stivarga [®]	Regorafenib	14	20
	Jakavi [®]	Ruxolitinib	18	31
	Caprelsa [®]	Vandetanib	26	38
	Zelboraf [®]	Vemurafenib	24	34
	Adcetris [®]	Brentuximab Vedotin	18	34
	Halaven [®]	Eribulin	35	46
	Erivedge [®]	Vismodegib	13	29
	Xtandi [®]	Enzalutamide	12	21
CARDIOVASCULAR 36 months behind first, 29 months behind average	Multaq [®]	Dronedarone	51	60
	Adempas [®]	Riociguat	7	11
DIABETES 39 months behind first, 30 months behind average	Jentaduetto [®]	Linagliptin and Metformin	22	29
	Victoza [®]	Liraglutide	53	66
	Lyxumia [®]	Lixisenatide	14	22
OTHERS 37 months behind first, 23 months behind average	Dificid [®]	Fidaxomicin	19	46
	Xiaflex [®]	Collagenase Clostridium Histolyticum	39	50
	Picato [®]	Ingenol Mebutate	17	29
	Betanis [®]	Mirabegron	18	39
	Teflaro [®]	Ceftaroline Fosamil	22	44
	Sovriad [®]	Simeprevir	5	12
	Sovaldi [®]	Sofosbuvir	6	11
	Zebinix [®]	Eslicarbazepine Acetate	43	62
	Trobal [®]	Retigabine	36	44

What's new this year?

The following new medicines were listed on the PBS in 2015. 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
Arthritis	Entyvio [®]	Vedolizumab	15 / 12 / 2015
Arthritis	Pomalyst [®]	Pomalidomide	15 / 12 / 2015
Cancer	Inlyta [®]	Axitinib	15 / 12 / 2015
Cancer	Halaven [®]	Eribulin	15 / 12 / 2015
Cancer	Arzerra [®]	Ofatumumab	15 / 12 / 2015
Cancer	Perjeta [®]	Pertuzumab	15 / 12 / 2015
Cancer	Kadcyla [®]	Trastuzumab Emtansine	15 / 12 / 2015
Cancer	Xalkori [®]	Crizotinib	15 / 12 / 2015
Cancer	Mekinist [®]	Trametinib	15 / 12 / 2015
Cancer	Gazyva [®]	Obinutuzumab	15 / 12 / 2015
Cancer	Iclusig [®]	Ponatinib	15 / 12 / 2015
Cancer	Keytruda [®]	Pembrolizumab	15 / 12 / 2015
Diabetes	Jardiance [®]	Empagliflozin	15 / 12 / 2015
Mental health	Vyvanse [®]	Lisdexamfetamine	15 / 12 / 2015
Mental health	Latuda [®]	Lurasidone	15 / 12 / 2015
Others	Plegridy [®]	Peginterferon Beta-1A	15 / 12 / 2015
Others	Velphoro [®]	Sucroferriic Oxyhydroxide	15 / 12 / 2015
Others	Adenuric [®]	Febuxostat	15 / 12 / 2015
Others	Cosentyx [®]	Secukinumab	15 / 12 / 2015
Others	Triumeq [®]	Abacavir Dolutegravir Lamivudine	15 / 12 / 2015
Others	Xeljanz [®]	Tofacitinib	15 / 12 / 2015

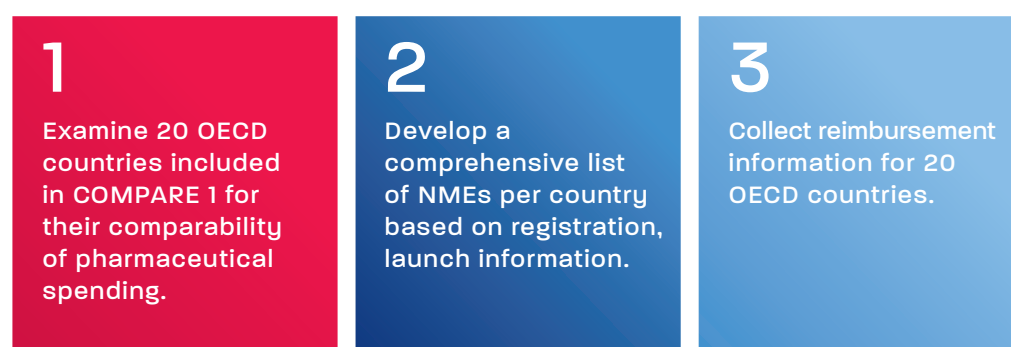
What has changed since COMPARE 2015

	COMPARE 1	COMPARE 2
Total number of reimbursed NMEs	59 NMEs (Rank 17th)	76 NMEs (Rank 17th)
Proportion of launched	65% (Rank 13th)	63% (Rank 13th)
Proportion of reimbursed	39% (Rank 18th)	46% (Rank 18th)
Average number of registered per year	25 NMEs	28 NMEs
Average number of launched per year	19 NMEs	17 NMEs
Average number of reimbursed per year	11 NMEs	13 NMEs

- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed NMEs, unchanged from COMPARE 1.
- The number of launched NMEs decreased marginally over the last three years.
- NMEs registered and reimbursed is on the rise in Australia.

Appendix

Method and Approach



Step 1.	National marketing approval data collection <ul style="list-style-type: none">• Identify a list of products reviewed and approved for marketing by national body.• Definition: the registration date considered in this report is the first date of where national marketing authorisation was achieved for <i>its very first indication</i>.
Step 2.	Check launch date <ul style="list-style-type: none">• Validate launch date to remove products launched previously in the country under a different product name.• Definition: launch date is the date of first recorded commercial sales of any pack in the target country.
Step 3.	New molecular entity / new combination <ul style="list-style-type: none">• The earliest marketing approval date is considered <i>regardless of indication or formulation</i>.• Combination were included only if the combination was registered between calendar year (CY) 2010-2015 <i>and at least one</i> of the molecule was launched between CY 2010-2015.• The analysis was conducted using information up to Dec 2015, because it is the most updated information available across the 20 countries in scope at the time of analysis (February 2016).

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