

MEDICINES
Australia

compare

COMPARISON OF
ACCESS AND
REIMBURSEMENT
ENVIRONMENTS

A report benchmarking Australia's
access to new medicines

Edition 3
2017

compare

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2017



Welcome to the third annual *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.

This report focuses on the first objective.

To understand Australia's access and reimbursement environment in a global context, Medicines Australia again commissioned QuintilesIMS 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 GDP values, and health expenditure as a proportion of GDP to Australia. The analysis also included New Zealand as a regional partner.

Building on the previous *COMPARE* reports, the analysis reviewed 441 new medicines¹ that were first registered in the 20 OECD countries over the period 1 January 2011 to 31 December 2016. The time period has been rolled forward one year from the previous *COMPARE 2* report for a longitudinal comparison between each successive *COMPARE* report.

We hope you find this a valuable resource and we would 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 2011 and 31 December 2016.

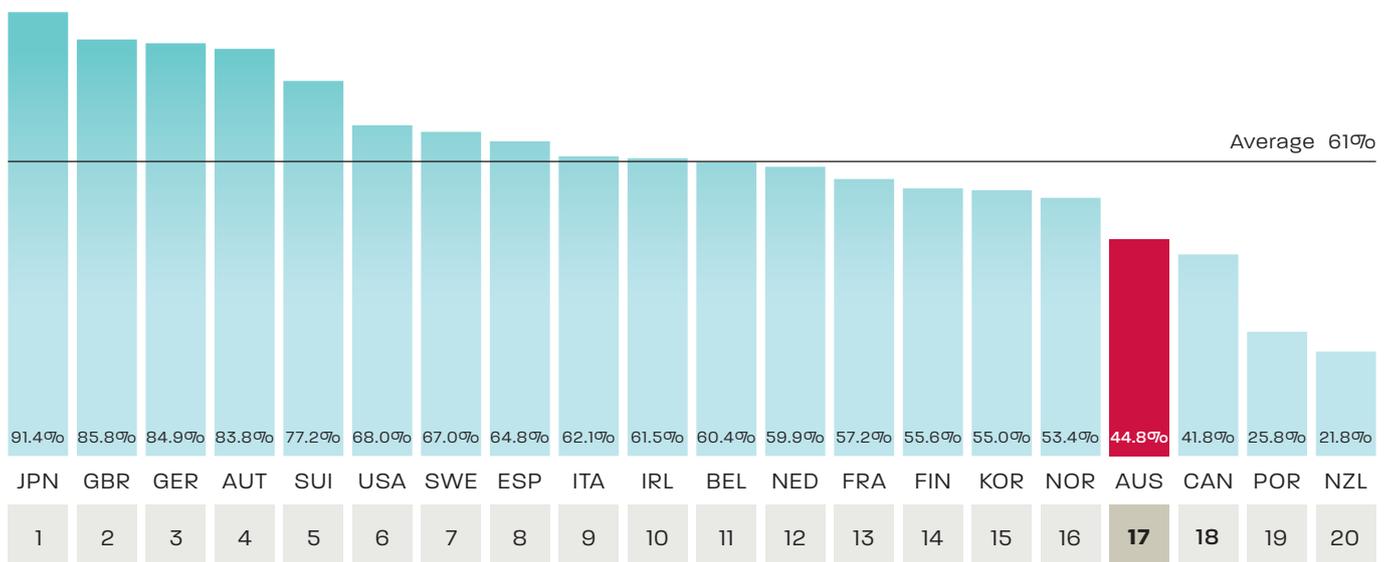
In Australia most NMEs achieved reimbursement more than one year after registration

Key Outcomes

- Australia ranks 17th by proportion of reimbursed New Molecular Entities (NMEs), an improvement of one place compared to *COMPARE 2*.
- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed NMEs; unchanged from *COMPARE 1* and 2.
- It takes up to three times longer on average for NMEs to achieve reimbursement in Australia (370 days; down 20 days from *COMPARE 2*) than the world leaders Japan (99 days; up one day from *COMPARE 2*), Germany (114 days; down three days from *COMPARE 2*) and Austria (124 days).
- Top 10 countries reimburse NMEs on an average time to reimbursement from registration of 183 days with Australia ranking 13th for average time to reimbursement from registration of 370 days.
- Australia compares favourably to top 10 OECD countries for the proportion of reimbursed NMEs due to the 18 reimbursement approvals in 2016.
- Although the number of reimbursed NMEs decreased the time to reimbursement from registration it still varies considerably between the areas of National Health Priorities: Cancer (534 days), mental health (499 days), arthritis (414 days) Diabetes (220 days) and Asthma (245 days).
- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed first-in-class (FIC) and NMEs with expedited designation, the same as *COMPARE 2*.
- 100 NMEs were registered but not reimbursed in Australia (figures current at end of December 2016).

**Australia ranks
17th out of 20
OECD countries
for access to
new medicines**

45% of medicines registered between 2011 and 2016 in Australia have subsequently been reimbursed in Australia.



Ranking

FIGURE 1 Proportion of new medicines reimbursed of those registered in each country, 2011-2016

This is a slight reduction in the proportion of NMEs that were reimbursed after registration to the COMPARE 2 period, where 46% of new medicines were reimbursed after registration.

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

61% of NMEs are launched in Australia versus over 69% for the average launch rate amongst the 20 countries.

Australia lists around half of all possible first 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.

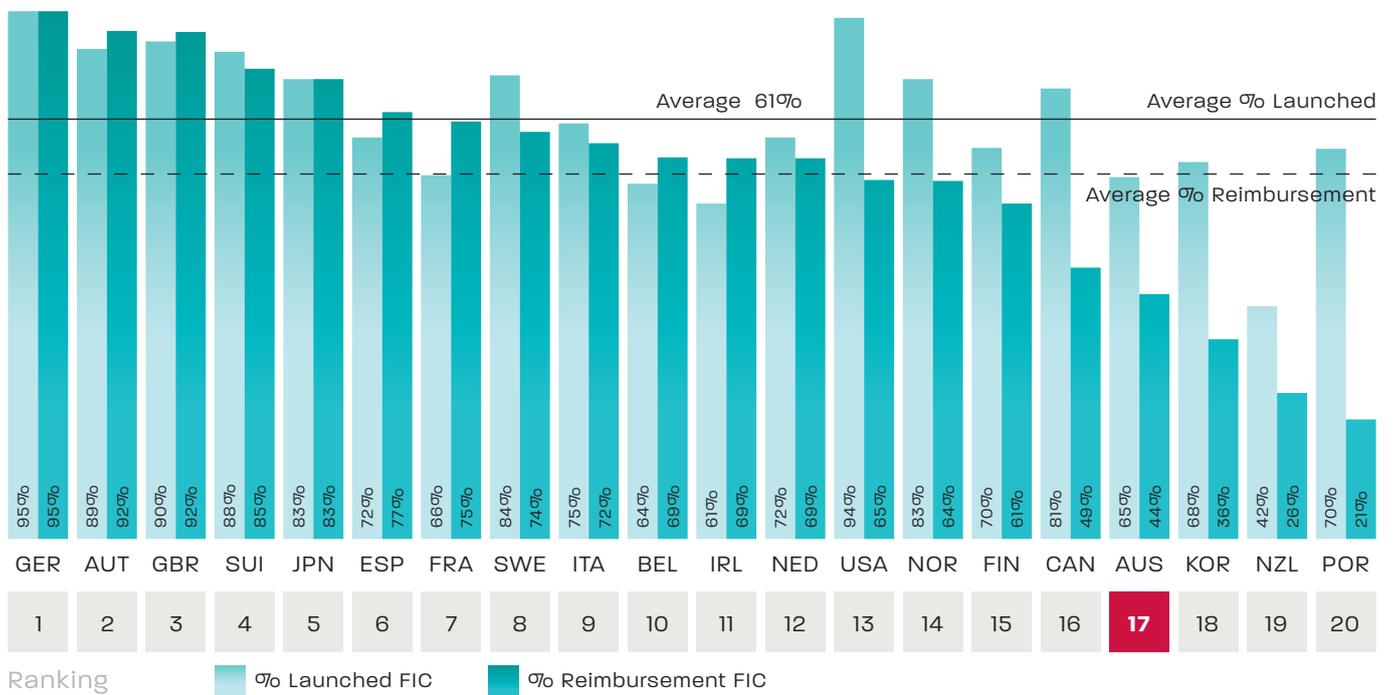
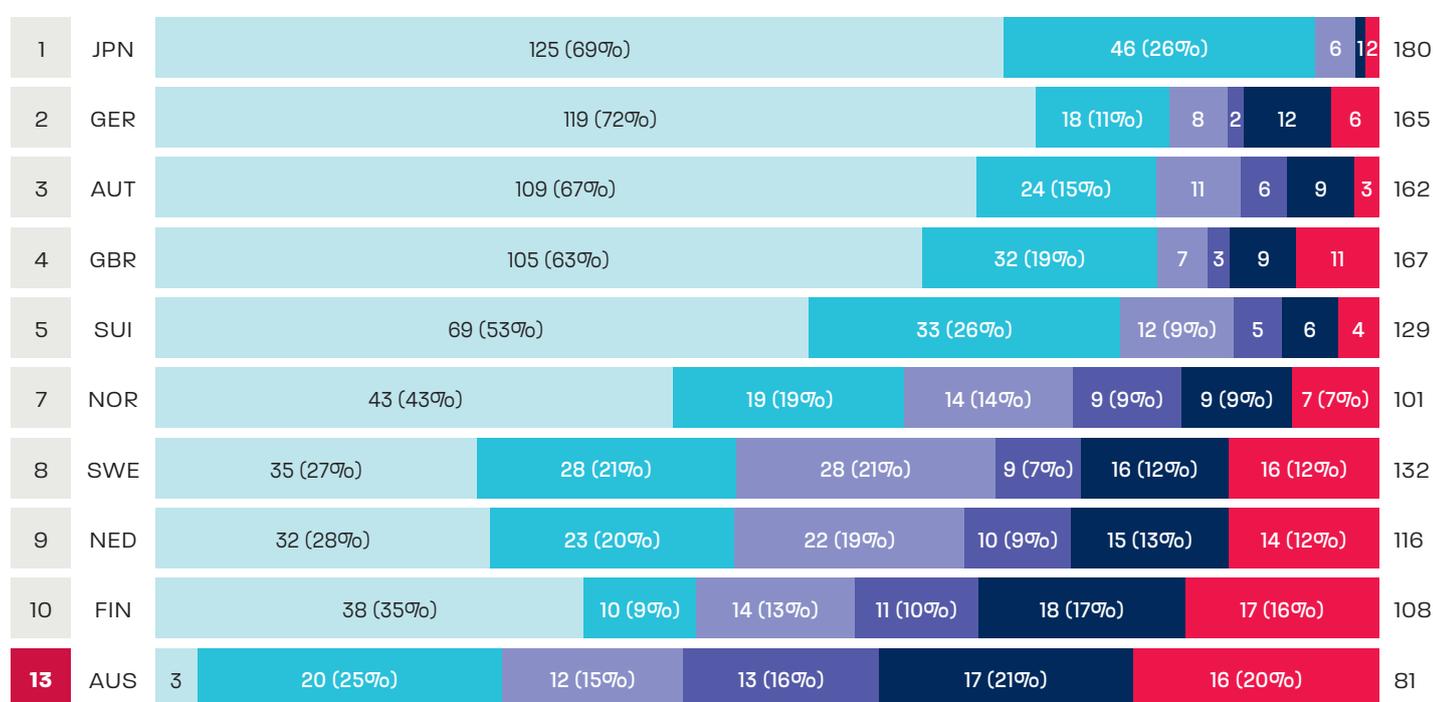


FIGURE 2 Proportion of first-in-class medicines reimbursed of those registered in each country, 2011-2016

The term first-in-class refers to innovative products considered important enough to have expedited, breakthrough or priority assessments. While access to first 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 catch up with the world leading countries in this area.

Australia compared to the top OECD countries – new medicines reimbursed

Approximately a third of the 441 medicines analysed in the report are not registered in Australia. Of those that were reimbursed, 33 took more than a year, and 25 took between six and 12 months.



Ranking

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

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

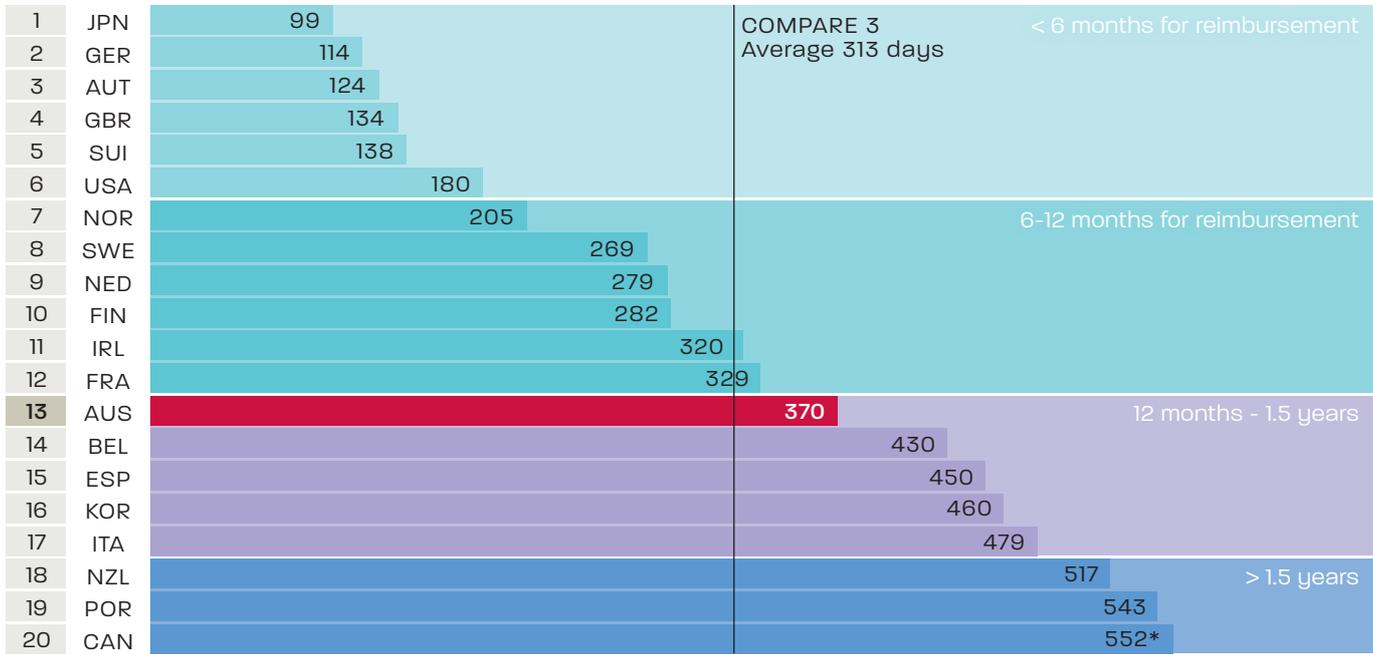
Similar to *COMPARE 2*, Australia listed 23 new medicines for reimbursement within a six month timeframe. The fastest a new medicine was PBS listed in Australia during 2011-2016 was 2.5 months after registration.

The top OECD countries include Japan, Germany, Austria and Great Britain 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 (370 days) for Australia to list a new medicine on the PBS following its registration. This has improved by 27 days since COMPARE 2 (397 days).



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 4.1 Average time to reimbursement from registration (days), NMEs registered 2011-2016

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

Before 2013, Australia was the fastest to reimburse in this category, however it has become the second slowest by the end of 2016.

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.

AUS	Average time from registration to reimbursement (days)	Range (min–max days)
Arthritis	414	414
Asthma/COPD	245	143-519
Cancer	534	110-1,237
Cardiovascular Disease	298	178 - 712
Dementia	0	N / A
Diabetes	220	89-454
Hepatitis C	353	150-624
Mental health	499	279-785
Obesity	0	N / A
Others	320	88-1,049
Average	370	

FIGURE 5 **Average time from registration to reimbursement (days) for new medicines by National Health Priority 2011-2016**

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 are made available more quickly than the average time of 370 days, at 180 and 281 days respectively.

New cancer medicines and medicines become available 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	3	4 years 3 months	3 years 4 months
Asthma/COPD	2	1 years 2 months	1 years 2 months
Cancer	21	1 years 7 months	2 years 4 months
Cardiovascular Disease	4	0 years 10 months	1 years 2 months
Diabetes	2	1 years 3 months	1 years 11 months
Hepatitis C	6	0 years 9 months	1 years 2 months
Other Disease Areas	42	1 years 8 months	2 years 6 months
TOTAL	69		

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. Others may take more time.

Fifty-nine NMEs are registered but not reimbursed in Australia (reimbursed by the end of December 2016), of which 36 NMEs registered before January 2015 are still waiting for reimbursement (allowing for on average one year reimbursement).

Although there were a number of medicines not reimbursed as of December 2016, two (Mepolizumab and Riociguat) were PBS listed on 1 January 2017.

Australia is slightly above the OECD average for spending on medicines, but the access to new medicines is lower than the average

Australia's pharmaceutical spending per capita is slightly above the OECD average. The percentage of new medicines reimbursed by the Government is lower than the OECD average.

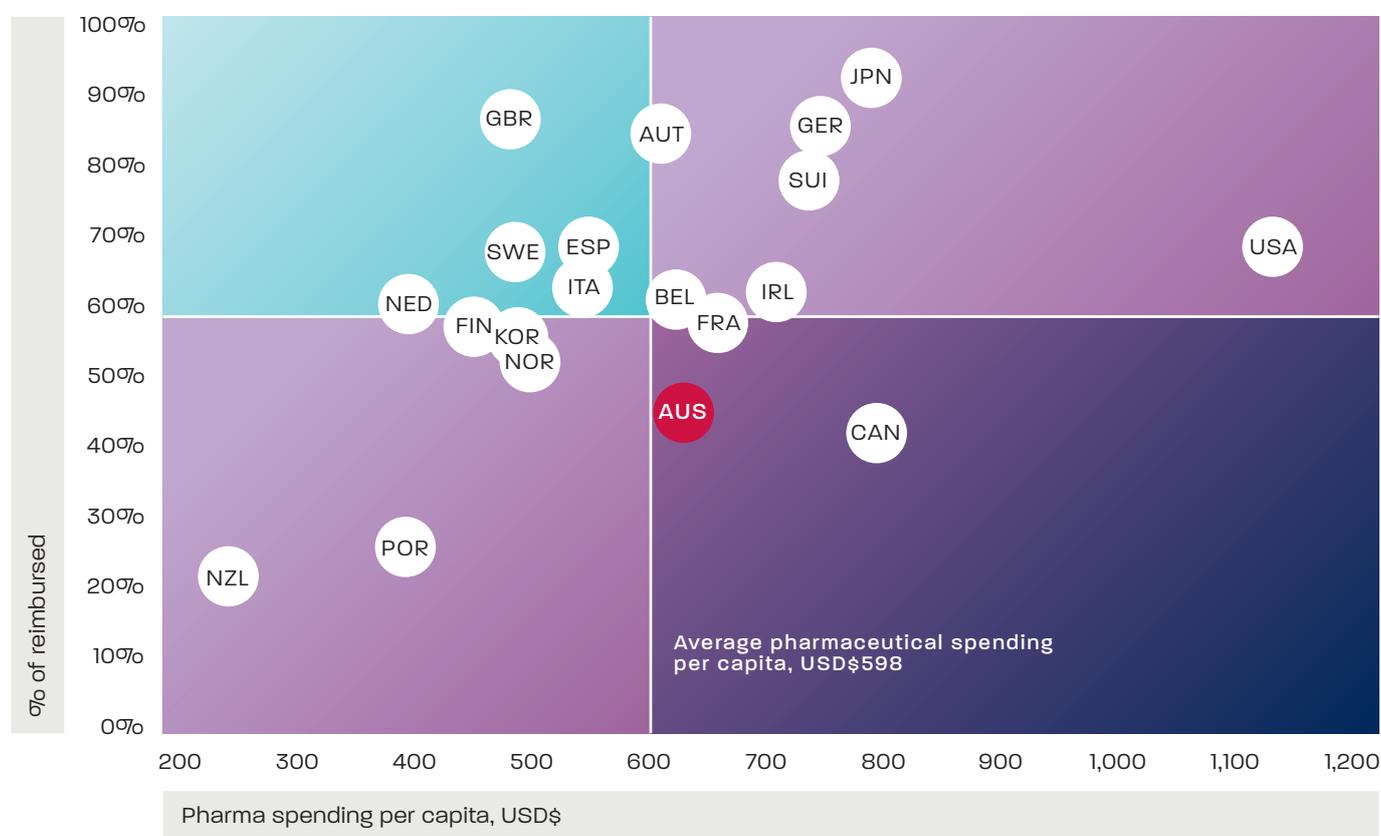


FIGURE 6 Proportion of NMEs reimbursed (2011-2016) vs. pharmaceutical spending per capita

Japan and Great Britain outperform other countries when comparing the value gained by publicly funding medicines. The chart shows that Japan and Great Britain 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 2016. 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	Product name	Molecule name	Months behind average reimbursement date of all countries of OECD countries in analysis		NATIONAL HEALTH PRIORITIES	Product name	Molecule name	Months behind average reimbursement date of all countries of OECD countries in analysis	
			Months behind average reimbursement date of all countries of OECD countries in analysis	Months behind first reimbursement date in OECD countries in analysis				Months behind average reimbursement date of all countries of OECD countries in analysis	Months behind first reimbursement date in OECD countries in analysis
ARTHRITIS 52 months behind first, 41 months behind average	Nulojix®	Belatacept	33	41	OTHERS 29 months behind first, 21 months behind average	Sunvepra®	Asunaprevir	17	17
	Benlysta®	Belimumab	34	40		Zepatier®	Elbasvir Grazoprevir	2	8
	Otezla®	Apremilast	15	23		Epclusa®	Sofosbuvir Velpatasvir	3	6
ASTHMA/COPD 19 months behind first, 17 months behind average	Striverdi Respimat®	Olodaterol	25	26		Belsomra®	Suvorexant	26	26
	Nucala®	Mepolizumab	9	12		Fampyra®	Fampridine	50	70
CANCER 30 months behind first, 20 months behind average	Zelboraf®	Vemurafenib	44	59		Picato®	Ingenol Mebutate	41	54
	Caprelsa®	Vandetanib	46	61		Zinforo®	Ceftaroline Fosamil	43	51
	Giotrif®	Afatinib	31	39		Difcid®	Fidaxomicin	44	71
	Stivarga®	Regorafenib	30	46		Trobalt®	Retigabine	62	70
	Erivedge®	Vismodegib	33	54		Betmiga®	Mirabegron	35	64
	Bosulif®	Bosutinib	39	47		Tybost®	Cobicicistat	33	36
	Xofigo®	Radium Ra-223	22	38		Vitekta®	Elvitegravir	37	38
	Zydelig®	Idelalisib	22	28		Novothirteen®	Catridecacog	24	30
	Imbruvica®	Ibrutinib	20	32		Novoeight®	Turoctocog Alfa	26	36
	Cyramza®	Ramucirumab	20	27		Rixubis®	Nonacog Gamma	10	27
	Odanzo®	Sonidegib	12	12		Brintellix®	Vortioxetine	17	34
	Sylvant®	Siltuximab	21	31		Alprolix®	Eftrenonacog Alfa	9	27
	Blinicyto®	Blinatumomab	9	13		Elelyso®	Taliglucerase Alfa	51	51
	Lynparza®	Olaparib	17	24		Elocate®	Efmoroctocog Alfa	8	22
	Zykadia®	Ceritinib	12	27		Nuwiq®	Simoctocog Alfa	22	26
	Farydak®	Panobinostat	12	17		Vimizim®	Elosulfase Alfa	17	31
	Cotellic®	Cobimetinib	9	13	Cerdelga®	Eliglustat	14	21	
	Tagrisso®	Osimertinib	8	11	Ofev®	Nintedanib	18	24	
	Empliciti®	Elotuzumab	5	8	Zerbaxa®	Ceftolozane Tazobactam	10	14	
	Ninlaro®	Ixazomib	8	8	Movantik®	Naloxegol	16	22	
Kyprolis®	Carfilzomib	13	48	Strensiq®	Asfotase Alfa	11	15		
CARDIOVASCULAR 18 months behind first, 13 months behind average	Adempas®	Riociguat	29	36	Orkambi®	Ivacaftor Lumacaftor	9	13	
	Entresto®	Sacubitril Valsartan	10	14	Stendra®	Avanafil	23	34	
	Uptravi®	Selexipag	5	7	Obizur®	Susoctocog Alfa	5	9	
DIABETES 36 months behind first, 27 months behind average	Praluent®	Alirocumab	9	15	Praxbind®	Idarucizumab	9	13	
	Lyxumia®	Lixisenatide	37	47	Briviact®	Brivaracetam	8	12	
	Trulicity®	Dulaglutide	16	24	Taltz®	Ixekizumab	3	7	
					Idelvion®	Albutrepenonacog Alfa	3	7	
					Zinbryta®	Daclizumab	11	12	

What's new this year?

The following new medicines were listed on the PBS in 2016. 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
Cancer	Jakavi [®]	Ruxolitinib	15 / 11 / 2016
Others	Signifor [®]	Pasireotide	15 / 09 / 2016
Hepatitis C	Sovaldi [®]	Sofosbuvir	15 / 03 / 2016
Others	Jetrea [®]	Ocriplasmin	15 / 12 / 2016
Others	Akynzeo [®]	Netupitant Palonosetron	15 / 04 / 2016
Hepatitis C	Harvoni [®]	Ledipasvir Sofosbuvir	15 / 03 / 2016
Hepatitis C	Daklinza [®]	Daclatasvir	15 / 03 / 2016
Hepatitis C	Viekira Pak [®]	Dasabuvir Ombitasvir Paritaprevir Ritonavir	15 / 05 / 2016
Hepatitis C	Viekira Pak-Rvb [®]	Dasabuvir Ombitasvir Paritaprevir Ribavirin Ritonavir	15 / 05 / 2016
Diabetes	Jardimet [®]	Empagliflozin Metformin	15 / 03 / 2016
Others	Evotaz [®]	Atazanavir Cobicistat	15 / 04 / 2016
Others	Prezcobix [®]	Cobicistat Darunavir	15 / 10 / 2016
Cancer	Lonquex [®]	Lipegfilgrastim	15 / 11 / 2016
Mental health	Nuvigil [®]	Armodafinil	15 / 11 / 2016
Cardiovascular	Repatha [®]	Evolocumab	15 / 12 / 2016
Cancer	Opdivo [®]	Nivolumab	15 / 05 / 2016
Others	Genvoya [®]	Cobicistat Elvitegravir Emtricitabine Tenofovir Alafenamide	15 / 04 / 2016
Cancer	Lenvima [®]	Lenvatinib	15 / 12 / 2016

Comparison between *COMPARE* reports

Over the three years of *COMPARE*, Australia's position has slightly improved with a higher number of NMEs and an increase in the proportion reimbursed, but challenges remain.

TABLE 4

	COMPARE 1	COMPARE 2	COMPARE 3
Total number of reimbursed NMEs	59 NMEs (Rank 17th)	76 NMEs (Rank 17th)	81 NMEs (Rank 17th)
Proportion of launched	65% (Rank 13th)	63% (Rank 13th)	61% (Rank 15th)
Proportion of reimbursed	39% (Rank 18th)	46% (Rank 18th)	45% (Rank 17th)
Average number of registered per year	25 NMEs	28 NMEs	30 NMEs
Average number of launched per year	19 NMEs	17 NMEs	18.5 NMEs
Average number of reimbursed per year	11 NMEs	13 NMEs	13.5 NMEs

Australia ranks 17th out of 20 OECD countries for the total number of reimbursed NMEs, the same as the first *COMPARE*.

The number of launched NMEs decreased marginally over the last three years, but NMEs registered and reimbursed is on the rise in Australia.

Longitudinal multi-country comparison

This year, an additional analysis has been completed that provides a longitudinal analysis of how each of the 20 OECD countries ranks relative to the leading country for time from registration to reimbursement and access.



FIGURE 7 Longitudinal analysis approach

Based on the three steps, a single ratio score is produced ranking each country compared to the leading country on the number of NMEs that are:

- not registered
- registered only
- registered and private launch
- reimbursed with a delay of over one year
- reimbursed in 6-12 months
- reimbursed under six months.

Australia's Market Access Score

On a market index, Australia scores 48% compared to the leading country's (Germany) time to reimbursement and access.

Country score for COMPARE 3		Change in score compared to COMPARE 2	Change in rank	
1	GER	100%	0.0%	No Change
2	GBR	100%	2.2%	No Change
3	AUT	98%	4.8%	▲ 1
4	USA	94%	-2.3%	▼ -1
5	SWE	81%	0.8%	No Change
6	NED	72%	-0.7%	▲ 1
7	NOR	72%	-1.4%	▲ 2
8	ESP	71%	6.9%	▲ 5
9	IRL	71%	1.5%	▲ 2
10	JPN	70%	-4.9%	▼ -4
11	SUI	70%	-1.6%	▼ -1
12	FIN	69%	-3.6%	▼ -4
13	ITA	68%	3.5%	▼ -1
14	FRA	67%	9.9%	▲ 1
15	BEL	64%	3.0%	▼ -1
16	CAN	48%	0.0%	No Change
17	AUS	48%	1.0%	No Change
18	POR	45%	1.1%	No Change
19	KOR	45%	4.2%	No Change
20	NZL	17%	5.5%	No Change

Ranking

FIGURE 8 Longitudinal comparison of 20 OECD countries' market access

Based on a longitudinal comparison, Australia has slightly improved on COMPARE 2, improving by 1%, although there is still room for improvement. Australia is still 17th which correlates with the overall ranking on time to access.

2016 Additional Analysis: Hepatitis C

In Australia, 2016 was a remarkable year for access to innovative Hepatitis C medicines.

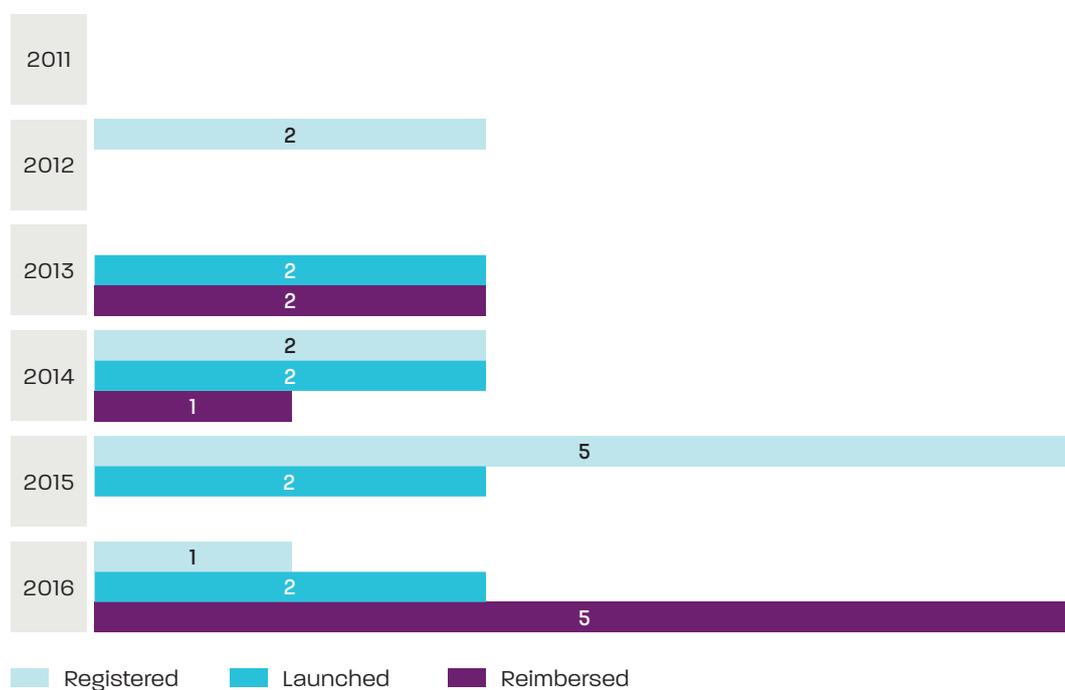


FIGURE 9 Number of NMEs registered, launched and reimbursed: Hepatitis C

For these innovative Hepatitis C medicines:

- Five Hepatitis C NMEs took on average 353 days to achieve reimbursement;
- Sales exceeded \$2.5 billion (excluding rebates) in less than a year post PBS listing; and
- Access to these new medicines has changed how the disease is viewed in Australia, with it expected to be cured within a generation.

Appendixes

APPENDIX A

Method and Approach for *COMPARE*



APPENDIX B

Pricing and reimbursement environment overview for the selected 20 OECD countries

An overview of the system elements of each of the countries included in the analysis is below.

COUNTRY	Price controls	Mandatory HTA	International reference pricing	Internal reference pricing	Generic substitution	Patient co-payment	Industry paybacks
Australia	Yes	Yes	Yes	Yes	Yes	Yes	No
Austria	Yes	Yes	Yes	No	No	Yes	No
Belgium	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Canada	Yes	Yes	Yes	Yes	Yes	Yes	No
Spain	Yes	No	Yes	Yes	Yes	Yes	Yes
Finland	Yes	Yes	Yes	Yes	Yes	Yes	No
France	Yes	Yes	Yes	Yes	Yes	Yes	Yes
United Kingdom	No	Yes	No	No	No	Yes	Yes
Germany	Yes	Yes	Yes	Yes	Yes	Yes	No
Ireland	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Italy	Yes	No	Yes	Yes	Yes	Yes	Yes
Japan	Yes	No	Yes	No	Yes	Yes	No
Korea	Yes	Yes	Yes	No	Yes	Yes	Yes
Netherlands	Yes	Yes	Yes	Yes	Yes	No	No
Norway	Yes	Yes	Yes	Yes	Yes	Yes	No
New Zealand	Yes	Yes	Yes	Yes	Yes	Yes	No
Portugal	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Switzerland	Yes	No	Yes	No	Yes	Yes	Yes
Sweden	Yes	Yes	No	No	Yes	Yes	No
United States	No	No	No	No	Yes	Yes	Yes

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