



Medicines
Australia



compare

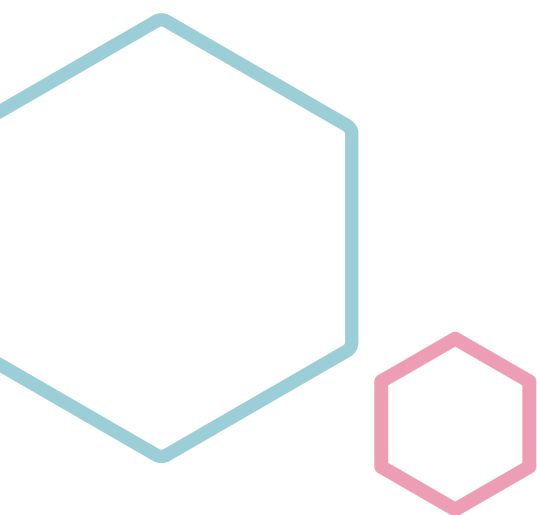
COMPARISON OF ACCESS AND REIMBURSEMENT ENVIRONMENTS

A report benchmarking
Australia's access to
new medicines

EDITION 4 • 2018



Edition 4
2018



Welcome to the fourth annual Comparison of Access and Reimbursement Environments (COMPARE) Report. This report provides information on the current state of access to prescription medicines in Australia and how we compare to 19 similar Organisation for Economic Co-operation and Development (OECD) countries.

The Australian Government provides subsidised prescription drugs to Australians through the Pharmaceutical Benefits Scheme (PBS), as part of the National Medicines Policy (NMP). This policy espouses four objectives:

1. Timely access to medicines that Australians need, at a cost an individual and the community can afford
2. Medicines meeting appropriate standards of quality, safety and efficacy
3. Quality use of medicines
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 IQVIA Consulting Group to undertake an independent analysis and report on how Australian patients fare when compared to 19 other OECD countries. The countries examined were selected because they have comparable Gross Domestic Product (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 462 new medicines that were first registered in the 20 OECD countries over the period 1 January 2012 to 31 December 2017.¹ The time period has been rolled forward one year from the previous COMPARE 3 report for a longitudinal comparison between each successive COMPARE report.

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 2012 and 31 December 2017.



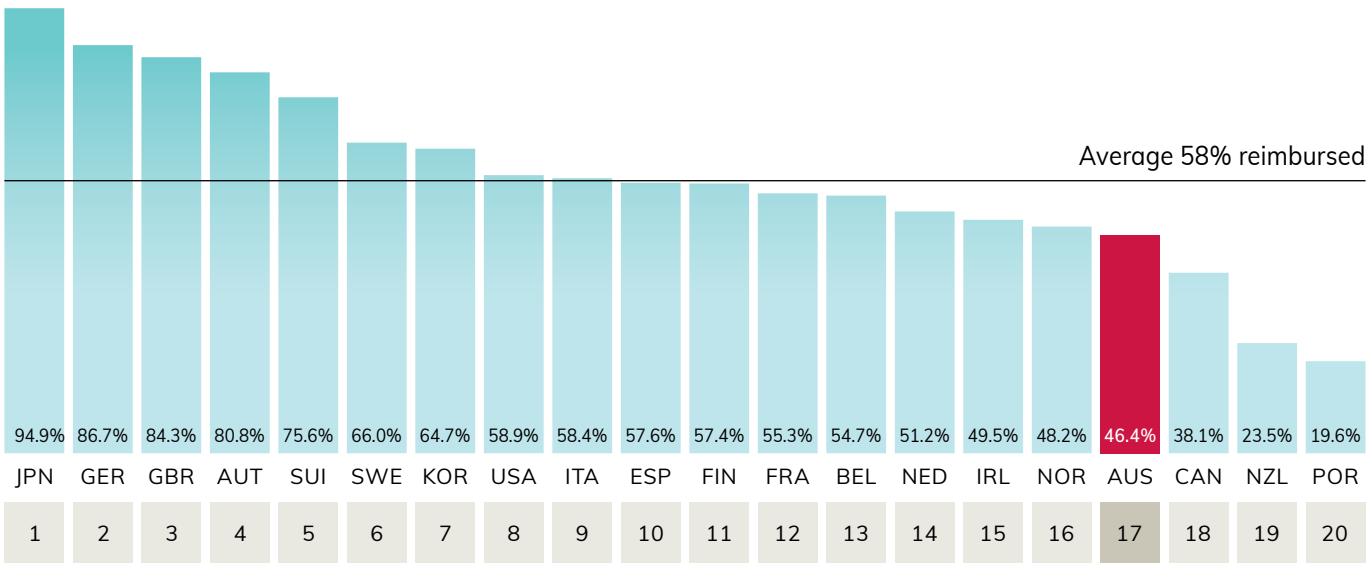
In Australia most NMEs achieved reimbursement more than one year after registration

Key Outcomes

- Australia ranks 17th by proportion of reimbursed New Molecular Entities (NMEs), unchanged from COMPARE 3.
- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed NMEs; unchanged from COMPARE 1,2 and 3.
- On average, it takes almost four times longer for NMEs to achieve reimbursement in Australia (426 days; 56 days longer than in COMPARE 3) than world leaders Japan (89 days; 10 days faster compared to COMPARE 3), Germany (117 days; three days longer in comparison to COMPARE 3) and Great Britain (128; six days faster compared to COMPARE 3).
- Top 10 countries will reimburse NMEs on average within 181 days. This includes time from reimbursement to registration. Australia ranks equal 13th with Belgium taking 426 days for average time to reimbursement from registration.
- Australia compares favourably to top 10 OECD countries for the proportion of reimbursed NMEs due to the 18 reimbursement approvals in 2017. Although the number of reimbursed NMEs decreased, the time to reimbursement from registration still varies considerably between national health priorities: Cancer (610 days), mental health (467 days), arthritis (414 days) Diabetes (234 days) and Asthma (262 days).
- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed First-in-Class (FIC) medicines and 16th in NMEs with expedited designation, up one position from COMPARE 3.
- 60 NMEs were registered but not reimbursed in Australia (figures current at end of December 2017), down from 100 in COMPARE 3.

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

46% of medicines registered between 2012 and 2017 in Australia have subsequently been reimbursed in Australia.



Ranking

FIGURE 1 Proportion of NME’s reimbursed of those registered in each country, 2012-2017

This is a slight increase in the proportion of NMEs that were reimbursed after registration to the COMPARE 3.

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).

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

**Australia lists
around 40
per cent of all
possible first
class medicines
on the PBS**

Australia has reimbursed 43% of all the possible first-in-class medicines that could be listed on the PBS.

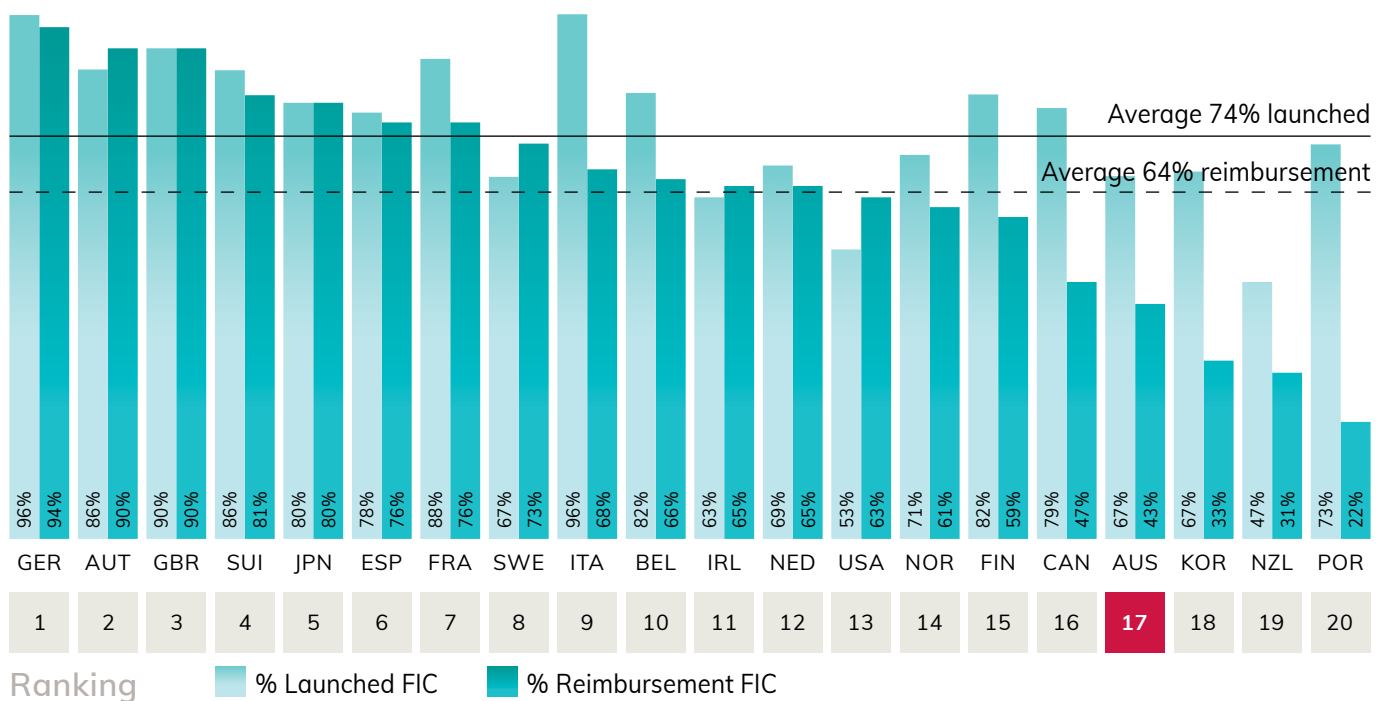
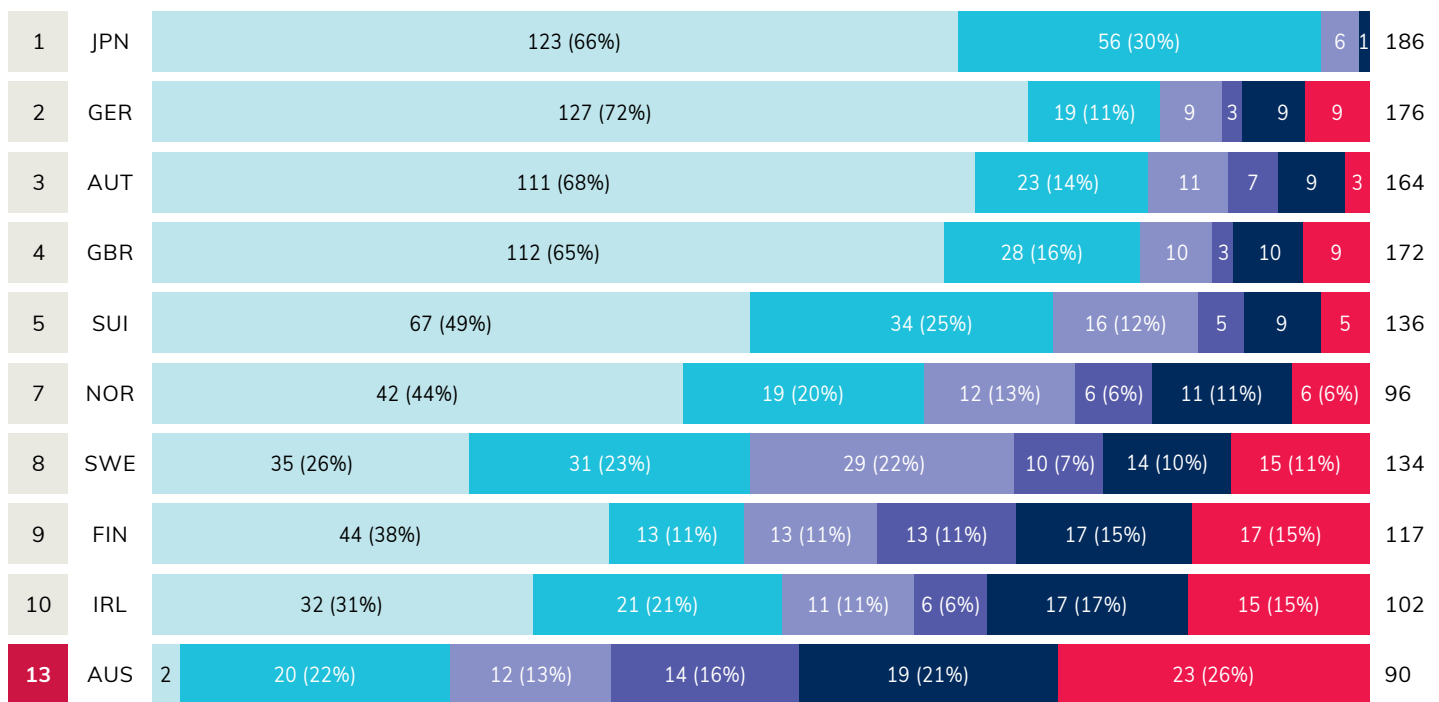


FIGURE 2 Proportion of FIC medicines launched and reimbursed per country over NMEs registered in each country, 2012-2017

FIC refers to innovative products considered important enough to have expedited, breakthrough or priority assessments. While access to FIC medicines in Australia has improved from 27% in COMPARE 1 we ranked 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 462 medicines analysed in the report are not registered in Australia. Ninety of those registered were also reimbursed. Of those, 42 took more than a year, and 26 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 two NMEs got reimbursement in under three months are: Nesina, Tivicay.
 Note: USA takes on average 180 days to reimburse all products – not represented here.

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

Australia listed 22 new medicines for reimbursement within a 6-month timeframe. This is a slightly reduced figure than that reported in COMPARE 3.

Two medicines achieved reimbursement in under two months in Australia.

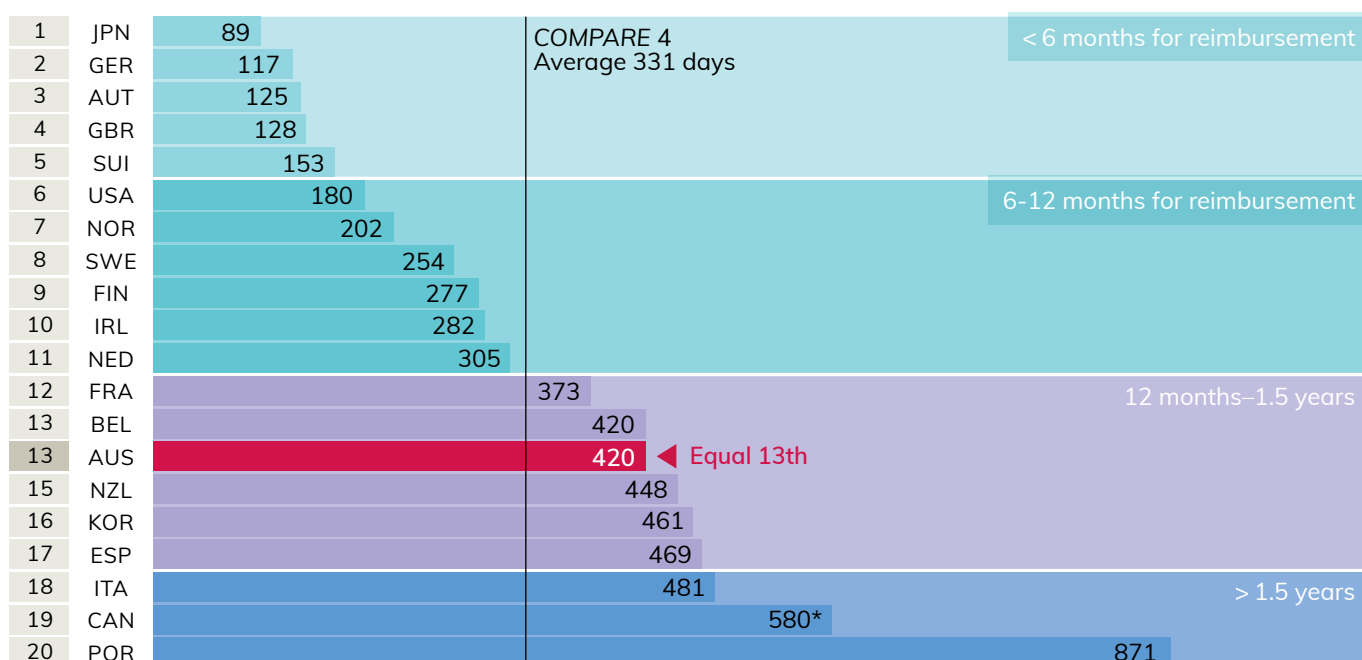
The top OECD countries include Japan, Germany, and Great Britain. These countries all reimbursed over 100 medicines within a three month time frame.

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



The average time to reimbursement from registration in Australia is 27% longer than the OECD average.

The average time to reimbursement has increased to 331 days compared to the 313 in COMPARE 3.



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 2012-2017

Australia is about three months behind the OECD average time to reimbursement. Our average is longer than the world-leading countries such as Japan, Germany, and Great Britain.

Australia is now equal 13th with Belgium.

New Zealand has increased four places for NMEs registered and reimbursed, however, a large number of NMEs still await reimbursement.

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	259	143-519
Cancer	610	110-1,801
Cardiovascular Disease	528	222-1,007
Dementia	0	N / A
Diabetes	217	89-419
Hepatitis C	320	139-624
Mental health	467	149-785
Obesity	0	N / A
Others	338	88-1,049
Average	420	

FIGURE 5 Average time from registration to reimbursement (days) for new medicines by National Health Priority 2012-2017

Figure 5 above 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 NME of 420 days, at 217 and 259 days respectively.

New cancer and cardiovascular medicines become available at least three months later than the average new medicine in Australia.



There are 31 new medicines that are reimbursed in 10 or more 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

	THERAPY AREA							
	Arthritis	Asthma/ COPD	Cancer	Cardiovascular	Diabetes	HepC	Mental health	Others
Number of Products not reimbursed in Au	1	2	20	2	3	1	1	30
Months behind average reimbursement date	26	22	20	16	36	19	37	26
Months behind first reimbursement country	35	27	32	23	48	29	38	34

Table 1 above 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.

60 NMEs are registered but not reimbursed in Australia (reimbursed by the end of December 2017),

79 NMEs registered before January 2017 are still waiting for reimbursement.

The 8 NMEs for arthritis, respiratory, cardiovascular and diabetes have been reimbursed in other OECD countries.

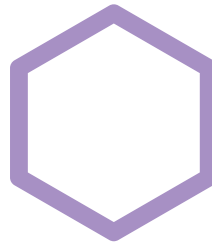
For cancer, 20 NMEs are registered, all have obtained reimbursement status in other OECD countries.

Six of those are launched privately in Australia.

Four NMEs are newly PBS listed in Australia in 2018. Due to the time cut-off they were not counted for the subsequent analyses; they are:

- Kyprolis and Alecensa reimbursed from 1 January 2018
- Ocrevus reimbursed from 1 February 2018
- Xigduo, Odomzom, Tecentriq (efficient funding of chemo) reimbursed from 1 April 2018
- Briviact, Giotrif reimbursed in May 2015
- Picato is RPBS listed only.

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



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

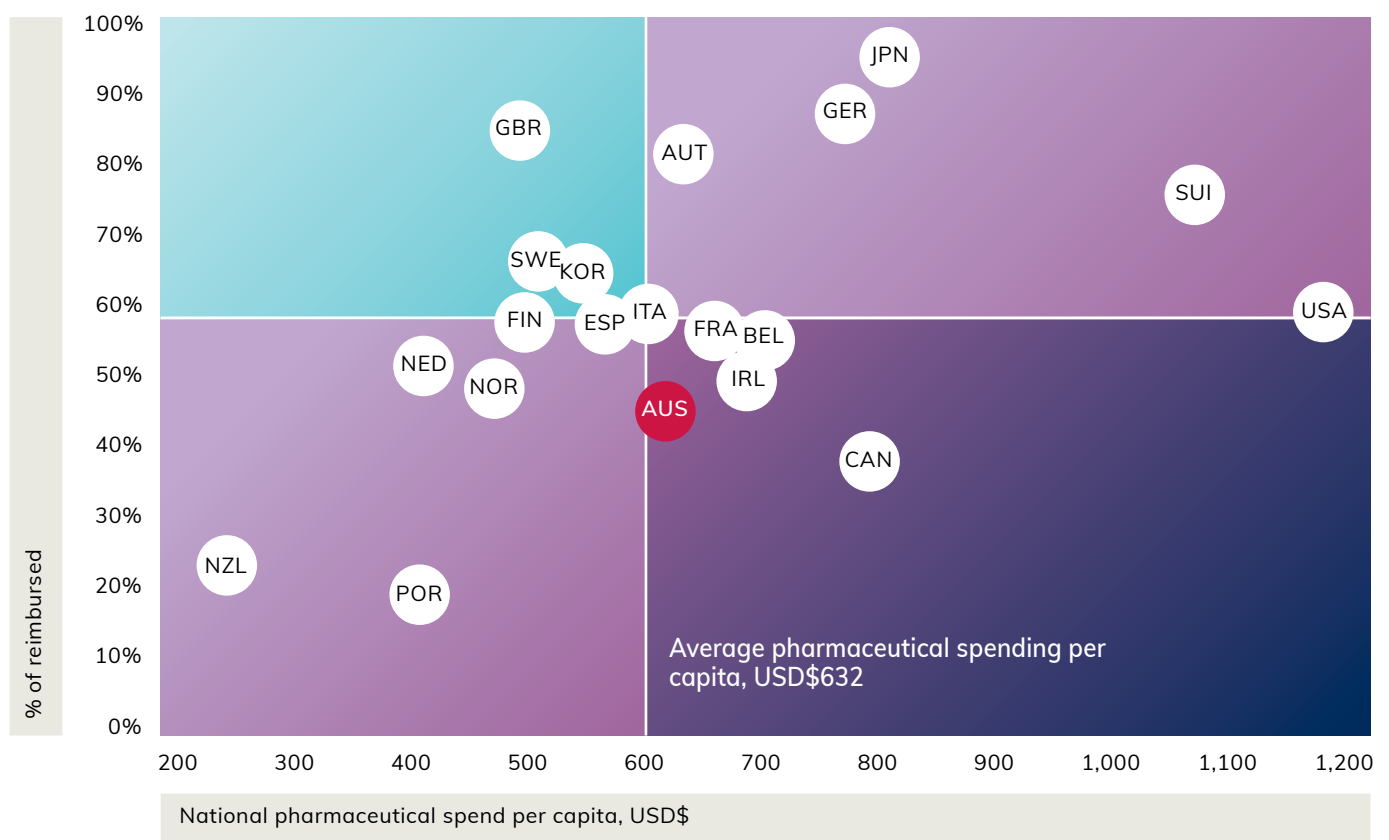


FIGURE 6 Proportion of NMEs reimbursed (2012-2017) vs. pharmaceutical spending per capita

Japan, Germany and Great Britain, for example outperform other countries when comparing the value gained by publicly funding medicines. The chart shows that Great Britain reimburses 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 30 December 2017. 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

Molecule	Product	Therapy Area	Months behind average reimbursement date	Months behind first reimbursement country
Apremilast	OTEZLA	Arthritis	26	35
Reslizumab	Cinqair	Asthma/COPD	11	16
Afatinib	Giotrif	Cancer	44	51
Regorafenib	Stivarga	Cancer	43	58
Bosutinib	Bosulif	Cancer	44	59
Radium Ra-223	Xofigo	Cancer	34	50
Ramucirumab	Cyramza	Cancer	29	39
Sonidegib	Odomzo	Cancer	24	24
Siltuximab	Sylvant	Cancer	30	43
Talimogene Laherparepvec	Imlygic	Cancer	1	1
Panobinostat	Farydak	Cancer	24	29
Osimertinib	Tagrisso	Cancer	17	23
Elotuzumab	Empliciti	Cancer	15	20
Ixazomib	Ninlaro	Cancer	12	20
Carfilzomib	Kyprolis	Cancer	23	60
Venetoclax	Venclexta	Cancer	11	15
Alectinib	Alecensa	Cancer	11	39
Palbociclib	Ibrance	Cancer	12	29
Tipiracil# Trifluridine	Lonsurf Combinat.T	Cancer	14	44
Daratumumab	Darzalex	Cancer	14	20
Atezolizumab	Tecentriq	Cancer	4	14
Ribociclib	Kisqali	Cancer	3	4
Selexipag	Upravi	Cardiovascular	12	19
Alirocumab	Praluent	Cardiovascular	20	27
Lixisenatide	Lyxumia	Diabetes	45	59
Dulaglutide	Trulicity	Diabetes	27	36
Asunaprevir	Sunvepra	HepC	19	29
Suvorexant	Belsomra	Mental health	37	38

Molecule	Product	Therapy Area	Months behind average reimbursement date	Months behind first reimbursement country
Elvitegravir	Vitekta	Others	49	50
Catridecacog	Novothirteen	Others	36	42
Turoctocog Alfa	Novoeight	Others	38	48
Nonacog Gamma	Rixubis	Others	22	39
Vortioxetine	Brintellix	Others	29	46
Eftrenonacog Alfa	Alprolix	Others	17	39
Taliglucerase Alfa	Elelyso	Others	63	63
Efmroctocog Alfa	Eloctate	Others	18	34
Simoctocog Alfa	Nuwiq	Others	27	38
Elosulfase Alfa	Vimizim	Others	29	43
Eliglustat	Cerdelga	Others	18	35
Ceftolozane# Tazobactam	Zerbaxa	Others	22	26
Naloxegol	Movantik	Others	20	34
Asfotase Alfa	Strensiq	Others	24	27
Susoctocog Alfa	Obizur	Others	17	21
Idarucizumab	Praxbind	Others	21	25
Brivaracetam	Briviact	Others	19	24
Albutrepenonacog Alfa	Idelvion	Others	15	19
Bazedoxifene# Estrogenic Substances, Conjugated	Duavive	Others	N/A*	N/A*
Follitropin Delta	Rekavelle	Others	N/A*	N/A*
Lonoctocog Alfa	Afstyla	Others	5	11
Teduglutide	Revestive	Others	34	55
Migalastat	Galafold	Others	13	19
Nusinersen	Spinraza	Others	4	7
Bezlotoxumab	Zinplava	Others	4	10
Patiromer Calcium	Veltassa	Others	N/A*	N/A*

* These products have not been reimbursed anywhere in the world.



The following new medicines were listed on the PBS in 2017. This list will be updated each year to highlight the new innovative medicines made available for patients since the previous COMPARE report.

TABLE 3

Product	Molecule	Reimbursement by 2017	NHP area
Zelboraf	Vemurafenib	15/04/2017	Cancer
Erivedge	Vismodegib	15/04/2017	Cancer
Adempas	Riociguat	15/01/2017	Cardiovascular
Zydelig	Idelalisib	15/09/2017	Cancer
Imbruvica	Ibrutinib	15/12/2017	Cancer
Ofev	Nintedanib	15/05/2017	Others
Blinicyto	Blinatumomab	15/05/2017	Cancer
Lynparza	Olaparib	15/02/2017	Cancer
Entresto	Sacubitril#Valsartan	15/06/2017	Cardiovascular
Nucala	Mepolizumab	15/01/2017	Asthma/COPD
Esbriet	Pirfenidone	15/07/2017	Others
Zykadia	Ceritinib	15/02/2017	Cancer
Cotellic	Cobimetinib	15/04/2017	Cancer
Zepatier	Elbasvir#Grazoprevir	15/01/2017	HepC
Taltz	Ixekizumab	15/02/2017	Others
Zinbryta	Daclizumab	15/05/2017	Others
Epclusa	Sofosbuvir#Velpatasvir	15/08/2017	HepC
Rexulti	Brexpirazole	15/10/2017	Mental health

Comparison between COMPARE Reports

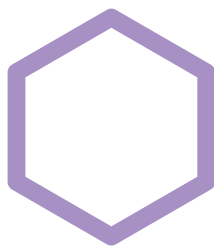
Over the four years of COMPARE, Australia's position has slightly improved with a higher number of NMEs and an increase in the proportion reimbursed, but challenges remain.

TABLE 4

	COMPARE 1	COMPARE 2	COMPARE 3	COMPARE 4
Total number of reimbursed NMEs	59 NMEs (Rank 17th)	76 NMEs (Rank 17th)	81 NMEs (Rank 17th)	90 NMEs (Rank 17th)
Proportion of launched	65% (Rank 13th)	63% (Rank 13th)	61% (Rank 15th)	62% (Rank 13th)
Proportion of reimbursed	39% (Rank 18th)	46% (Rank 18th)	45% (Rank 17th)	46% (Rank 17th)
Average number of registered per year	25 NMEs	28 NMEs	30 NMEs	32.3 NMEs
Average number of launched per year	19 NMEs	17 NMEs	18.5 NMEs	20 NMEs
Average number of reimbursed per year	11 NMEs	13 NMEs	13.5 NMEs	15 NMEs

- Australia ranks 17th out of 20 OECD countries for the total number of reimbursed FIC medicines and 16th for NMEs with expedited designation.
- Percentages of reimbursed innovative NMEs are increasing in other countries.
- The proportion of innovative NMEs launched and/or reimbursed in Australia is below average compared to other OECD countries. 62% of NMEs are launched in Australia versus over 68% for the average launch rate amongst the 20 countries. 462 unique NMEs were analysed among 20 OECD countries.
- The total numbers of registered/launched/reimbursed NMEs per country is on the rise across 20 OECD countries.
- Australia ranks 13th by proportion of launched NMEs, an improvement of two places.
- 46% of available NMEs are reimbursed in Australia.

Longitudinal multi-country comparison



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.

Approach



Check list by using this score

- A single number measurement of market access.
- A relative score against the number one ranked country.
- Take into consideration each year the set of NMEs can differ.
- Allows longitudinal comparison by year across all countries.
- Stages of market access are weighted.

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 1 year
- reimbursed in 6-12 months
- reimbursed under 6 months.



Australia's Market Access Score

On a market index, Australia scores 44% compared to the leading country's (Germany) time to reimbursement and access.

Country score for COMPARE 4		Change in score compared to COMPARE 3	Change in rank	
1	GER	100%	0.0%	No Change
2	GBR	97%	-3.3%	No Change
3	AUT	92%	-6.5%	No Change
4	USA	85%	-8.9%	No Change
5	SWE	79%	-2.3%	No Change
6	NOR	68%	-4.1%	▲ 1
7	FIN	67%	-1.3%	▲ 5
8	SUI	65%	-4.4%	▲ 3
9	JPN	65%	-4.8%	▲ 1
10	ITA	65%	-3.4%	▲ 3
11	NED	63%	-8.5%	▼ -5
12	FRA	62%	-5.5%	▲ 2
13	ESP	62%	-9.7%	▼ -5
14	BEL	59%	-5.5%	▲ 1
15	IRL	57%	-13.6%	▼ -6
16	KOR	47%	2.2%	▲ 3
17	AUS	44%	-3.5%	No Change
18	CAN	44%	-4.3%	▼ -2
19	POR	42%	-3.2%	▼ -1
20	NZL	12%	-1.8%	No Change

Ranking

FIGURE 8 Longitudinal comparison of 20 OECD countries' market access

There has been a slight regression in Australia's overall market access score by 3.5% in comparison with COMPARE 3. This indicates there is room for further improvement. Australia's ranking remains unchanged, at 17th. Based on a longitudinal comparison, Australia has slightly weakened from COMPARE 2, however, Australia's rank remains unchanged at 17th.

2017 Additional Analysis: Hepatitis C and oncology products

2017 was a good year for oncology products, with eight NMEs reimbursed. However, the delay to reimbursement has extended to 610 days.

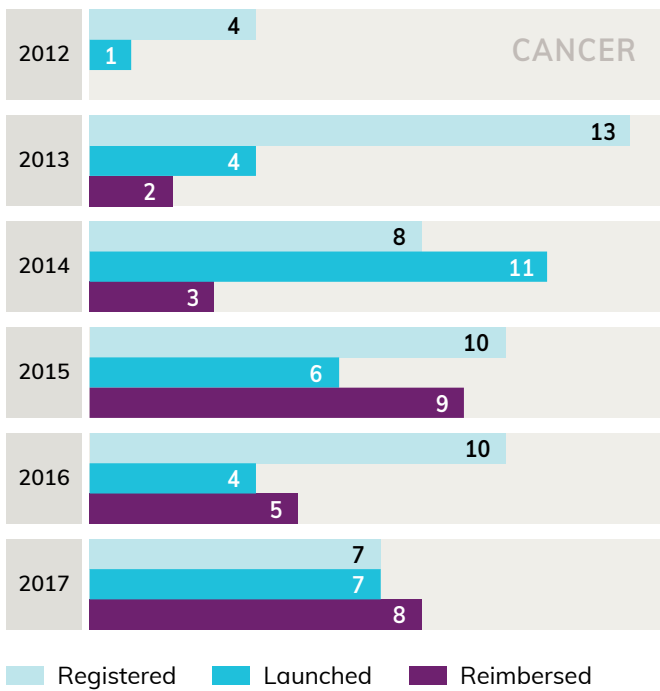


FIGURE 9 Number of NMEs registered, launched and reimbursed: Cancer

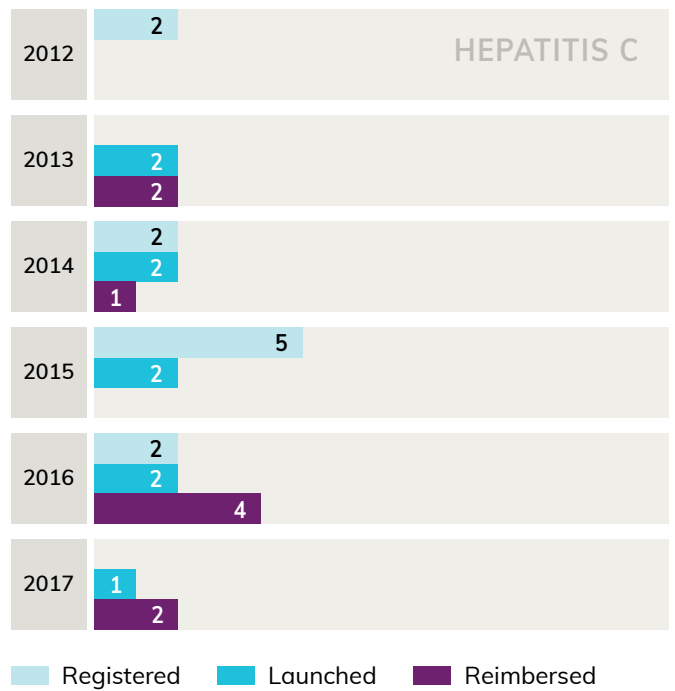


FIGURE 10 Number of NMEs registered, launched and reimbursed: Hepatitis C

In Australia, 2017 saw an additional two Hepatitis C innovative medicines reimbursed. Between 2012 and 2017, the two Hepatitis C NMEs took an average of 322 days to achieve reimbursement between. A total of 11 products were registered.

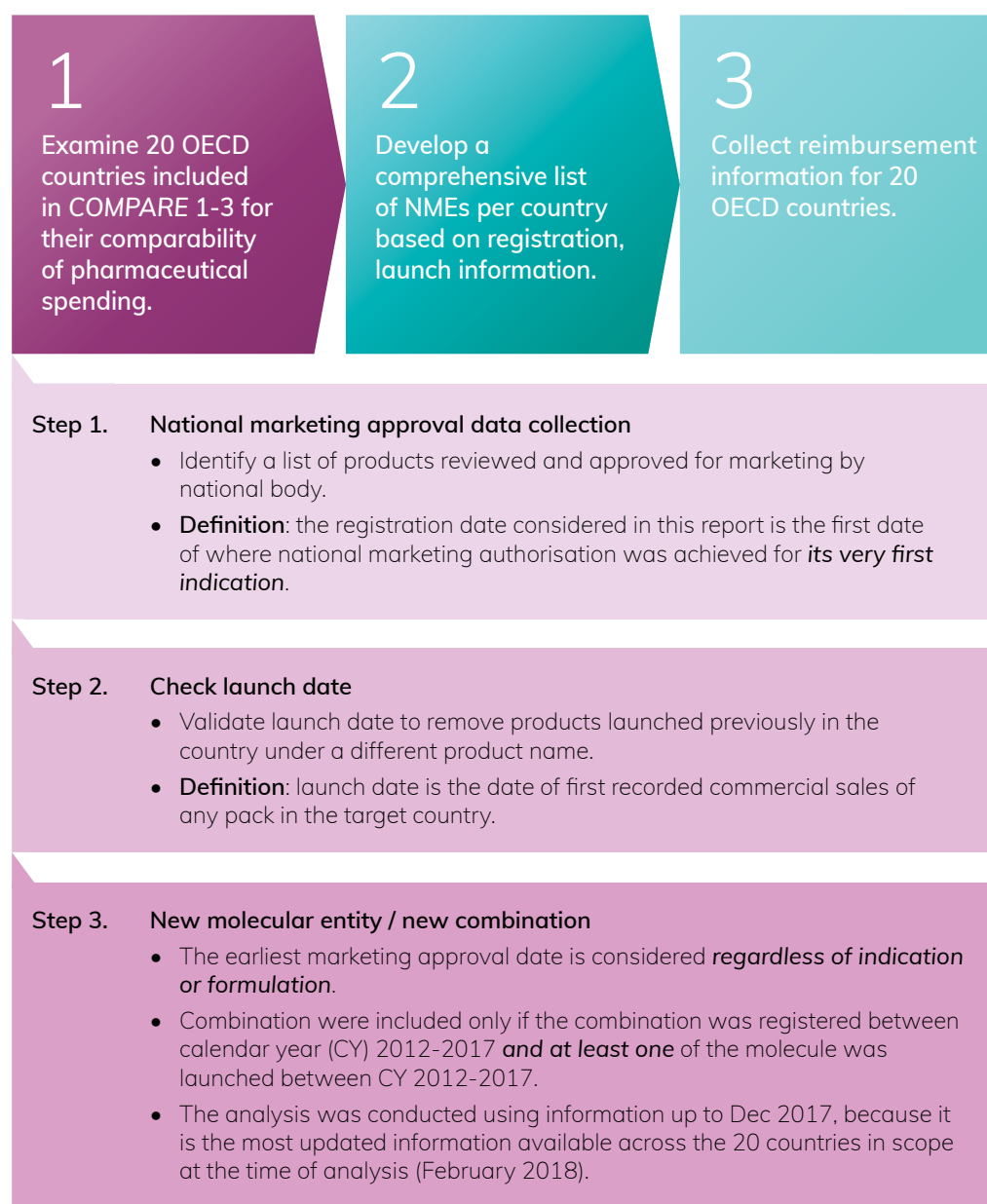
Access to these new medicines has changed how the disease is viewed in Australia, with it expected to be cured within a generation.

Appendixes

APPENDIX A

Method and Approach for COMPARE.

The key notion of product reimbursement was defined across countries to compare access to new medicines.



APPENDIX B

Pricing and reimbursement environment overview for the selected 20 OECD countries.

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

Country code	Country	Price controls	Mandatory HTA	International reference pricing	Internal reference pricing	Generic substitution	Patient co-payment	Industry paybacks
AUS	Australia	Yes	Yes	Yes	Yes	Yes	Yes	No
AUT	Austria	Yes	Yes	Yes	No	No	Yes	No
BEL	Belgium	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CAN	Canada	Yes	Yes	Yes	Yes	Yes	Yes	No
ESP	Spain	Yes	No	Yes	Yes	Yes	Yes	Yes
FIN	Finland	Yes	Yes	Yes	Yes	Yes	Yes	No
FRA	France	Yes	Yes	Yes	Yes	Yes	Yes	Yes
GBR	United Kingdom	No	Yes	No	No	No	Yes	Yes
GER	Germany	Yes	Yes	Yes	Yes	Yes	Yes	No
IRL	Ireland	Yes	Yes	Yes	Yes	Yes	Yes	Yes
ITA	Italy	Yes	No	Yes	Yes	Yes	Yes	Yes
JPN	Japan	Yes	No	Yes	No	Yes	Yes	No
KOR	Korea	Yes	Yes	Yes	No	Yes	Yes	Yes
NED	Netherlands	Yes	Yes	Yes	Yes	Yes	No	No
NOR	Norway	Yes	Yes	Yes	Yes	Yes	Yes	No
NZL	New Zealand	Yes	Yes	Yes	Yes	Yes	Yes	No
POR	Portugal	Yes	Yes	Yes	Yes	Yes	Yes	Yes
SUI	Switzerland	Yes	No	Yes	No	Yes	Yes	Yes
SWE	Sweden	Yes	Yes	No	No	Yes	Yes	No
USA	United States	No	No	No	No	Yes	Yes	Yes



Medicines
Australia

www.medaus.com.au



compare