Medicines Matter 2022

Australia's Access to Medicines 2016-2021

Medicines Australia

Better health through research & innovation

Contents

Introduction and Purpose of Report

Welcome to the Medicines Matter 2022 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 has four central pillars:

1. equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost that individuals and the community can afford
2. medicines meet the required standards of quality, safety and efficacy
3. quality use of medicines and medicines safety
4. collaborative, innovative and sustainable medicines industry and research sectors with the capability, capacity and expertise to respond to current and future health needs.

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 Medicines Matter reports, the analysis reviewed 472 New Molecular Entities (NMEs) that were first registered in at least one of the 20 OECD countries from 1 January 2016 to 31 December 2021. The time period has been rolled forward one year from the Medicines Matter 2021 report for a longitudinal comparison between each successive report.

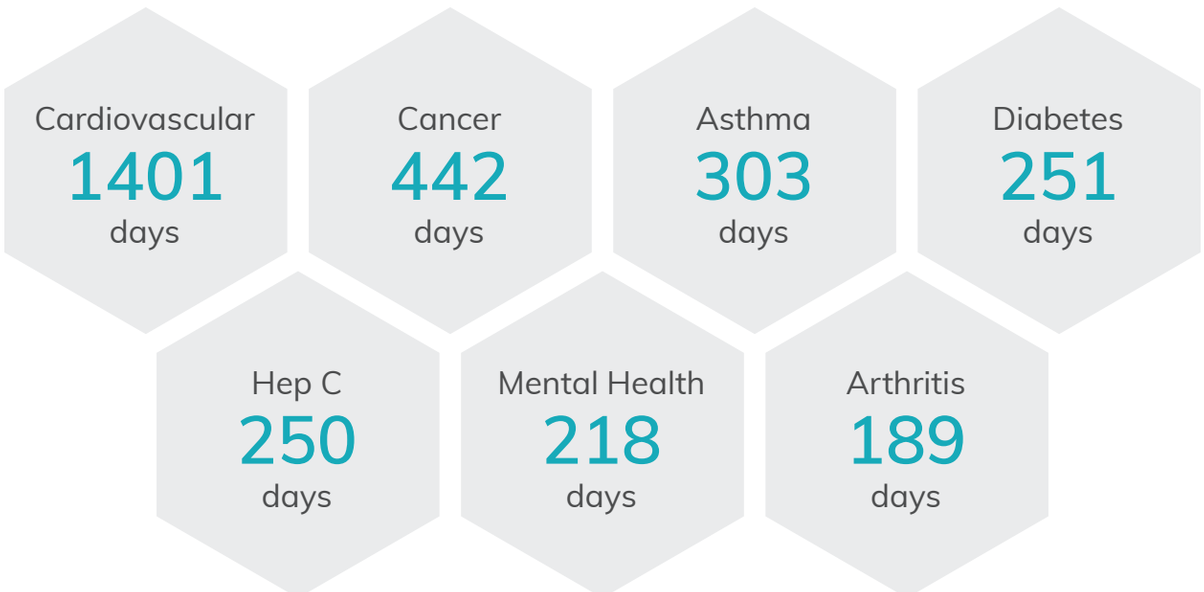
As part of Medicine Australia's five-year Strategic Agreement with the Federal Government an independent review of Australia's Health Technology Assessment (HTA) system is currently underway – the first of its kind in nearly 30 years. The Australian public has high expectations for government to deliver a world-class healthcare system, which includes universal and timely access to new medicines. To deliver on these expectations, the HTA system must be improved to provide faster time to access, more patient engagement and fit-for-purpose evaluation and funding pathways for innovative medicines.

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.

Summary of Report Findings

1. From 2016-2021, Australia ranked 16th for the number of reimbursed NMEs, an increase of one place on the previous Medicines Matter report.
2. Australia has remained in 15th position out of 20 for the proportion of reimbursed NMEs, 9% below the OECD average.
3. The top four countries reimbursed more than 70% of NMEs in less than 6 months from registration, while only 17% of NMEs were reimbursed in Australia in less than 6 months.
4. The average time from registration to reimbursement for all 20 OECD countries has increased to 384 days, with Australia's average at 466 days.
5. NME registration to reimbursement timeframes vary significantly between therapeutic areas.

Average number of days it takes for a medicine to be reimbursed on the PBS after it is registered (2016-2021)



1. From 2016-2021, Australia ranked 16th for the number of reimbursed NMEs, an increase of one place on the previous Medicines Matter report

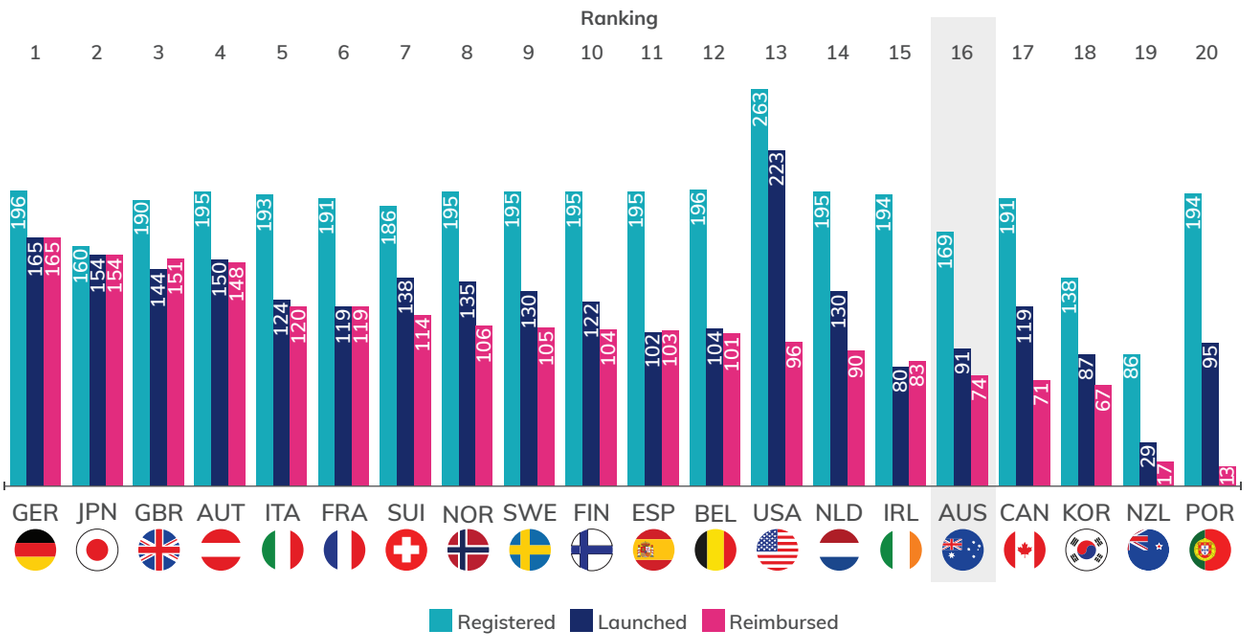


Figure 1: Number of NMEs registered, launched and reimbursed per country in 2016-2021 (ranked by number of NMEs reimbursed)

Between 2016 and 2021 Australia had fewer NMEs registered, launched and reimbursed compared to the average of the OECD nations.

Australia registered 169 NMEs in this period, 9.4% less than the average of 186.7 across the other 19 OECD nations.

Australia launched 91 NMEs in this period, 26.4% less than the average of 123.6 across the other 19 OECD nations.

Australia reimbursed 74 NMEs in this time period, 27.2% less than the average of 101.5 across the other 19 OECD nations. The gap to the top four comparable nations of Germany, Great Britain, Austria and Japan was more pronounced, with these countries reimbursing on average 80.5 more NMEs in this period than Australia.

2. Australia retains the rank of 15th for the proportion of registered NMEs reimbursed, 9% below the OECD average

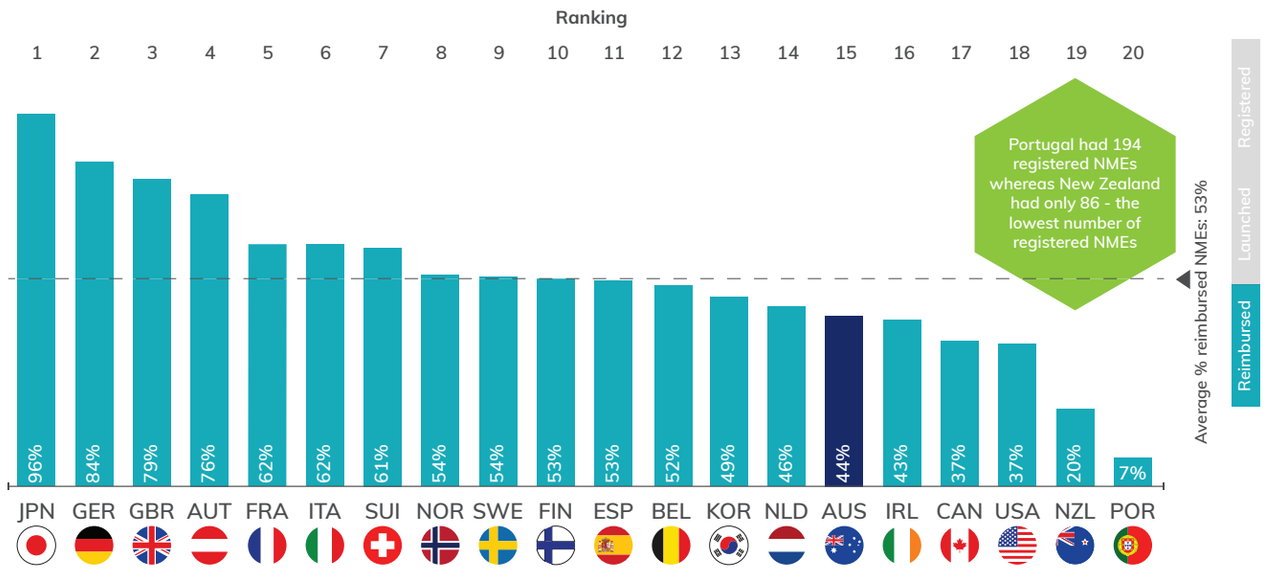


Figure 2: Proportion of NMEs reimbursed per country over NMEs registered from 2016-2021

To allow 1 year for reimbursement, Figure 3 below excludes NMEs registered in 2021. In excluding NMEs registered in 2021, the proportion of reimbursed NMEs increased by 1%, with Australia's position advanced from 15th (Figure 2) to 13th (Figure 3).[h]

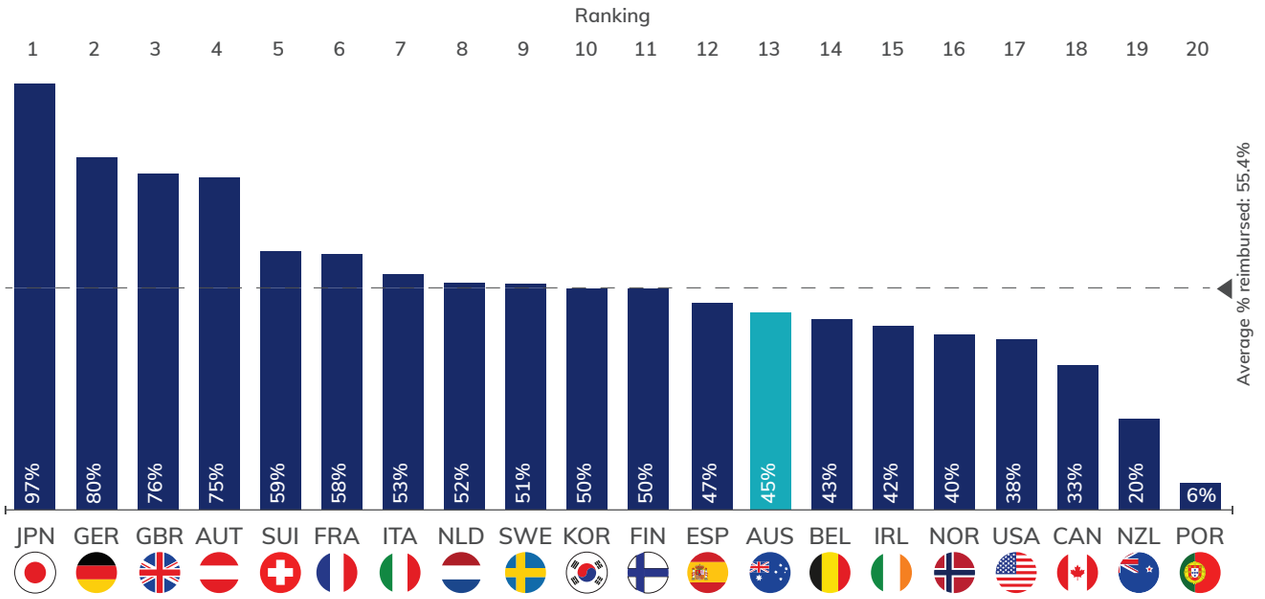


Figure 3: Proportion of NMEs reimbursed per country over NMEs registered from 2016-2020

3. The top 4 countries reimbursed more than 70% of NMEs in less than 6 months from registration, while only 17% of NMEs were reimbursed in Australia in less than 6 months

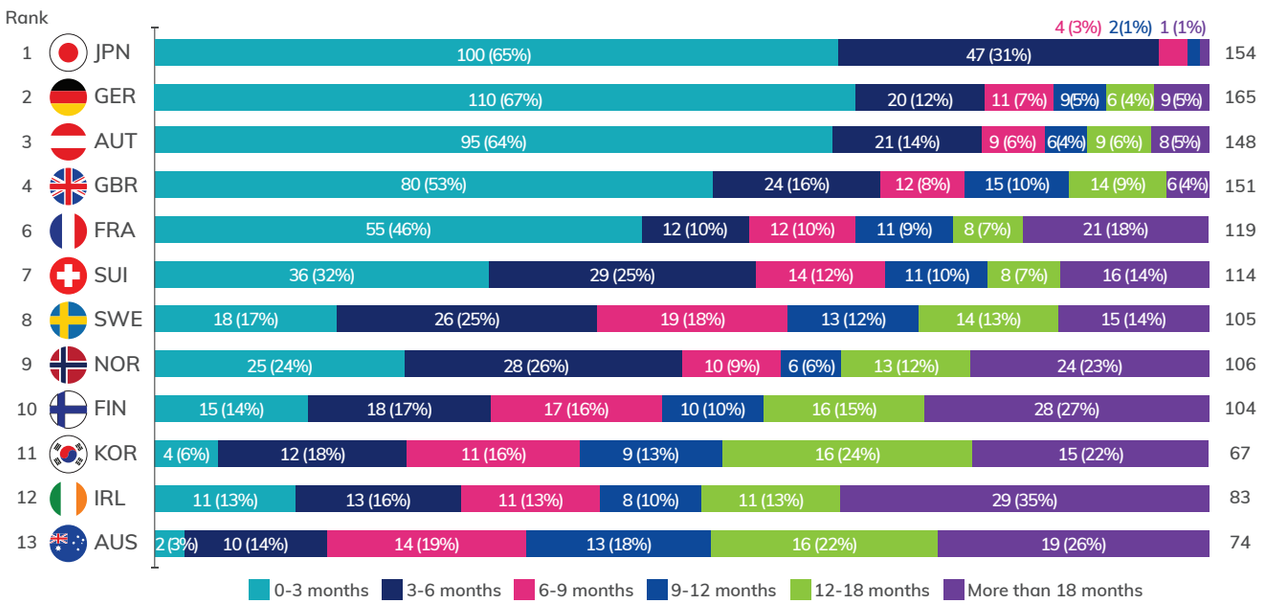


Figure 4: The time from registration to reimbursement in other OECD nations from 2016-2021

Figure 4 compares time from registration to reimbursement for Australia and other comparable OECD countries. Across the 12 other OECD countries included in this calculation, on average, around 50% of medicines are reimbursed within 6 months of registration in comparison to 17 per cent in Australia.

Figure 4 shows that Japan, Germany and Austria achieve an impressive reimbursement rate of over 60% within the first 3 months (accounting for differences in process).

4. The average time from registration to reimbursement for all 20 OECD countries has increased to 384 days, with Australia's average at 466 days

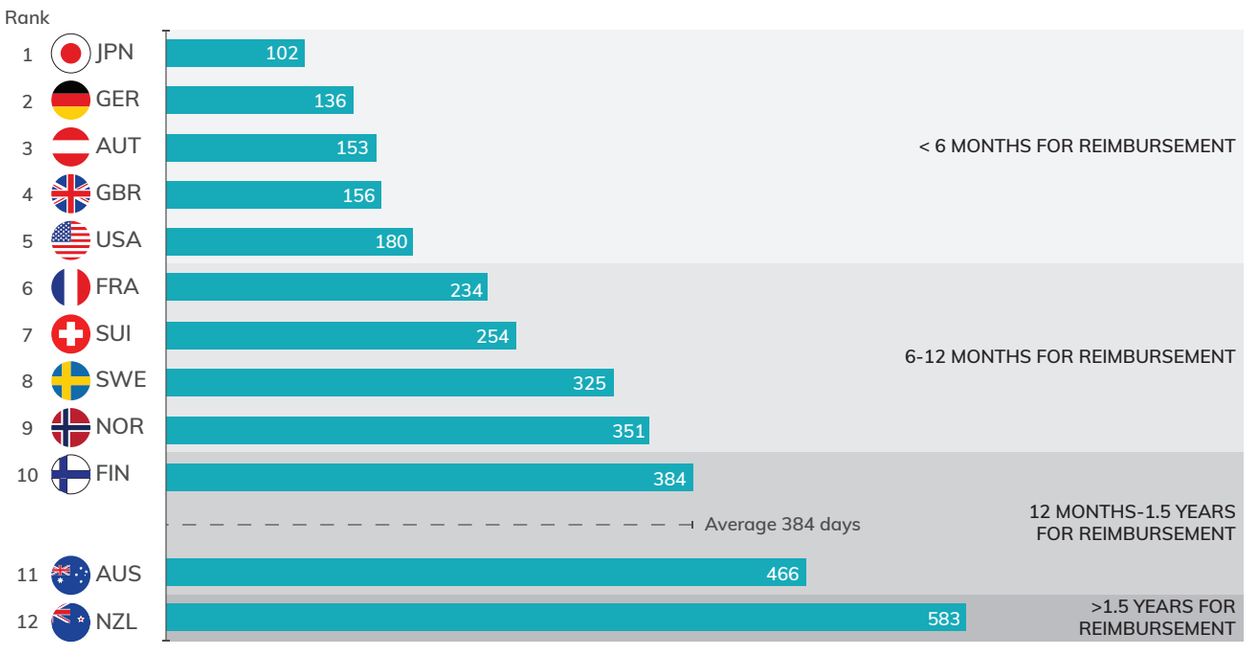


Figure 5: The average time from registration to reimbursement in other OECD nations from 2016-2021

The average time to reimbursement for all 20 OECD nations included in the analysis has increased from 377 days in 2015–2020 to 384 days in 2016–2021. Time from registration to reimbursement in Australia has increased from 413 days to 466 days in the same time period. The average time to reimbursement was impacted by a small number of medicines with a longer-than-usual time from registration to reimbursement in Australia.

5. NME registration to reimbursement timeframes vary significantly between therapeutic areas

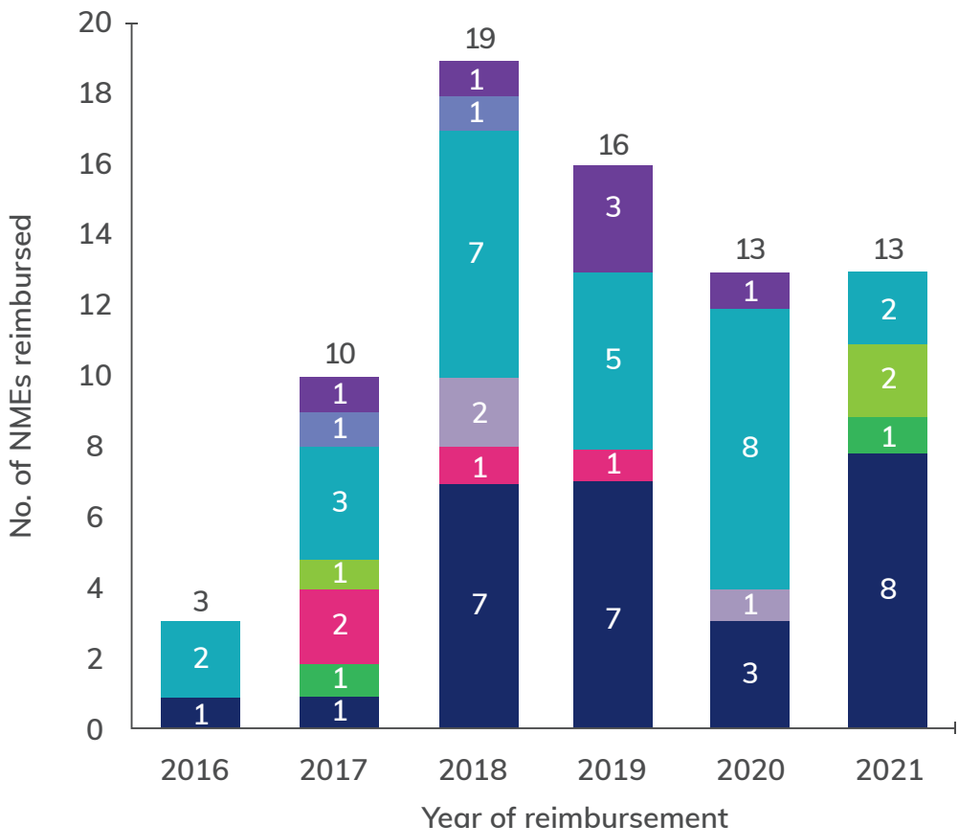


Figure 6: Number of reimbursed NMEs per year by therapeutic area from 2016-2021

Key – therapeutic area

- Arthritis & Psoriasis
- Asthma/COPD
- Cancer
- Cardiovascular
- Diabetes
- HepC
- Mental Health
- Others

Table 1: The time from registration to reimbursement for new medicines by therapeutic area from 2016-2021.

Therapeutic area	Average time-to-reimbursement	Number of reimbursed products
Arthritis & Psoriasis	189 days	6
Asthma/COPD	303 days	2
Cancer	442 days	27
Cardiovascular	1401 days	3
Diabetes	251 days	3
HepC	250 days	4
Mental Health	218 days	2
Others	531 days	27

- Oncology products comprised a lower fraction of reimbursed products in 2021, compared with the previous 2 years.
- The number of NMEs reimbursed in 2020 and 2021 was the same (13 NMEs).
- The average time from registration to reimbursement in Australia for medicines for arthritis (189 days), asthma/COPD (303 days), diabetes (251 days), hepatitis C (250 days) and mental health (218 days) was faster than the average for all therapeutic areas (466 days, Figure 5).
- For the first time, the average time from registration to reimbursement for oncology medicines in 2021 (442 days) was less than the average across therapeutic areas (466 days, Figure 5).
- Oncology medicines also saw a reduced average time from registration to reimbursement (442 days) compared to the previous analysis from 2015–2020 (496 days).
- In contrast, the average time from registration to reimbursement for cardiovascular medicines more than tripled, from 442 days in 2015–2020 to 1401 days in 2016–2021.

Note: the Medicines Matter analysis only includes NMEs registered between 2016 and 2021.

Appendix - 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 systems

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

Assessing the timelines for comparison – IQVIA analysis

Steps

1. Examine 20 OECD countries included in previous analysis[1] 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 data 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.
- Combinations were included only if the combination was registered between calendar year (CY) 2016-2021 AND at least one of the molecules were launched between CY 2016-2021.
- The analysis was conducted using information up to December 2021, because it is the most updated information available across the 20 countries in scope at the time of analysis (June 2022).

[1] Medicines Matter reports: https://www.medicinesaustralia.com.au/publications/medicines-matter/

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