Medicines Matter

Australia's Access to Medicines 2014-2019

Medicines Australia

Better health through research and innovation

Contents

Introduction and Purpose of Report 3

Methodology 5

Summary of Report Findings 7

Summary of Steps for Medicines Approval 9

Detailed Assessment Findings 11

Cost Recovery Fees 27

References 28

Medicines Australia
17 Denison Street, Deakin ACT 2600
Phone: (02) 6147 6500

Introduction and Purpose of Report

Australia's healthcare system is considered one of the best in the world, providing Australians with quality, safe, and affordable healthcare.[1] A strong and reliable health system is one of the main reasons that Australians have longer, healthy life expectancies.

Access to new and innovative medicines and vaccines is a fundamental pillar of this system. Research has shown that pharmaceutical innovation is directly responsible for the decline in premature mortality in Australia, as well as being responsible for the reduction in the number of days Australians receive care in hospital.[2]

Not only does the development and use of new medicines make an important improvement to the health of Australians, it also significantly contributes to the nation's wealth and productivity. New medicines contribute to individual and national wealth by increasing the healthy life expectancy of Australians, increasing workforce participation and productivity and keeping patients contributing to the community and out of the hospital system. This has never been more important than with COVID-19. Preventing hospitalisation in order to free-up health services to manage emergency needs has been essential to avoid acutely overwhelming the system.

In addition to ensuring the supply of important medicines to keep Australians out of hospital, the pharmaceutical industry is supporting a strong recovery from the pandemic through the development of new diagnostics, treatments and vaccines.

The Pharmaceutical Benefits Scheme (PBS) is the cornerstone Australian Government program that helps Australian patients affordably access life-saving medicines when they need them. The PBS provides reliable and affordable access to medicines through Government subsidisation. It helps protect the most vulnerable people in our society, helps those with chronic conditions and helps people contribute to society, participate in the community and retain their livelihoods.

Trends show that older Australians are increasingly becoming the majority users of PBS medicines, as the proportion of those aged over 65 years now account for over half of the PBS by expenditure.[3] This age group accounts for over two-thirds of all growth in PBS expenditure even though they only make up around 16 per cent of the population.[4] This shows the increasing trends of chronic diseases in older age groups, such as cardiovascular disease, diabetes, hypertension and other diseases that impact on healthy living.

The PBS safety net protects the most vulnerable by providing a threshold for patients and families who require an extensive number of prescriptions. Once a patient hits the threshold, they qualify to receive the medicines that they need at a lower (or no) cost, helping those who need access to medicines the most.

This Medicines Matter Insights report aims to provide a snapshot of Australia's access to innovative medicines over the years 2014-2019. As we outline below, there is news worth celebrating from the perspective of patients, industry and Government – process reforms in TGA and PBAC have seen improvements in registration and reimbursement times for new medicines and international work sharing between regulatory authorities has also helped.

However, when we examine the Australian experience against many of our OECD peers, there remain areas where we could do better – again there is responsibility on all stakeholders including industry, TGA and PBAC. While the treatments are becoming increasingly complex, especially in oncology including personalised or precision medicines and the rise in cell and gene therapy, the gains they provide to patients are substantial. Timely delivery must remain the focus.

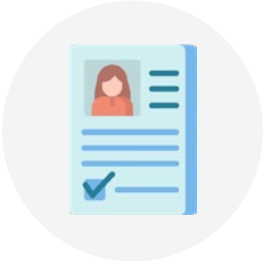
Disruption and Transformation with COVID-19

The timing of vaccine and treatment availability is now an urgent focus to contain COVID-19 and support the economic recovery. Increasing efficiencies and timeliness of the developmental and review processes to assess the arriving vaccines and treatments is being witnessed around the globe. This disruption of health technology assessments will hopefully not only bring COVID-19 solutions to the world as quickly as possible, but also establish improved efficiencies into the review system and speed up timely access of medicines and solutions more widely for the community.

Medicines Australia wants this report to be a resource for the ongoing discussion between all stakeholders on necessary improvements to ensure patient access to new medicines and treatments can be world leading.

Methodology

Medicines Australia worked with IQVIA to develop a methodology that could standardise the timelines for medicines registration (market authorisation) and reimbursement across a variety of healthcare systems compared to Australia.

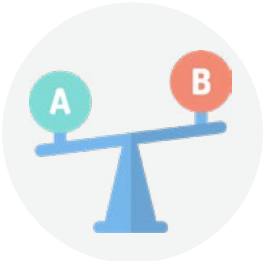


Outlining the registration and reimbursement process in Australia

The registration and reimbursement process requirements, and estimated timeframes for each step are sourced from the Australian Department of Health, Pharmaceutical Benefits Scheme, and Therapeutic Goods Administration websites.

International work-sharing

The international work sharing information is sourced from the U.S. Food and Drug Administration, the Australian Department of Health, the Australia-Canada-Singapore-Switzerland Consortium, and the Therapeutic Goods Administration. Additional information is sourced from a presentation by the Department of Health on assessment pathways for new disease treatments.



International systems

The comparisons of international systems are sourced from the IQVIA Pharma Pricing and Reimbursement Guide 2018.

Assessing the timelines for comparison – IQVIA analysis

Steps

1. Examine 20 similar OECD countries included in previous analyses[5] for their comparability of pharmaceutical spending.
2. Develop a comprehensive list of new molecular entities (NMEs) per country based on registration and launch information.
3. Collect reimbursement information for 20 OECD countries.
4. Measure timeframes from registration to reimbursement.

Marketing approval data collection

- 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 **its very first indication.**

Launch date confirmation

- 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.

New Molecular entity/ new combination

- The earliest marketing approval date is considered regardless of indication or formulation.
- Combination were included only if the combination was registered between calendar year (CY) 2014-2019 AND at **least one** of the molecules was launched between CY 2014-2019.
- The analysis was conducted using information up to Dec 2019, because it is the most updated information available across the 20 countries in scope at the time of analysis (March 2020).

Summary of Report Findings

Priority Registration Pathways have seen improvements in the TGA registration times

- The implementation of both the TGA priority review and provisional registration pathway in Australia have helped reduce the evaluation and approval time for the TGA thereby speeding up the timeline for the registration of innovative medicines.[6]
- During 2018 and 2019 six medicines went through the Priority Review Pathway, and on average they were processed 182 days, or just over 6 months, quicker than medicines on the standard review pathway.
- Of the six medicines which have been approved for this pathway, none have yet been listed on the PBS. Reasons include PBAC rejections, PBAC deferrals and negotiations between the Department and the sponsor.

International collaboration

International collaborations and work sharing processes (Project Orbis and ACSS) have significantly improved registration timeframes and outcomes.

Timeframes from registration to reimbursement are getting shorter, but there is room for further improvement relative to similar OECD markets

- Close to two out of three (or 60 per cent) new medicines achieve PBS reimbursement in Australia within 12 months from submission to the PBAC.
- Australia's average time-to-reimbursement on the PBS has shortened by 10 days from previous analyses.[7]
- Of the OECD countries assessed, on average, more than 60 per cent of medicines are reimbursed within 6 months, in comparison to Australia's 22 per cent.
- In 3 top OECD countries, they achieve reimbursement of 60 per cent within 3 months.
- Many new medicines are complex oncology products, which have some of the longest listing times, in this assessment ranging from 125 to 1144 days, for a range of reasons.

Access to medicines requires further focus and improvement

- Of the 96 New Molecular Entities (NME) that are registered but not reimbursed in Australia (as of the end of December 2019) a third have been launched privately and the remaining two thirds still require reimbursement outcomes.
- There are 33 medicines that are currently not on the PBS that have been reimbursed in at least one other comparable OECD country.

Medicines Australia is working actively with the Government to address these areas of concern.

Summary of Steps For Medicines Approval In Australia

Before a patient can affordably access a new medicine, it needs to be first approved for registration on the Australian Register of Therapeutic Goods (ARTG) which affirms the quality, safety and efficacy of a product.

Following registration, a product must be recommended for PBS listing to achieve government subsidisation. This means a product must meet both the regulatory approval standards of the Therapeutic Goods Administration (TGA) and the Health Technology Assessment (HTA) requirements through the Pharmaceutical Benefits Advisory Committee (PBAC). The steps are:

Step 1: TGA Registration. Before registration:

The legal requirement for the marketing of therapeutic goods in Australia are defined in the *Therapeutic Goods Act 1989*, administered by the TGA.[8]

- TGA conduct a pre-market evaluation of quality, safety and efficacy within a statutory timeframe (255 working days).
- The TGA determine the clinical claim (how much benefit) and the population (who benefits).

Expected timeframe: *Planned evaluation time by the TGA is 10.5 months but can be expedited (priority review) or extended, by agreement.*

Step 2: PBAC Recommendation. A medicine is recommended for subsidy on the PBS if:

- It is assessed by the PBAC to have comparable safety and clinical effectiveness as existing treatments for the same condition.
- If the benefits of the treatment are assessed by the PBAC to justify the cost (value for money).

Expected timeframe: *The PBAC process starts 21 weeks before the meeting with an application of intent to apply. A sponsor of a new medicine can put forward a submission to the PBAC at one of three PBAC meetings which occur each year (every 17 weeks). The time from submission of a major application to full publication of summary documents of PBAC decision making is 33-35 weeks.*

Step 3: PBS Listing. After PBAC recommendation the Government will list the new medicine on the PBS for subsidy if:

- The government and the medicine sponsor can agree on an acceptable price for the medicine to be listed.
- The Department can find the equivalent amount in cost offsets (Policy changed in 2020 to remove offset requirement).

Expected timeframe: *The average time from PBAC minutes with a positive recommendation to PBS listing was 105 days (or approximately 3.5 months) in 2019.*

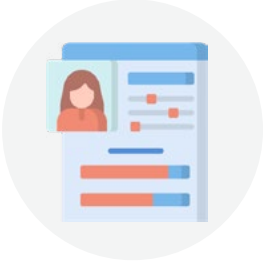
Detailed Assessment Findings

Priority Review Pathway

In July 2017 the TGA implemented the priority review pathway for the registration of novel prescription medicines for Australian patients. This was in direct response to the Review of Medicines and Medical Devices Regulation recommendations.

Objective

The objective of the pathway was to provide a formal mechanism with a faster assessment for vital and life-saving prescription medicines, which also aligned with overseas regulatory bodies (FDA, EMA)[9] that offer these pathways. This includes a target timeframe of **150 working days** to process applications, which is **three months shorter** than the standard registration process.

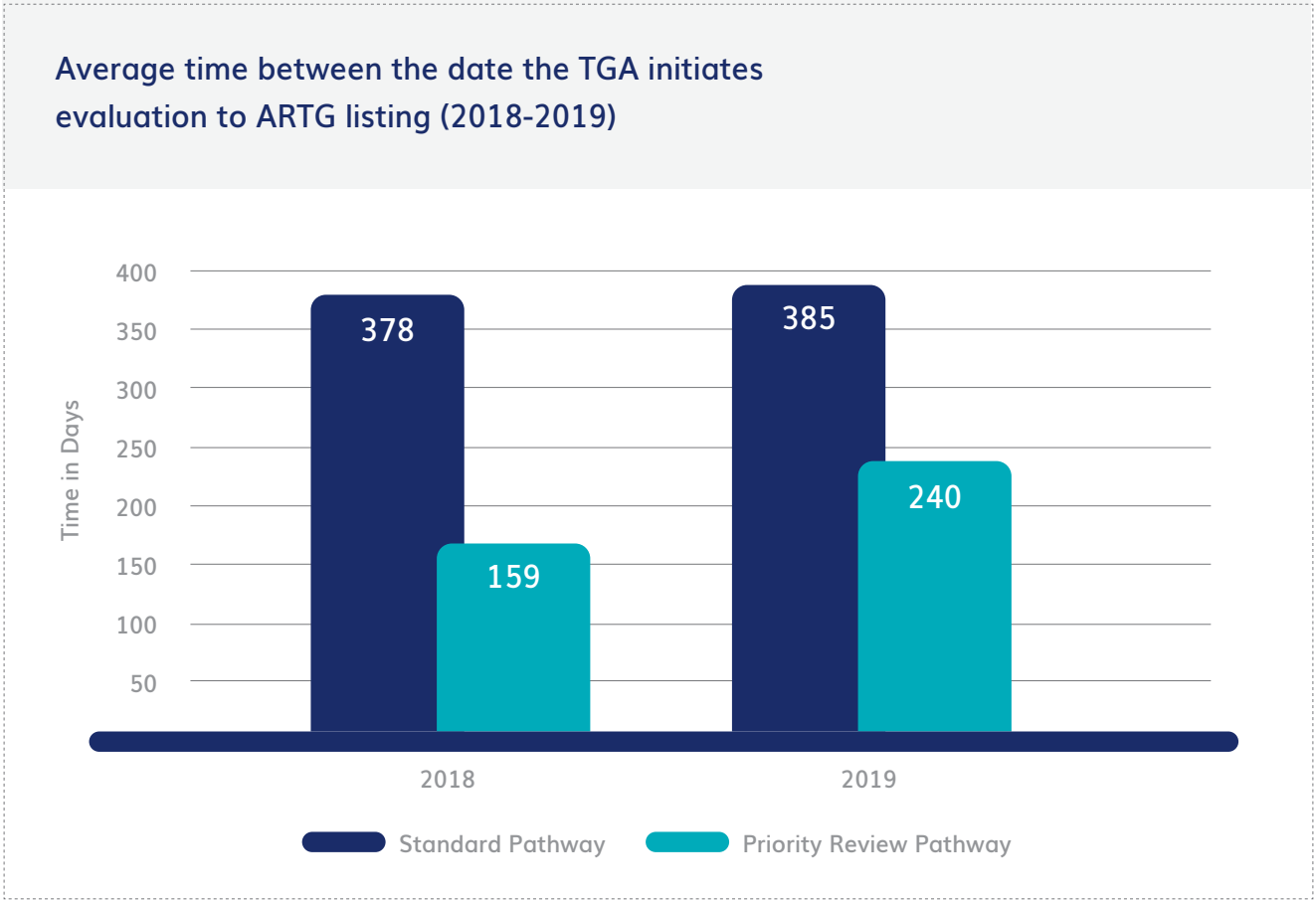


Eligibility

Before lodging a registration application, sponsors must apply for a priority determination, and have the application approved. A new medicine is eligible for the priority review pathway if:

- It is a new prescription medicine or new indication for an existing medicine.
- It will treat, prevent, or diagnose a life threatening or seriously debilitating condition.
- There is no alternative treatment on the ARTG, or if other options are available, must have substantial evidence to demonstrate that the new drug presents a significant improvement to the currently available options.
- There is substantial evidence demonstrating a major therapeutic advance.

Figure 1. The average time it takes to review, and ARTG to list priority medicines is almost half the time of standard reviews.



As seen in Figure 1, the average time it takes from TGA evaluation initiation to ARTG listing has been much faster than the Standard Pathway.

Six medicines have been approved for the Priority Review pathway in 2018-2019

Table 1. The six medicines that have been approved for the Priority Review Pathway.

Product	Molecule	Market authorisation date	Days from TGA evaluation to registration	Reimbursed?	Status
Hemlibra	EMICIZUMAB	23 February 2018	154 days	No	Negotiations ongoing between Dept and sponsor
Erlyand	APALUTAMIDE	5 July 2018	120 days	No	Rejected July 2019, considered Nov 2020
Brineura	CERLIPONASE ALFA	28 August 2018	204 days	No	Rejected July 2018
Takhzyro	LANADELUMAB	30 January 2019	250 days	No	Rejected July 2019, deferred July 2020
Oxervate	CENEGERMIN	1 October 2019	281 days	No	No record of PBAC submission
Polivy	POLATUZUMAB	21 October 2019	189 days	No	Rejected Nov 2019

Looking at Table 1, although the medicines that go through this pathway find quick registration on the ARTG, it does not ensure a quick transition to PBS reimbursed listing for Australian patients. Over 2018 and 2019 six medicines were designated for this pathway but all are still waiting PBS listing to give Australian patients affordable access to these treatments, even though they were medicines that were classified as vital, life-saving and meeting a demand. There will be various reasons for these delays, but they highlight the real opportunities for further improvements in our system today.

Parallel Processing

Medicine and vaccines submissions can be made under the parallel processing arrangement, which enables registration and reimbursement evaluation for major submissions to take place in parallel.[10]

Submissions made under this arrangement must satisfy set criteria, such as being a major submission and must not be a medicine considered a biosimilar. The PBAC will generally not be able to make a positive recommendation if the TGA delegate has not provided a positive overview. Without this overview the submission is likely to be deferred.

A PBS listing cannot occur prior to the product being listed on the ARTG for the relevant indication. Any additional costs in processing the PBAC application because of misalignment of applications will be borne by the sponsor through cost recovery arrangements.

International Work Sharing

Project Orbis

Project Orbis is an initiative of the United States FDA Oncology Center of Excellence (OCE), and provides a framework where concurrent submission and review of oncology products can be shared between international partners.[11] Collaboration across the U.S Food and Drug Administration, the Australian Therapeutic Goods Administration, and Health Canada may allow patients with cancer to receive earlier access to products in other countries where there can be delays to regulatory submissions.

Table 2.[12] Medicines expedited through Project Orbis in Australia.

Product	Molecule	Therapy area	Number of working days to approval	Registration year
Lenvima	LENVATINIB (as MESILATE)	Cancer	54	2019
Keytruda	PEMBROLIZUMAB	Cancer	54	2019
Calquence	ACALABRUTINIB	Cancer	73	2019

Australia-Canada-Singapore-Switzerland Consortium (ACSS)

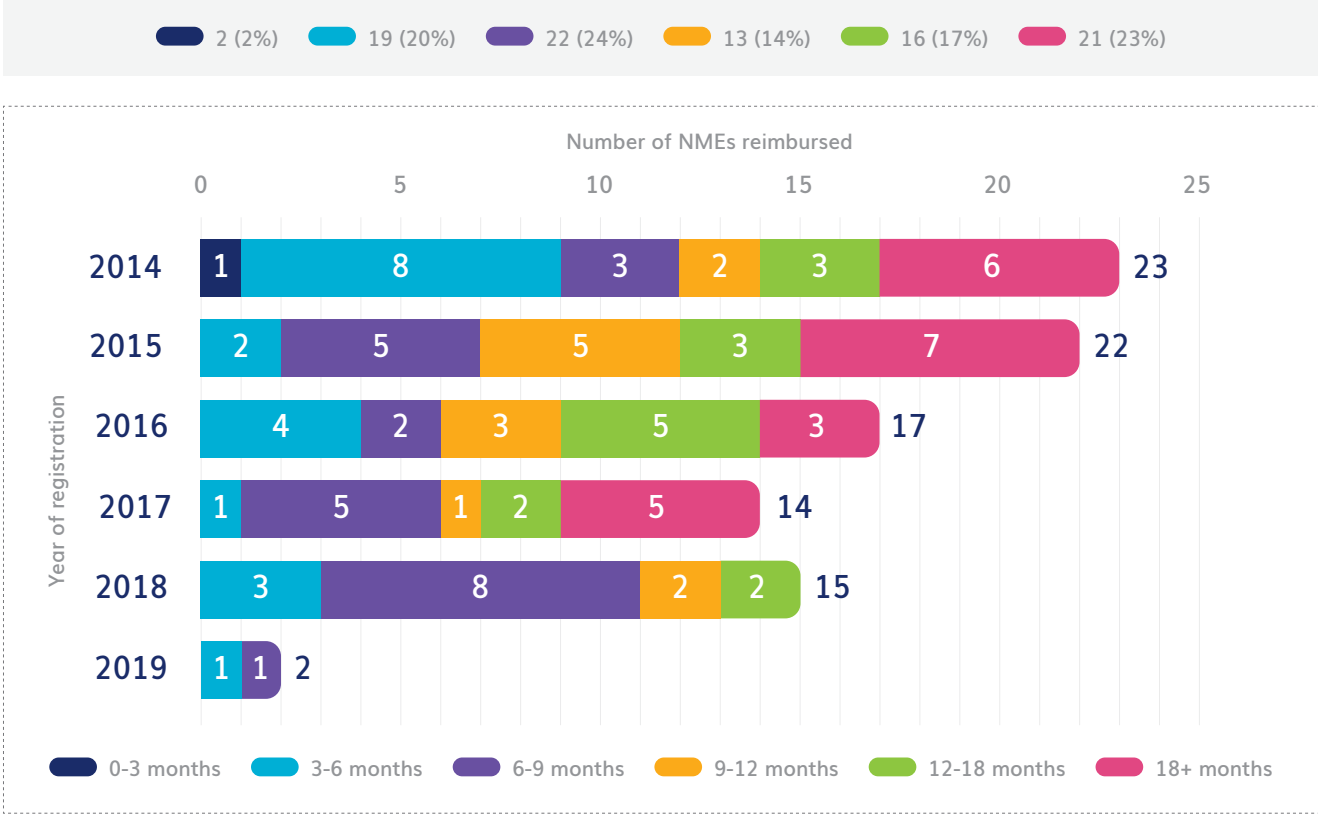
The Australian TGA is part of the ACSS Consortium, which was formed in 2007 by like-minded regulatory authorities to promote regulatory collaboration.[13] The goal is to maximise the international cooperation and reduce duplication to ensure patients have timely access to therapeutic products.

Table 3. Medicines expedited through ACSS in Australia.

Product	Molecule	Therapy area	Number of working days to approval	Registration year
Verzenio	ABEMACICLIB	Cancer	141	2019
Zejula	NIRAPARIB (as TOSILATE MONOHYDRATE)	Cancer	180	2019
Xofluza	BALOXAVIR MARBOXIL	Other	161	2020
Nubeqa	DAROLUTAMIDE	Cancer	220	2020

60 per cent of new medicines achieved PBS listing within 12 months of registration (between 2014-2019)

Figure 2[14]: The time to listing from registration 2014 to 2019.



The Process

Before patients can affordably access a medicine: the medicine must be registered on the ARTG following evaluation of quality, safety and efficacy by the TGA; the medicine must receive a positive recommendation from the PBAC, and finally the sponsor must finalise a negotiation with the Department of Health to settle on the price and risk sharing arrangements before listing on the PBS and subsidisation by government for patient access. This process can vary depending on how easily it progresses through each step.

Figure 2 above shows the timeframes for new medicines registered between 2014 and 2019 to achieve listing on the PBS. Figure 2 shows that 60 per cent of these medicines achieved PBS listing within 12 months of registration, however, there were some variable results.[15]

The number achieving reimbursement in the 6-9-month timeframe is increasing according to this data and further improvements can be achieved through ongoing process refinements.

Of the OECD countries assessed, on average, more than 60 per cent of medicines are reimbursed within 6 months

Figure 3: The time from Registration to listing in other OECD nations.

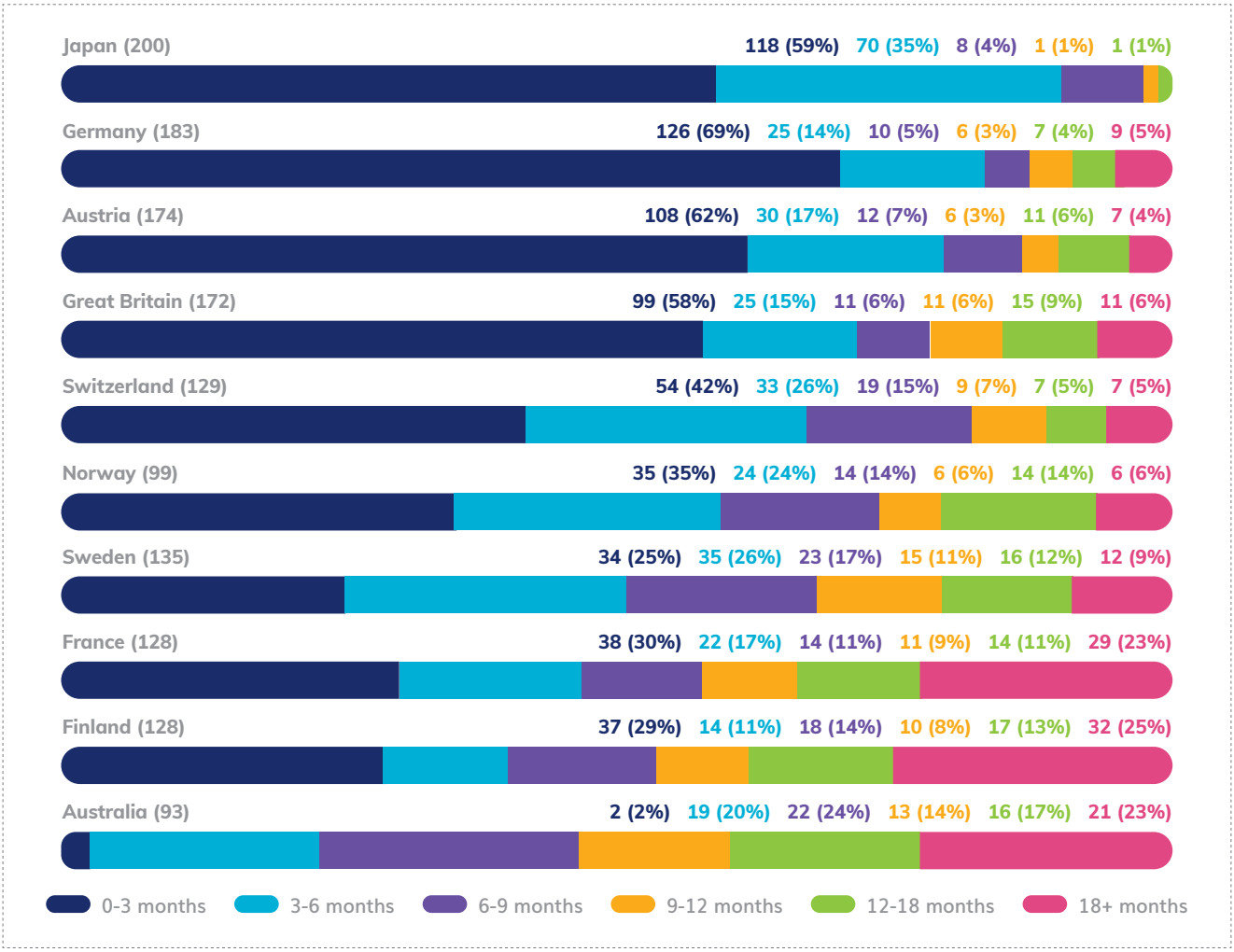


Figure 3 above shows a comparison of Australia's reimbursement timeframe outlined in Figure 1, against other comparable OECD countries timeframes for the equivalent process to achieve similar government reimbursement after registration.

Across the OECD countries assessed, on average, more than 60 per cent of medicines are reimbursed within 6 months in comparison to Australia's 22 per cent.

As seen above, some countries achieve an aspirational reimbursement rate of 60 per cent within the first three months (accounting for differences in process).

Figure 4. Average timeframes in other countries

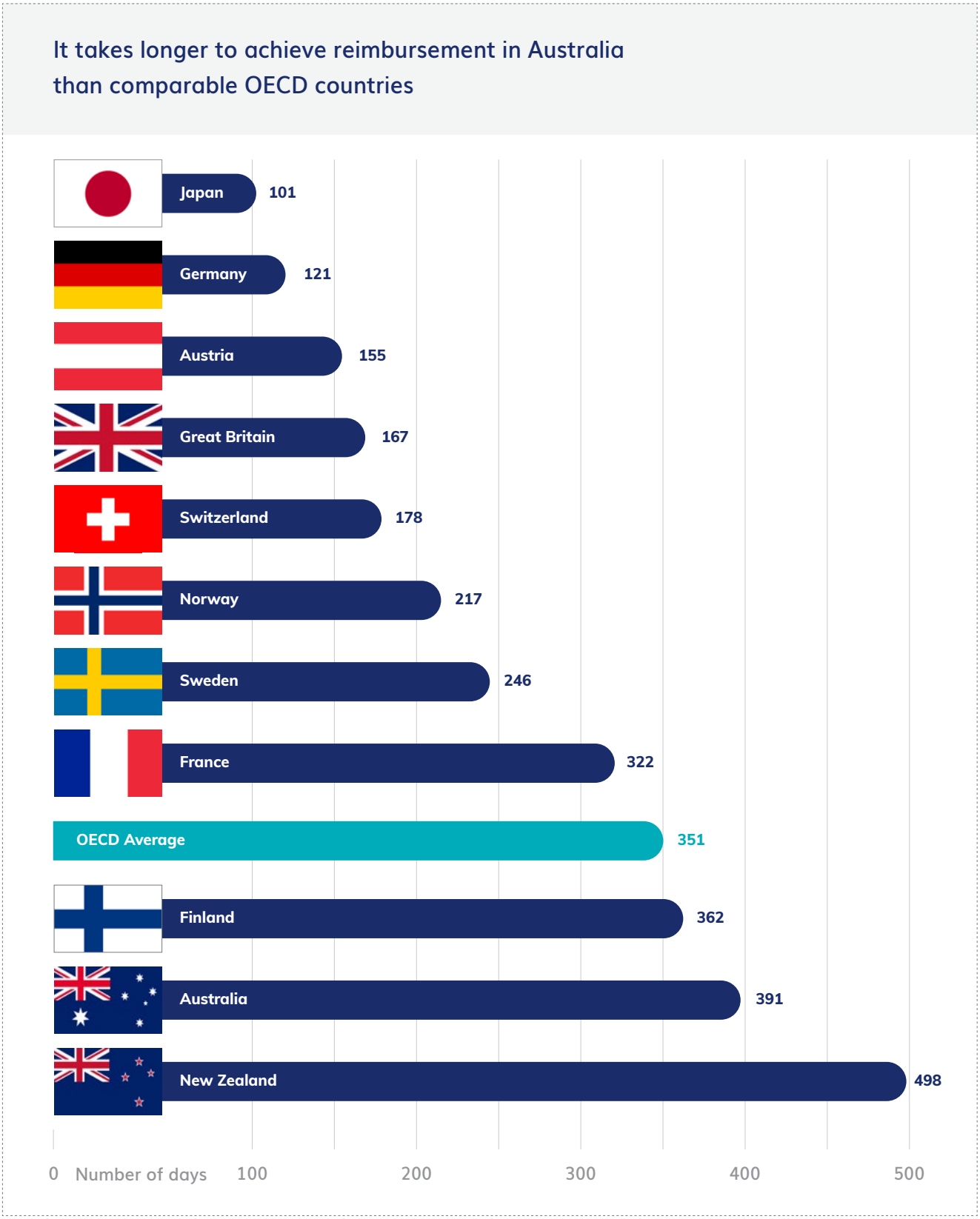


Figure 4 above shows the average number of days it took for a medicine to achieve public reimbursement from registration between 2014 and 2019. As seen in Table 1, Japan, Germany, Austria, Great Britain and Switzerland are all able to complete this process in under 200 days, compared to almost 400 days in Australia.

Examples of how other countries have attempted to address access issues

The Cancer Drug Fund in Great Britain has enabled faster access for cancer patients[16]

New medicines are automatically reimbursed in the National Health Service (NHS) for all approved indications upon receiving marketing authorization from the EMA or the Medicines and Healthcare Products Regulatory Agency if it is considered cost effective. Medicines that have been deemed not cost effective are unlikely to be prioritized for funding.

In England, Northern Ireland and Wales (except Scotland), the National Institute for Health and Care Excellence's (NICE) recommendations are taken into consideration by funding bodies within those countries when deciding whether to fund the new medicine. NICE makes recommendations based on cost-effectiveness calculations using Quality Life Adjusted Years, and positive recommendations usually result in the medicine being funded.

The Cancer Drugs Fund (CDF) acts as a managed access pathway for new cancer medicines, and all new cancer medicines are referred to NICE for appraisal by the Department of Health and Social Care. A cancer medicine cannot be funded by CDF if is not recommended by NICE for routine NHS funding. The introduction of CDF has enabled patients to gain access to cancer medicines in the NHS at least 4 months earlier than was previously the case.

In Germany a new medicine is reimbursed at market entry and reviewed in the second year after launch[17]

In Germany, new prescription medicines are automatically reimbursed following registration, but non-prescription medicines (with some exceptions) and lifestyle medicines are excluded from reimbursement. There are no reimbursement categories; medicines are either reimbursed or not.

On market entry, a new medicine is reimbursed at its launch price for the first year, pending the completion of an early benefit assessment. In the second year of launch, depending on the outcome of the early benefit assessment, the reimbursement price is determined either by:

1. Compulsory rebate negotiations with the GKV-Spitzenverband (Federal Association of Health Insurance Funds) for medicines with an additional benefit versus a competitor.

2. A reference price system where medicines with no additional benefit are reimbursed at the reference price, and patients pay the excess if they opt for a more expensive medicine. The prices are periodically reviewed by the GKV-Spitzenverband.

The Gemeinsamer Bundesausschuss (Federal Joint Committee) can determine on an ad hoc basis to remove a medicine from reimbursement or restrict the medicine's reimbursed status so that the use of the medicine is deemed economically efficient.

In Japan, the Drug Pricing Organisation must determine if a new drug should be listed within 60 days of market authorisation[18]

For a new medicine to be eligible for reimbursement in Japan, it must:

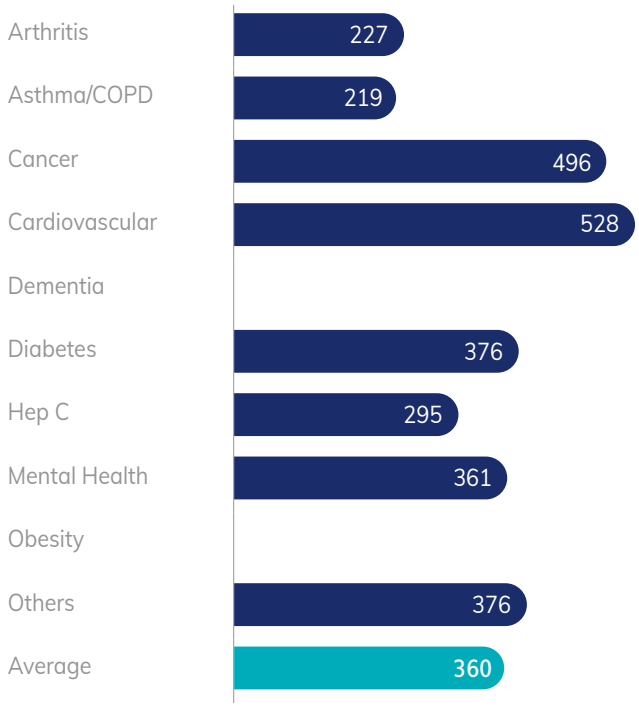
1. Have marketing authorisation from Pharmaceutical and Medical Devices Agency (PMDA);
2. Be included in the National Health Insurance reimbursement price list; and
3. Not be specifically excluded from reimbursement (e.g. lifestyle products).

Medicines are reimbursed at the price listed on the National Health Insurance (NHI) reimbursement price list which applies equally to patients covered by the NHI, Employee Health Insurance (EHI) and Long-Life Medical Care System. Reimbursed drugs are subjected to price controls which included a price revision in 2018, resulting in an average 7.1 per cent price cut on all reimbursed medicines.

The speed of the reimbursement of Japan's system is a result of a timeframe requirement on the Drug Pricing Organisation. The Organisation must decide whether to include a new medicine on the NHI reimbursement price list within 60 days of marketing authorisation, or up to 90 days if the manufacturer appeals the proposed reimbursement price.

Many new medicines are oncology products, but these have some of the longest times to listing

Figure 5: The time from registration to listing for new medicines by therapy area.



	Range (min-max days)	Number of products reimbursed	Number of products registered
Arthritis	152-337	8	12
Asthma/COPD	143-348	6	8
Cancer	125-1144	31	56
Cardiovascular	222-1007	4	8
Dementia			
Diabetes	212-1243	7	9
Hep C	139-624	10	11
Mental Health	149-578	3	5
Obesity			
Others	88-951	24	80
Average		93	189

Figure 5 shows the time it took from registration to reimbursement for new medicines in Australia between 2014 and 2019 by therapy area. As seen in Figure 5, oncology and cardiovascular products had the longest average timeframe to listing, while asthma and arthritis products had the fastest average timeframe.

Key observations from Figure 5:

- No asthma, cardiovascular, dementia, diabetes, mental health, and obesity products were reimbursed in 2019.
- Average time-to-reimbursement in Australia has reduced for arthritis & immunosuppressants, asthma/COPD, cancer, mental health, and products for other therapeutic areas while diabetes products and Hep C products have increased.
- It takes on average 210 days for a product to obtain PBS listing after a PBAC positive recommendation.
- Therapy areas such as arthritis, asthma, Hep C, and mental health had reasonably small ranges in timeframes for medicine reimbursement. However, other therapy areas such as cancer, cardiovascular and diabetes had much more significant ranges as demonstrated above.

Timeframe examples

Table 4 below shows the medicines which had notably different timeframes from registration to reimbursement.

Table 4. Time examples

Product	Molecule	Therapy area	Number of days
Opdivo	NIVOLUMAB	Cancer	125
Folotyn	PRALATREXATE	Cancer	1144
Opsumit	MACITENTAN	Cardiovascular	222
Adempas	RIOCIGUAT	Cardiovascular	1007
Steglatro	ERTUGLIFLOZIN	Diabetes	212
Trulicity	DULAGLUTIDE	Diabetes	1243

As seen in Table 4 there are significant differences in the number of days for different medicines to achieve listing in Australia within the same therapy area. The table above also indicates that there is inconsistency with timelines for reimbursement within therapy areas, which means it may not be adequately linked to delivering on unmet clinical need. Additionally, some of the examples of medicines moving through this process quickly include medicines that are not the first to market, which are usually approved on a cost minimisation basis. Including these medicines in an assessment of timeframes may not necessarily represent what patients might consider most important.

Hep C products saw most listings in 2016, cancer products saw most listings in 2017 and 2018

The Government outlined its National Health Priority Areas in 1997 being cardiovascular health, cancer control, injury prevention, mental health, and diabetes.[19] More priority areas were added in subsequent years including asthma, arthritis and musculoskeletal conditions, obesity and dementia.

While all of the National Health Priority areas are covered in Figure 4, the number of days it takes to achieve listing and reimbursement varies depending on the area.

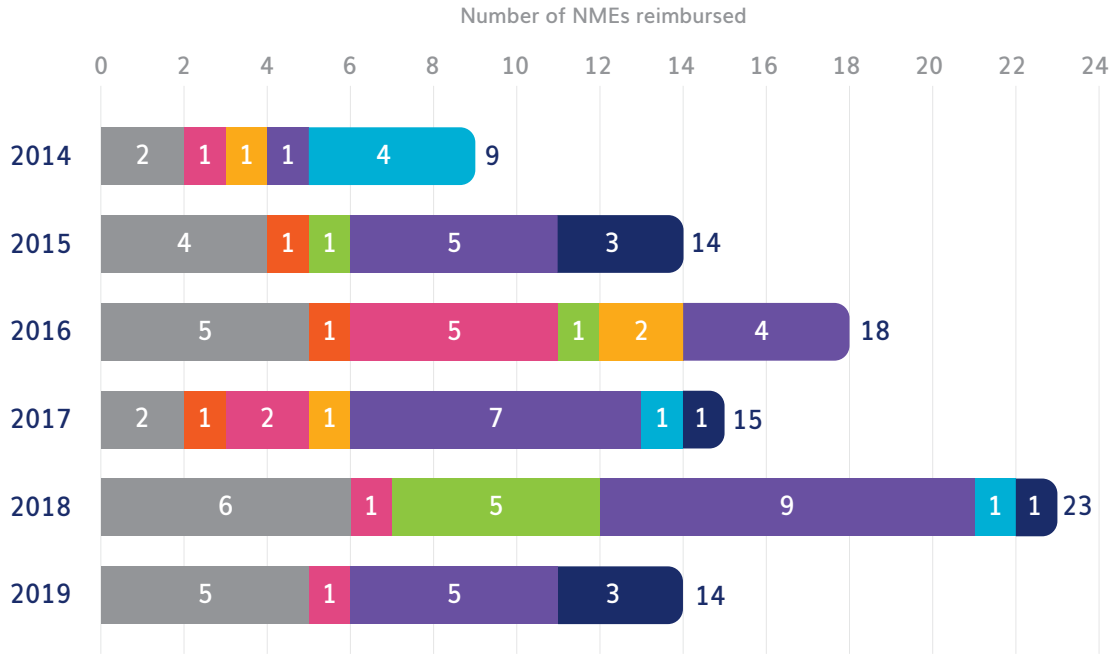
Looking at Figure 6 (on the next page) it is clear that 2018 was a notable year for new medicines to achieve listing on the PBS.

Key points include:

- Arthritis and asthma medicines have the fastest average time to listing, with 3 new arthritis medicines listed in 2019.
- 2018 was such a significant year for listing that 2019 only saw 60 per cent of the 2018 number for listing.
- Over the period analysed there have been 56 cancer medicines reimbursed, by far the most (not including the "others" category).

Figure 6. Number of reimbursements per year by therapy area.

Number of reimbursed NMEs per year and per therapy area (2014-2019)



Therapy Area	Average time-to-reimbursement	Number of registered products
Arthritis	227 days	12
Asthma/COPD	219 days	8
Cancer	496 days	56
Cardiovascular	528 days	8
Diabetes	376 days	9
Hep C	295 days	11
Mental Health	361 days	5
Others	376 days	80

- The number of **NMEs reimbursed in 2019** was only **60% of the number of NMEs reimbursed in 2018** (**14 vs 23**) reaching to that level that was in 2015.
- The **average time-to-reimbursement for arthritis, cancer and mental health have** however **shortened significantly** by at least a month.

What Medicines Are Not Available in Australia?

Between 2014 and 2019 there were 96 medicines that were registered in Australia that had not achieved reimbursed PBS listing for Australians to receive affordable access. 68 of those medicines were registered before January 2019, while 30 of those medicines have been launched privately.

There are 33 medicines that are currently not on the PBS but have been reimbursed in at least one other comparable OECD country.

Table 5 below lists these medicines.

Product	Molecule	Therapy area	Number of other OECD Countries reimbursed	Launched in Australia?	Registration year
Brintellix	VORTIOXETINE	Mental Health	3	Yes	2014
Bosulif	BOSUTINIB	Cancer	2	No	2014
Xofigo	RADIUM RA-223	Cancer	1	Yes	2014
Otezla	APREMILAST	Arthritis, Psoriasis	13	Yes	2015
Sunvepra	ASUNAPREVIR	Hep C	3	No	2015
Cyramza	RAMUCIRUMAB	Cancer	18	No	2015
Sylvant	SILTUXIMAB	Cancer	17	Yes	2015
Zurampic	LESINURAD	Arthritis, Psoriasis	8	No	2016
Uptravi	SELEXIPAG	Cardiovascular	16	No	2016
Praluent	ALIROCUMAB	Cardiovascular	15	No	2016
Belsomra	SUVOREXANT	Mental Health	2	Yes	2016
Farydak	PANOBINOSTAT	Cancer	11	No	2016
Empliciti	ELOTUZUMAB	Cancer	13	No	2016

Table 5 continued...

Product	Molecule	Therapy area	Number of other OECD Countries reimbursed	Launched in Australia?	Registration year
Ninlaro	IXAZOMIB	Cancer	14	No	2016
Cinqair	RESLIZUMAB	Respiratory	11	No	2017
Soliqua	INSULIN GLARGINE, LIXISENATIDE	Diabetes	1	No	2017
Darzalex	DARATUMUMAB	Cancer	17	Yes	2017
Oncaspar	PEGASPARGASE	Cancer	7	Yes	2017
Dupixent	DUPILUMAB	Arthritis, Psoriasis	8	No	2018
Kevzara	SARILUMAB	Arthritis, Psoriasis	14	No	2018
Erleada	APALUTAMIDE	Cancer	6	Yes	2018
Imfinzi	DURVALUMAB	Cancer	13	Yes	2018
Ozempic	SEMAGLUTIDE	Diabetes	15	No	2019
Mektovi	BINIMETINIB	Cancer	14	No	2019
Braftovi	ENCORAFENIB	Cancer	14	No	2019
Alunbrig	BRIGATINIB	Cancer	11	No	2019
Nerlynx	NERATINIB	Cancer	4	No	2019
Verzenio	ABEMACICLIB	Cancer	13	No	2019
Zejula	NIRAPARIB	Cancer	12	No	2019
Ultomiris	RAVULIZUMAB	Cancer	4	No	2019
Polivy	POLATUZUMAB VEDOTIN	Cancer	1	No	2019
Talzenna	TALAZOPARIB	Cancer	5	No	2019
Calquence	ACALABRUTINIB	Cancer	1	No	2019

As seen above in Table 5 there are a number of medicines that have been reimbursed in other comparable OECD countries, but have not yet been reimbursed in Australia. Some notable medicines that treat cancers such as CYRAMZA and SYLVANT have been reimbursed in more than 17 other OECD countries, but have not been reimbursed in Australia. CYRAMZA was originally recommended in March 2018 and reconsidered in July 2019, with the March 2018 PBAC decision being upheld. SYLVANT has been on the ARTG since 2015 and there is no record of a submission to the PBAC for reimbursement.

Other medicines such as UPTRAVI and PRALUENT in the cardiovascular therapy area were registered back in 2016 and have been reimbursed in 15 other OECD countries, but have not yet been listed in Australia. UPTRAVI was recommended by PBAC in July 2020 and PRALUENT was recommended by PBAC in March 2020 and therefore both are currently navigating the post PBAC process.

Cost Recovery Fees

The cost-recoverable services for the PBS as of 1 July 2020 listing and management process as outlined by the department are listed below.

Pre-submission meetings

$16,290 – 1st meeting

$21,360 – 2nd or subsequent

Notice of intent for pricing (prior notice) and positive recommendation (pricing) pathways

$120,810 – Pricing pathway A

$93,700 – Pricing pathway B

$58,920 – Pricing pathway C

$19,910 – Pricing pathway D

$10,890 – Pricing secretariat

Intent to Apply (prior notice) and applications for submission services

$225,180 – Major including intent to apply

$40,470 – Minor including intent to apply

$11,280 – Committee secretariat

$5,320 – Generics

$224,780 – Independent review

List management services, including price increase requests and ministerial discretion requests

$2,370 – Price increase request

$3,540 – Ministerial discretion request

Independent reviews

To undertake the activities required for a new innovative medicine to navigate the process of ARTG and PBS listing, a sponsor is likely to incur costs, on average over $500,000. This does not include the significant costs related to evidence generation and submission preparation. Based on the fees, it is important to consider whether this cost may be a significant barrier for entry in Australia.

References

1 Australian Department of Health, *The Australian Health System* *www.health.gov.au/about-us/the-australian-health-system*

2 Lichtenberg. F, 2019. Measuring the impact of pharmaceutical innovation in Australia 1998 – 2018.

3 Australian Department of Health, 2013, Trends in and drivers of Pharmaceutical Benefits Scheme expenditure.

4 Australian Bureau of Statistics, Catalogue 3222.0 Population projections, Australia.

5 COMPARE reports *medicinesaustralia.com.au/publications/reportsandoccasionalpapers*

6 The Review of Medicines and Medical Devices Regulation in 2017 made several recommendations supported by industry and other stakeholders, including provisional registration and priority review pathways.

7 Compare 4 & 5 *medicinesaustralia.com.au/publications/reportsandoccasionalpapers*

8 'The Textbook of Pharmaceutical Medicine', Edited by Griffin, JP., Posner, J., Barker, GR., 7th ed., John Wiley & Sons, 2013.

9 FDA – USA Food and Drug Administration; EMA – European Medicines Agency – Comparable regulatory agencies to the TGA

10 Australian Department of Health, TGA and PBAC Parallel Process Requirements, The Pharmaceutical Benefits Scheme.

11 U.S. Food and Drug Administration, Project Orbis.

12 Cook,J, 2020. Busting myths about the assessment pathway for new disease treatments for rare diseases. Australian Department of Health.

13 Australian Department of Health, Australia-Canada-Singapore-Switzerland (ACSS) Consortium, Therapeutic Goods Administration.

14 In 2019, the number of registered NMEs taking >12 months to be reimbursed is 0 due to cut-off time i.e. the cut-off time for reimbursement is 31 December 2019.

15 These IQVIA data are reviewing the outcome of positive reimbursement rather than the outcome of PBAC decision (which may be negative) which is assessed by the Centre for Innovation in Regulatory Science (CIRS).

16 Source: IQVIA Pharma Pricing & Reimbursement Country Guide – UK December 2018

17 Source: IQVIA Pharma Pricing & Reimbursement Country Guide – Germany September 2018

18 Source: IQVIA Pharma Pricing & Reimbursement Country Guide – Japan June 2018

Medicines Australia
17 Denison Street, Deakin ACT 2600
Phone: (02) 6147 6500

Medicines Australia

Better health through research and innovation

www.medaus.com.au