

EDITION 5

Compare

Comparison
of Access and
Reimbursement
Environments
2019



**Medicines
Australia**

Better health
through research
and innovation

Compare 5

Edition 5, 2019

Glossary	3
Welcome	4
Key Outcomes	5
Comparisons	17
About	22

01. Glossary

National Medicines Policy	A framework based on partnerships between Governments (Commonwealth, States and Territories), health stakeholders, and the medicines industry to work towards timely, affordable medicines, that meet the appropriate standards of quality, safety and efficacy, used appropriately, while maintaining a responsible and viable industry.
Pharmaceutical Benefits Scheme (PBS)	Part of the Government's broader National Medicines Policy and managed by the Department of Health, the scheme subsidises the cost of medicines for most medical conditions providing Australians with access to vital medicines.
Pharmaceutical Benefits Advisory Committee (PBAC)	An independent expert body appointed by the government which makes recommendations for new medicines to be listed on the PBS, based on clinical effectiveness, safety, and cost-effectiveness compared with other treatments.
New Molecular Entity (NME)	These are innovative pharmaceutical medicines (including biological medicines) that contain a molecule first registered in any of the assessed countries between 1 January 2013 and 31 December 2018.
First in Class Medicine (FIC)	A newly developed medicine which has a unique mechanism of action for treating a medical condition compared with existing therapies.
Registration	The first date of where national marketing authorization was achieved for the first edition of the New Molecular Entity.
Launch	The date of first recorded commercial sales of any pack in the target country.
Reimbursement	The first date the New Molecular Entity was granted public reimbursement and/or included in a government-mandated reimbursement formulary, regardless of indication.
National Health Priority Areas	An initiative to focus public attention to health areas which contribute the most illness to the country, namely, cardiovascular disease, cancer, injury prevention, mental health, diabetes mellitus, and asthma.

02. Welcome



Welcome to the fifth 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 medicines 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 primarily on the first objective.

To understand Australia's access and reimbursement environment in a global context, Medicines Australia commissioned IQVIA Consulting Group to undertake an independent analysis and report on how Australian patients fare when compared to 19 other OECD countries. The OECD countries examined were selected because they have comparable Gross Domestic Product (GDP) values and health expenditure as a proportion of GDP to Australia, or they are considered a regional partner.

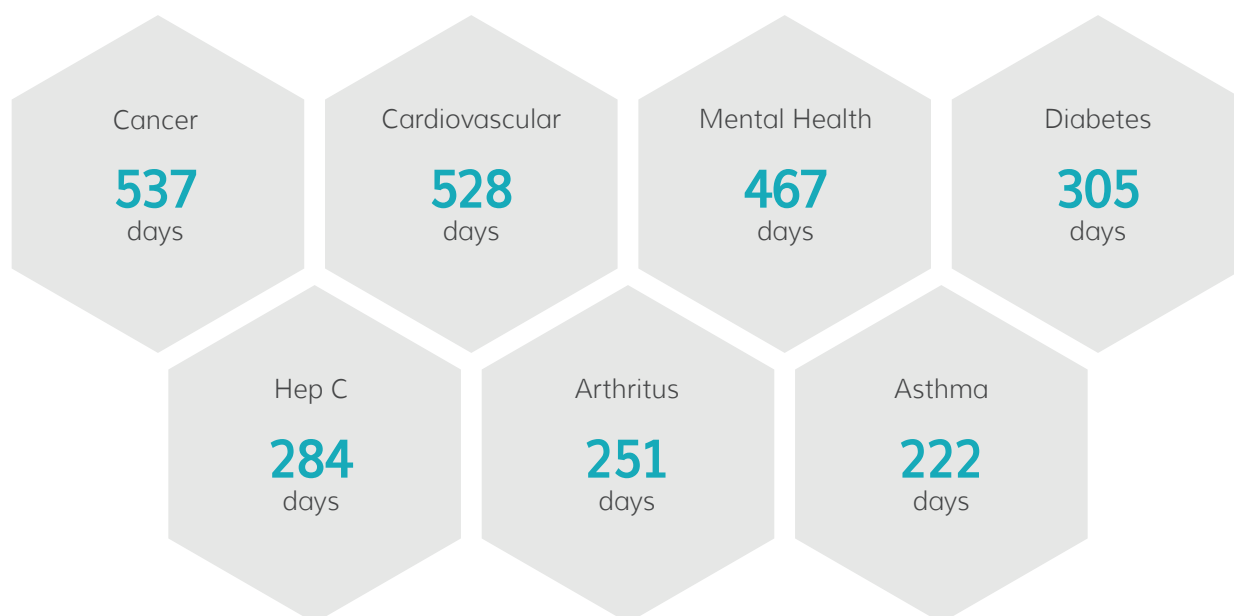
Building on the previous COMPARE reports, the analysis reviewed 520 New Molecular Entities (NMEs) that were first registered in the 20 OECD countries from 1 January 2013 to 31 December 2018. The time period has been rolled forward one year from the previous COMPARE 4 report for a longitudinal comparison between each successive COMPARE report.

The Australian public have high expectations for government to deliver a world-class healthcare system, which includes universal access to new medicines as a foundation component of that system. Compare 5 provides an insight to Australia's system of access, and how it performs compared to similar OECD nations.

03. Key Outcomes

Over the five years of COMPARE, Australia has **improved the number of NMEs reimbursed** and the proportion of NMEs reimbursed.

- Australia ranks 17th out of 20 comparable nations for the total number of reimbursed NMEs (97 NMEs), the same rank as COMPARE 4.
- Australia ranks 15th out of 20 comparable nations for the proportion of registered NMEs which have been reimbursed (50%), up from the rank of 17th in COMPARE 4.
- Australia ranks 13th out of 20 comparable nations for the proportion of registered First-In-Class (FIC) medicines which have been reimbursed (53%), a big improvement from the rank of 17th in COMPARE 4.
- Australia ranks 13th out of 20 comparable nations for the average time from registration to reimbursement, the same rank as COMPARE 4.
- It takes roughly three to four times longer for NMEs to achieve reimbursement in Australia (410 days) than world leaders Japan (98 days), Germany (119 days), Austria (148 days), and Switzerland (149 days).
- NME registration to reimbursement time frames vary significantly between the national health priority areas of:



- 57 NMEs were registered but not reimbursed in Australia (figures current at end of December 2018), down from 60 in COMPARE 4.
- Australia's pharmaceutical spending per capita is below the comparable OECD nation average.
- Australia ranks 16th out of 20 comparable nations for new medicine market access, an improvement on the rank of 17th in COMPARE 4.

Australia ranks 17th out of 20 comparable nations for the total number of reimbursed NMEs.

Between 2013 and 2018 Australia reimbursed 97 NMEs, of which 31 were FIC medicines.

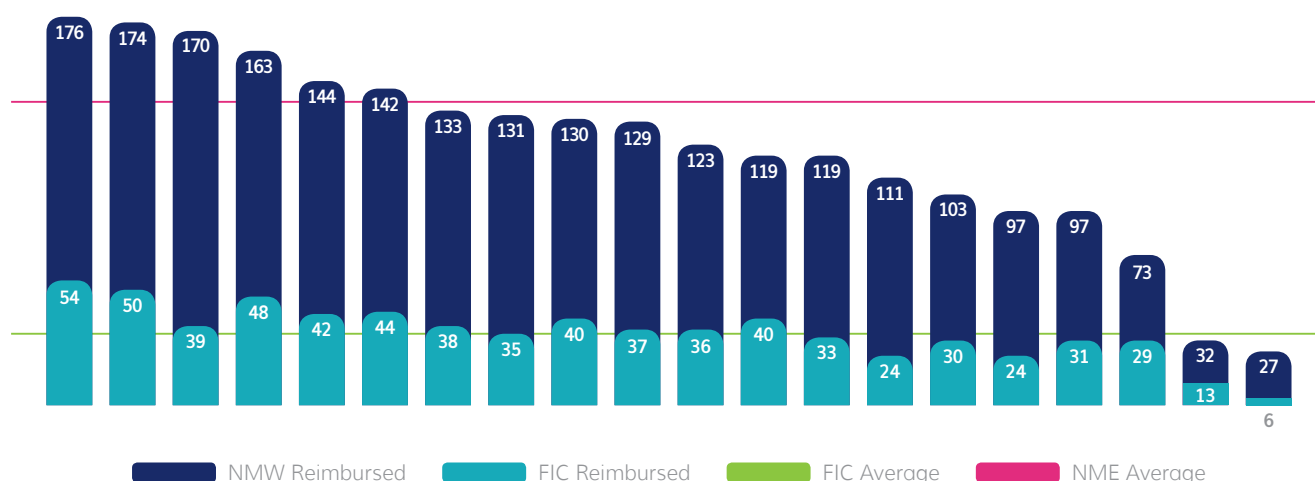


Figure 1: The number of NMEs and FIC's reimbursed in Australia and each comparable country between 2013 and 2018.

Between 2013 and 2018 Australia had fewer NMEs reimbursed¹ compared to the average of the 20 comparable OECD nations. Australia reimbursed 97 NMEs in this time period, compared to an OECD average of 119.65. The gap to the top four comparable nations of Germany, Australia, Japan and Great Britain was more pronounced.

Between 2013 and 2018 Australia had slightly fewer FIC medicines reimbursed compared to the average of the 20 comparable OECD nations. Australia reimbursed 31 FIC medicines in this time period, compared to an OECD average of 34.65.

Australia's rank of 17th for the number of NMEs reimbursed was the same rank as the last report, although there was a slight increase in the number of NMEs reimbursed, with 97 recorded, up from 90.

¹ During this time Australia also had fewer NMEs registered and launched compared to the average of the 20 OECD nations. For FIC medicines, Australia had more registered than the average, but fewer launched.

Australia ranks 15th out of 20 comparable nations for the proportion of reimbursed NMEs

Between 2013 and 2018 Australia reimbursed 50.3% of registered NMEs.

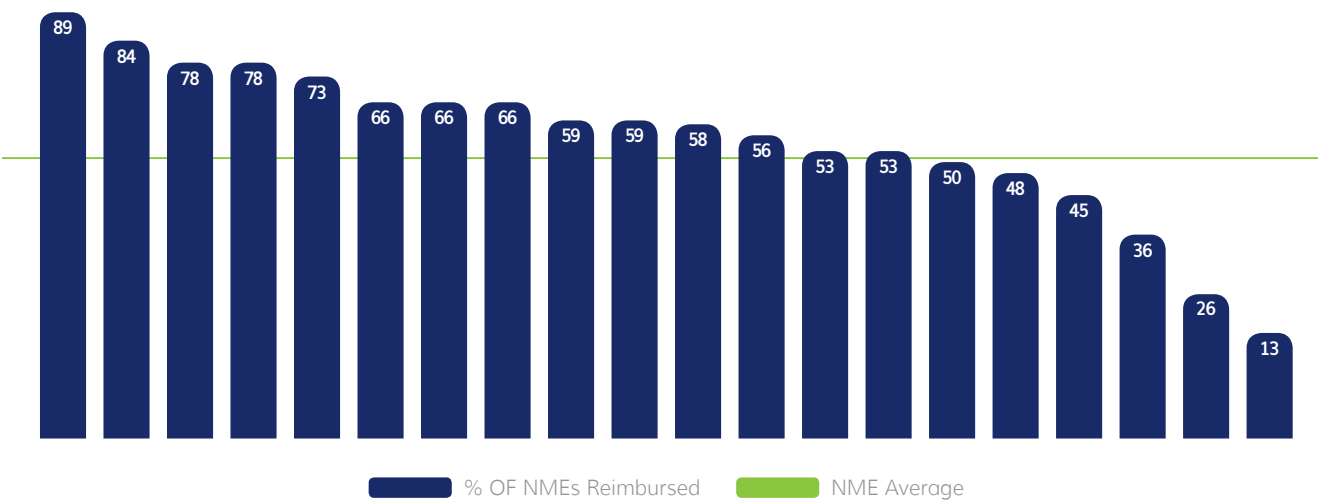


Figure 2: The proportion of NMEs reimbursed in Australia and each comparable country between 2013 and 2018.

Between 2013 and 2018 Australia was below the OECD comparable average for reimbursement proportions of NMEs of 58.2%. Australia’s reimbursement proportion is even further behind leading nations of Japan, Germany, Austria and Great Britain.

Australia ranks 15th out of 20 comparable nations for the proportion of reimbursed NMEs, which is an improvement on the rank of 17th recorded in 2018. Australia’s proportion of reimbursed NMEs has increased to 50.3% from 46.4% a year ago.

Australia ranks 13th out of 20 for the proportion of reimbursed FIC medicines.

Between 2013 and 2018 Australia reimbursed 53% of registered FIC medicines.



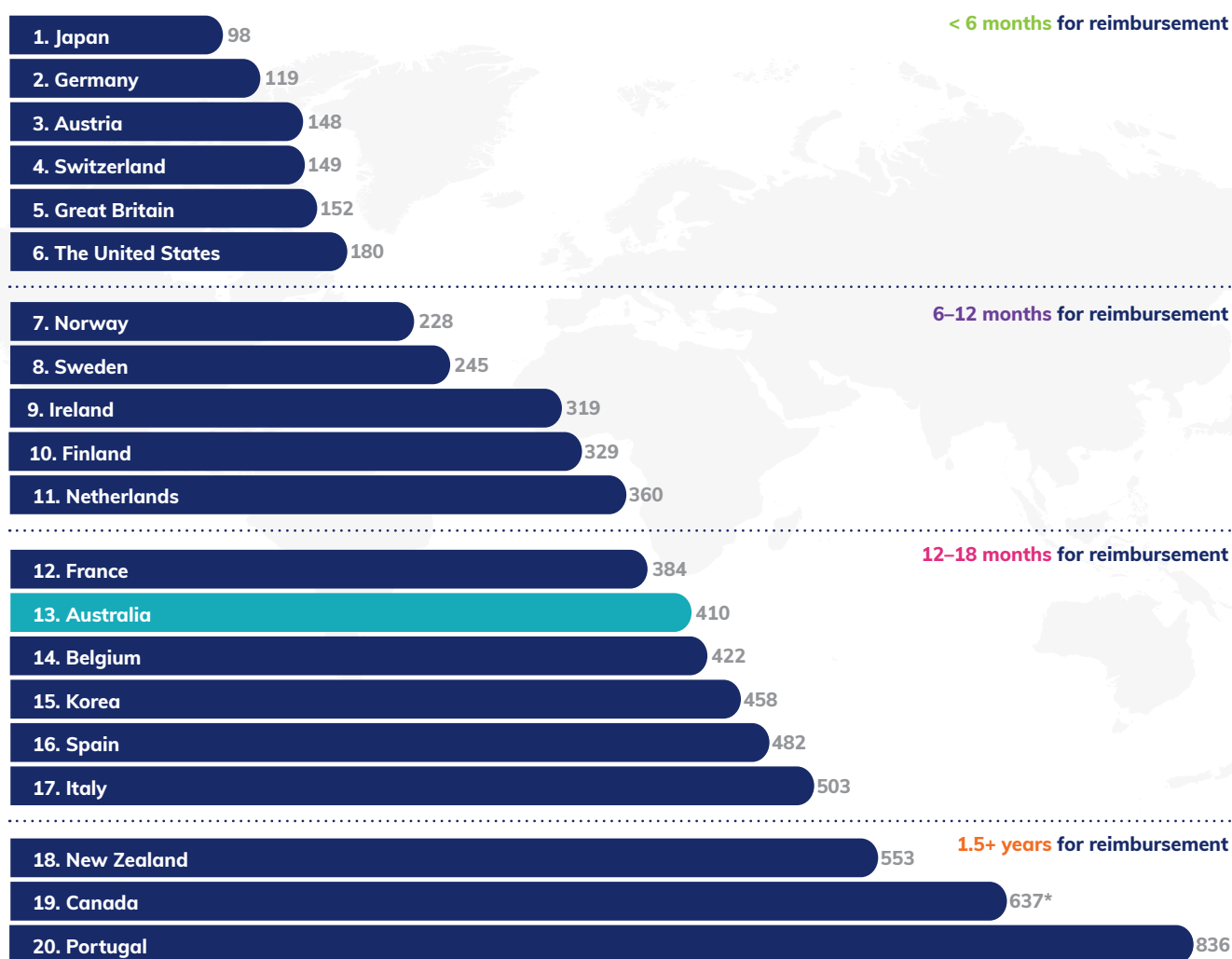
Figure 3: The proportion of FIC medicines launched and reimbursed in each comparable country between 2013 and 2018.

FIC medicines are commonly innovative products, and they can often be considered for expedited, breakthrough or priority assessments. Australia ranks 13th out of 20 comparable nations for the proportion of reimbursed FIC medicines, a notable improvement on the rank of 17th recorded in the previous report.

Between 2013 and 2018 Australia was below the OECD comparable average for reimbursement proportions of FIC medicines. Australia was also behind the OECD comparable average for the proportion of FIC medicines launched in this time period.

Australia ranks 13th out of 20 comparable OECD nations for the average time from NME registration to reimbursement.

Between 2013 and 2018 the average time to reimbursement for an NME in Australia was 410 days.



*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.

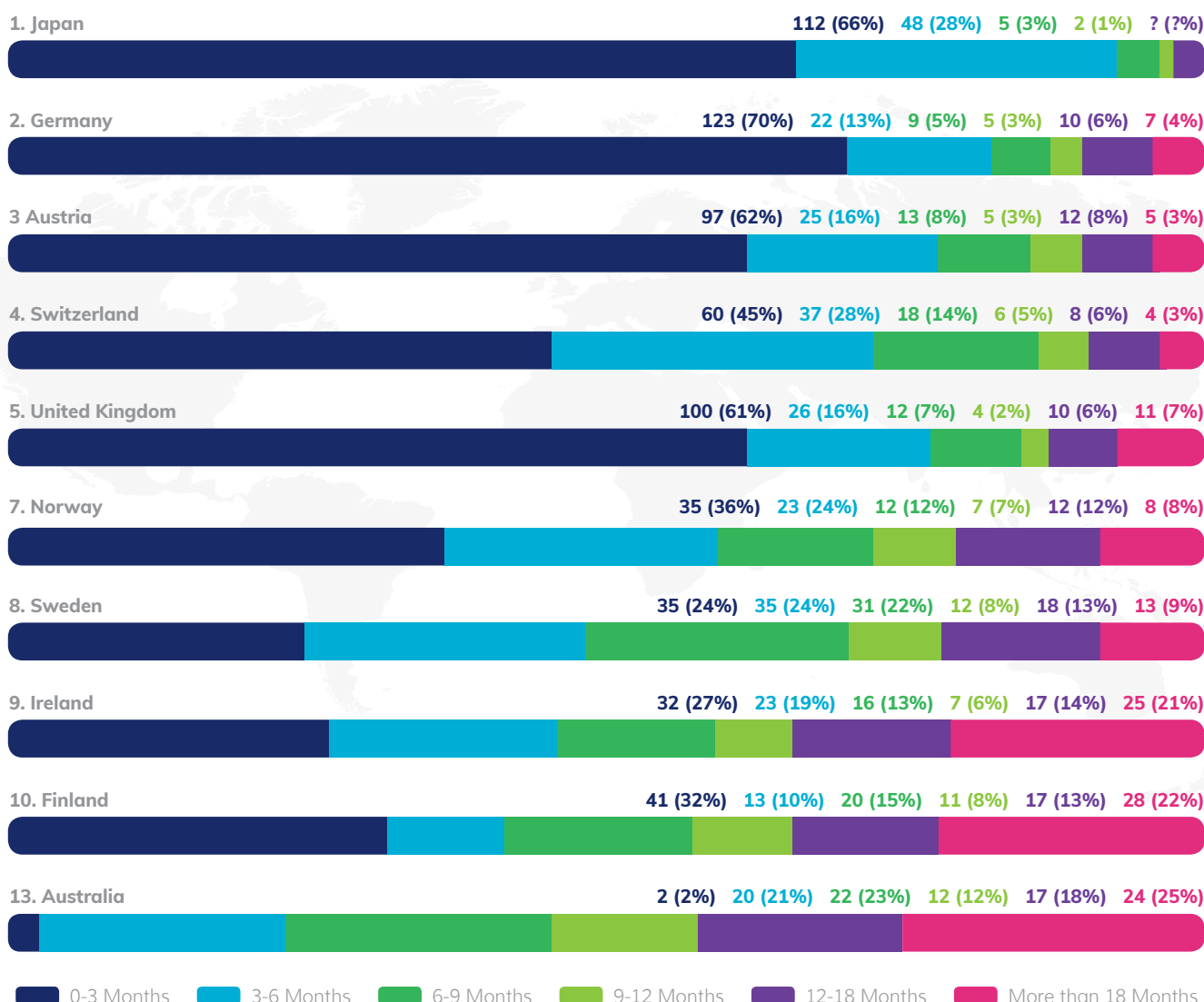
Figure 4: The average time to reimbursement from registration (days) in comparable OECD countries, for NMEs registered between 2013 and 2018.

Between 2013 and 2018 Australia (410 days) was behind the 20 OECD countries average (351 days) for the average time it takes for an NME to be reimbursed from its registration date. This average time frame is notably longer than the average in world-leading countries such as Japan (98 days), Germany (119 days), Austria (148 days), Switzerland (149 days), and Great Britain (152 days).

Australia's time frame of 410 days, has shortened slightly from the average time frame of 420 days since the last report, resulting in an improvement of one-place, and a ranking of 13th out of 20.

Australia's NME reimbursement time frames are improving but are slower than the top performing OECD nations.

Between 2013 and 2018 Australia reimbursed 58% of NMEs within 12 months of registration.



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

Figure 5: The time frames from registration to reimbursement for Australia compared to the top performing OECD nations.

Between 2013 and 2018 Australia listed 22 NMEs (23% of all reimbursements in this time frame) within a six-month period. The top OECD countries have high proportions of reimbursement within a six-month time frame; leaders are Japan (94%), Germany (82%), Austria (78%), Switzerland (73%), and Great Britain (77%).

The top five nations had less than 15% of reimbursements taking 12 months or longer, compared to 42% for Australia.

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

NME registration to reimbursement time frames vary significantly between the national health priority areas.

The Australian Government has National Health Priority Areas on which it seeks to focus public attention and advance health policy.

The average time to list a new cancer, cardiovascular, mental health or arthritis medicines was longer than Australia’s overall average time².

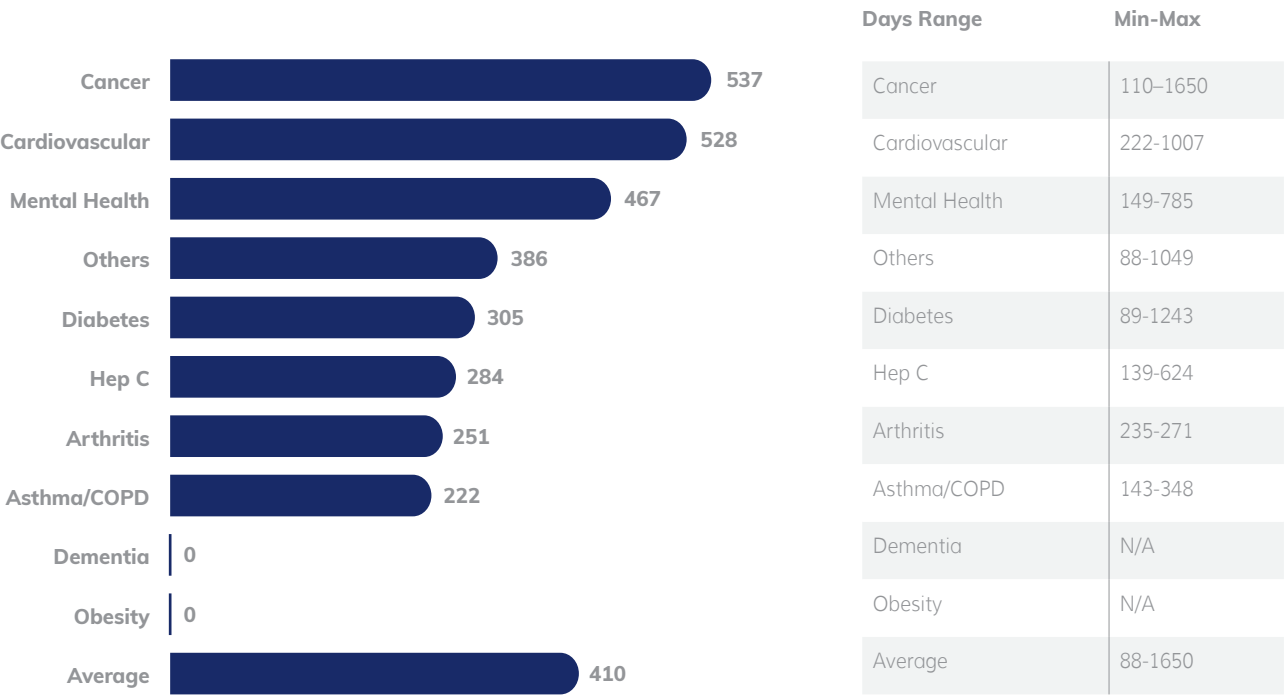


Figure 6: The average time from registration to reimbursement (days) for new medicines by National Health Priority 2013-2018.

Between 2013 and 2018 the time from registration to reimbursement varied significantly between national health priority areas, with the longest time frames for NMEs for cancer (537 days), cardiovascular disease (528 days) and mental health (467 days).

Diabetes (305 days), Hep C (284 days), arthritis (251 days) and asthma (222 days) are reimbursed on average at a quicker rate than the overall average time.

While cancer makes up the largest proportion of NMEs registered in Australia by health area, they also have the longest average time frame to reimbursement. Cardiovascular NMEs have the second longest wait time of NMEs, however, there are much fewer numbers of these NMEs registered.

² This is the average time from the registration date of the very first indication through to the date of public reimbursement, regardless of indication. Subsequent reimbursement for different indications are not included.

What medicines are we still waiting for?

The following lists of medicines have been registered in Australia between 2013 and 2018³ but have not been reimbursed as of December 2018. These NMEs have been reimbursed in at least one other comparable OECD country.

Table 1: Cancer NMEs registered in Australia but not yet reimbursed 2013–2018.

Therapy Area	Product Name	Molecule	% of other OECD Countries Reimbursed	Months behind ARD	RIA	Launched
Cancer	Sylvant	Siltuximab	85	39	Aug 2015	No
Cancer	Tagrisso	Osimertinib	80	23	Aug 2016	Yes
Cancer	Cyramza	Ramucirumab	75	39	Jul 2015	No
Cancer	Darzalex	Daratumumab	75	24	Jul 2017	No
Cancer	Ninlaro	Ixazomib	70	15	Nov-16	No
Cancer	Ibrance	Palbociclib	70	17	May 2017	Yes
Cancer	Venclexta	Venetoclax	65	16	Jan 2017	Yes
Cancer	Empliciti	Elotuzumab	65	25	Sep 2016	No
Cancer	Bavencio	Avelumab	60	10	Jan 2018	No
Cancer	Farydak	Panobinostat	55	34	Mar 2016	No
Cancer	Besponsa	Inotuzumab Ozogamicin	55	12	May 2018	Yes
Cancer	Xofigo	Radium Ra-223	50	46	May 2014	Yes
Cancer	Xermelo	Telotristat Etiprate	40	8	Sep 2018	No
Cancer	Imfinzi	Durvalumab	30	2	Oct 2018	No
Cancer	Erleada	Apalutamide	5	5	Jul 2018	No
Cancer	Imlygic	Talimogene Laherparepvec	5	13	Dec 2015	No

Table 2: Health priority areas – NMEs registered in Australia between 2013-2018 but not yet reimbursed

Therapy Area	Product Name	Molecule	% of other OECD Countries Reimbursed	Months behind ARD	RIA	Launched
RA	Otezla	Apremilast	60	38	Mar 2015	Yes
RA	Kevzara	Sarilumab	60	10	Sep 2018	No
Resp	Cinqair	Reslizumab	55	20	Jul 2017	No
Cardio	Uptravi	Selexipag	75	22	Mar 2016	No
Cardio	Praluent	Alirocumab	70	29	Mar 2016	No
Diab	Lyxumia	Lixisenatide	65	58	Apr 2013	No
Diab	Soliqua	Insulin Glargine, Lixisenatide	5	10	Oct 2017	No
Hep C	Sunvepra	Asunaprevir	10	31	May 2015	No
Hep C	Vosevi	Sofosbuvir, Velpatasvir, Voxilaprevir	70	10	Mar 2018	No
Mental Health	Brintellix	Vortioxetine	75	41	Mar 2014	Yes
Mental Health	Belsomra	Suvorexant	10	49	Nov 2016	Yes
Psoriasis	Tremfya	Guselkumab	10	2	Mar 2018	Yes
Psoriasis	Ilumya	Tildrakizumab	50	4	Sep 2018	No
HIV	Biktarvy		60	8	Jul 2018	No

Table 3: All other health areas – NMEs registered in Australia between 2013-2018 but not yet reimbursed.

Therapy Area	Product Name	Molecule	% of other OECD Countries Reimbursed	Months behind ARD	RIA	Launched
Others	Cerdelga	Eliglustat	65	26	Feb 2015	No
Others	Zerbaxa	Ceftolozane, Tazobactam	65	35	Nov 2015	Yes
Others	Movantik	Naloxegol	65	32	Jan 2016	No
Others	Zinplava	Bezlotoxumab	60	12	Nov 2017	No
Others	Novoeight	Turoctocog Alfa	55	47	Jan 2014	No
Others	Rixubis	Nonacog Gamma	55	29	Feb 2014	Yes
Others	Nuwiq	Simoctocog Alfa	55	39	Nov 2014	No
Others	Eloctate	Efmoroctocog Alfa	55	30	Jun 2014	Yes
Others	Galafold	Migalastat	55	18	Aug 2017	No
Others	Afstyla	Lonoctocog Alfa	50	14	Apr 2017	No
Others	Xadago	Safinamide	50	32	Nov 2018	No
Others	Alprolix	Eftrenonacog Alfa	45	24	May 2014	No
Others	Vimizim	Elosulfase Alfa	45	41	Dec 2014	No
Others	Kanuma	Sebelipase Alfa	45	25	May 2017	No
Others	Hemlibra	Emicizumab	45	6	Feb 2018	No
Others	Idelvion	Albutrepenonacog Alfa	45	25	Sep 2016	No
Others	Dupixent	Dupilumab	35	9	Jan 2018	No
Others	Strensiq	Asfotase Alfa	30	30	Jan 2016	No
Others	Zurampic	Lesinurad	30	13	Jun 2016	No
Others	Veltassa	Patiromer Calcium	30	12	Dec 2017	No
Others	Ocaliva	Obeticholic Acid	30	16	Sep 2018	No
Others	Obizur	Susoctocog Alfa	25	22	Aug 2016	No
Others	Brineura	Cerliponase Alfa	25	9	Aug 2018	No
Others	Aimovig	Erenumab	20	2	Jul 2018	No
Others	Prevymis	Letermovir	15	9	Jun 2018	No
Others	Elelyso	Taliglucerase Alfa	5	5	May 2014	Yes
Others	Duavive	Bazedoxifene, Conjugated Estrogenic Substances	5	58	Dec 2016	Yes

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

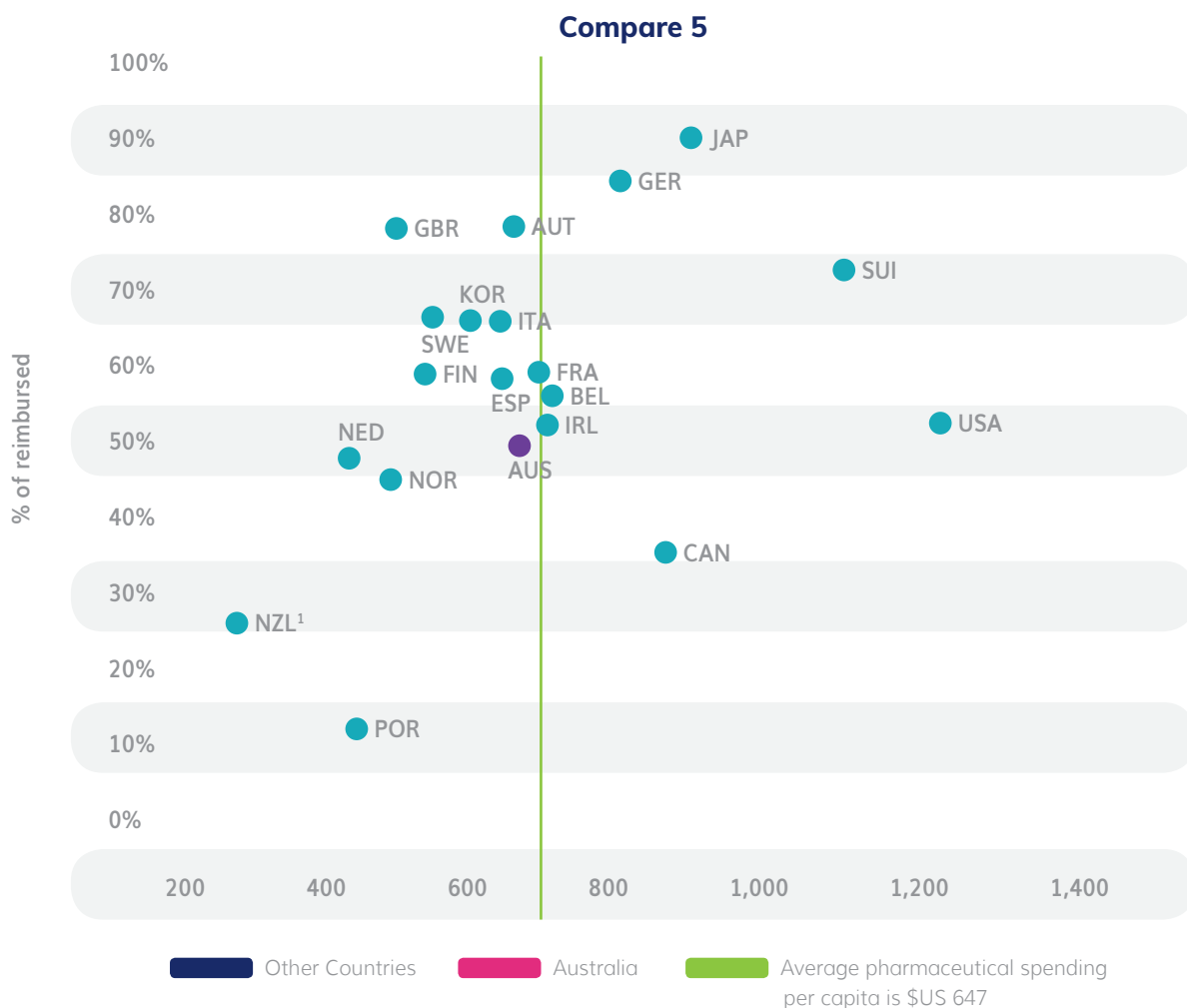


Figure 7: The proportion of NMEs reimbursed (2013 to 2018) vs. pharmaceutical spending per capita.

Japan, Germany, Austria, and Great Britain 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.

The average pharmaceutical spend per capita in Australia was \$640, just under the 20 comparable average of \$646.70.

Australia's Market Access Score has improved.

The Market Access Index is a single number measurement of market access, which is generated by a relevant score against the top ranked country. It takes into consideration the difference in the set of NMEs as well as their changes in the market access stage, in order to allow longitudinal comparison by year across the countries⁴.

On a market index Australia scores 48.7% compared to the leading country's (Germany) time to reimbursement and access.

	Country Score for Compare 5	Change in Score Compare to Compare 4	Change in Rank
1. Germany	100%	0.0%	No Change
2 Austria	97.4%	5.5%	+ 2
3. USA	95.9%	10.8%	- 1
4. United Kingdom	96.1%	- 5.1%	- 1
5. Sweden	83.6%	4.7%	No Change
6. Italy	72.3%	7.5%	+ 4
7. Finland	70.2%	2.7%	No Change
8. Japan	70.2%	4.9%	+ 4
9. Norway	68.1%	0.3%	- 3
10. Spain	66.6%	4.8%	- 1
11. France	66.3%	4.5%	+ 3
12. Belgium	65.3%	6.5%	+ 1
13. Ireland	64.6%	7.3%	- 2
14. Switzerland	63.8%	- 1.5%	+ 1
15. Netherlands	59.0%	- 4.5%	+ 7
16. Australia	48.7%	4.9%	+ 1
17. Canada	46.1%	2.5%	+ 1
18. Korea	45.4%	- 1.3%	- 2
19. Portugal	39.0%	- 2.7%	No Change
20. New Zealand	17.3%	2.0%	No Change

Figure 8: Longitudinal comparison of 20 OECD countries' market access

There has been a clear improvement in Australia's overall market access score of 4.9% in comparison to the score in COMPARE 4. However, there has also been improvement in the score for the majority of comparable OECD nations, which has resulted in Australia only moving up one place in the market access rankings from COMPARE 4 to 16th.

The leading nations for market access are Germany, Austria, the United States, Great Britain (despite a fall from COMPARE 4) and Sweden, which all have scores above 80%.

⁴ Methodology for calculating the Market Access Score can be found in Appendix B.

04. Comparisons

The number of NMEs and the proportion of NMEs reimbursed has improved since the first report. Although there are improvements, Australia has not made considerable improvements in its ranking in these categories as other nations have also improved.

Australia's average time to reimbursement has not improved over the course of five COMPARE reports. The average time to reimbursement has consistently been slower than the comparable country average, and the proportion reimbursed within six-months has been falling.

Table 4: COMPARE report comparisons for Australia's access to new medicines.

	Compare 1	Compare 2	Compare 3	Compare 4	Compare 5
Total number of reimbursed NMEs	59 (rank 17th)	76 (rank 17th)	81 (rank 17th)	90 (rank 17th)	97 (rank 17th)
Proportion of reimbursed	39% (rank 18th)	46% (rank 18th)	45% (rank 17th)	46% (rank 17th)	50% (rank 15th)
Ave number of NMEs reimbursed per year	11	13	13.5	15	16.2
Proportion and number of NMEs reimbursed in Australia within 6 months	18 NMEs (32%)	23 NMEs (30%)	23NMEs (29%)	22 NMEs (24%)	22 NMEs (23%)
Australia's average time to reimbursement from registration	383 days (rank 13th)	397 days (rank 13th)	370 days (rank 13th)	420 days (rank 13th)	410 days (rank 13th)
Australia's market access score	Rank 17th Score 21.2%	Rank 17th Score 47%	Rank 17th Score 48%	Rank 17th Score 44%	Rank 16th Score 48.7%

Appendix A

Method and approach for COMPARE.

Building on previous COMPARE reports, the analysis reviewed new medicines (520) that were registered in the 20 OECD countries over the period 1 January 2013 to 31 December 2018. The key notion of product reimbursement was defined across countries to compare medicines.

Step 1

Examine 20 OECD countries included in COMPARE 1-4 for their comparability of pharmaceutical spending.

- In COMPARE 5, 20 of the top OECD countries ranked by highest GDP per capita and/or total GDP were selected. This subset of OECD countries was selected because these countries were the most similar to Australia in terms of social and economic factors and complete data were available to measure reimbursement.
- South Korea was selected as a representative in the Asia-Pacific region, most high-cost products are reimbursed and reimbursement may require significant price reductions.
- New Zealand was ranked 18th for GDP per capita and its strict reimbursement environment represents an extreme case of market access.

Step 2

Develop a comprehensive list of NMEs per country based on registration and launch information.

a) National market approval data collection

- Identify a list of products reviewed and approved for marketing

b) Check launch date

- Validate launch date to remove products launched previously in the country under a different product name

c) New molecular entity/new combination

- The earliest marketing approval date is considered regardless of indication or formula
- Combination were included only if the combination was registered between calendar year (CY 2013-2018) and at least one of the molecule was launched between CY 2013-2018
- The analysis was conducted using information up to December 2018, because it is the most updated information available across the 20 countries in scope at the time of analysis (March 2019).

Step 3

Collect reimbursement information for 20 OECD countries.

- Focuses only on public reimbursement of medicines that apply to the eligible population
- Subsequent reimbursement for different indications are out of scope for this project
- This analysis considers reimbursement as a binary metric where level of access is not measured, NMEs are either reimbursed or not
- Most countries make decisions about reimbursement on a national level
- In countries such as Canada and USA, reimbursement of medicine is managed at state level by state government or contracted private health insurance providers.

Appendix B

Market Access Score methodology.

The Market Access Index Score is a single measurement of market access that takes into consideration the differences in the set of NMEs as well as their changes in the market access stage. This is a longitudinal analysis of 20 OECD countries.



Check list by using this score

- ✓ A single number measurement of market access
- ✓ A relative score against the #1 ranked country
- ✓ Take into consideration each year the set of NMEs can differ
- ✓ Allows longitudinal comparison by year across all countries
- ✓ Stage of market access are weighted

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.

Appendix C

Pricing and reimbursement environment overview in the 20 selected countries.

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
U.K.	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
Nether- Lands	Yes	Yes	Yes	Yes	Yes	No	No
Norway	Yes	Yes	Yes	Yes	Yes	Yes	No
New Zealand	Yes	Yes	No	No	Yes	Yes	No
Portugal	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Switzer- Land	Yes	No	Yes	No	Yes	Yes	Yes
Sweden	Yes	Yes	No	No	Yes	Yes	No
U.S.A.	No	No	No	No	Yes	Yes	Yes

05. About



About Medicines Australia – Who we are and what we do.

Medicines Australia represents the discovery-driven pharmaceutical industry in Australia. Our member companies invent, manufacture and supply innovative medicines and vaccines to the Australian community. Those medicines keep Australians out of hospitals, prevent disease and play a pivotal role in ensuring a productive and healthy community.

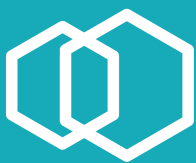
Medicines Australia represents the innovative medicines industry by:

- engaging with government and government departments, the Australian Medicines Industry, consumer groups and health professionals to develop health and industry policy
- building and maintaining relationships with government for fair reimbursement of medicines (through the Pharmaceuticals Benefits Scheme) to ensure the continuation of a viable medicines industry
- administering the Medicines Australia Code of Conduct which sets the standard for the ethical marketing and promotion of prescription medicines
- working with other health professional and consumer organisations on issues of mutual concern
- providing specialist advice to member companies
- educating the community about industry activities

Our vision is for a longer and healthier life for Australians through availability and choice of world leading innovative medicines.



Better health
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