

# Medicines Matter

## Access to Medicines 2014-2019 Report

Medicines Australia leads the research-based medicines industry of Australia. Our Members discover, develop and manufacture prescription medicine products, biotherapeutic products and vaccines that bring health, social and economic benefits to Australia.

The report assesses the timelines for registration and reimbursement of new medicines, specifically new molecular entities, for Australia against other OECD countries for the years 2014-2019 and finds faster registration is being achieved by the Therapeutic Goods Administration (TGA), but broader access and reimbursement is behind international standards.

The report involves a unique methodology developed by IQVIA which standardises timelines for medicines registration and reimbursement across a variety of healthcare systems within ten comparable OECD countries, including Australia.

### Priority Registration Pathways have seen improvements in TGA registration times

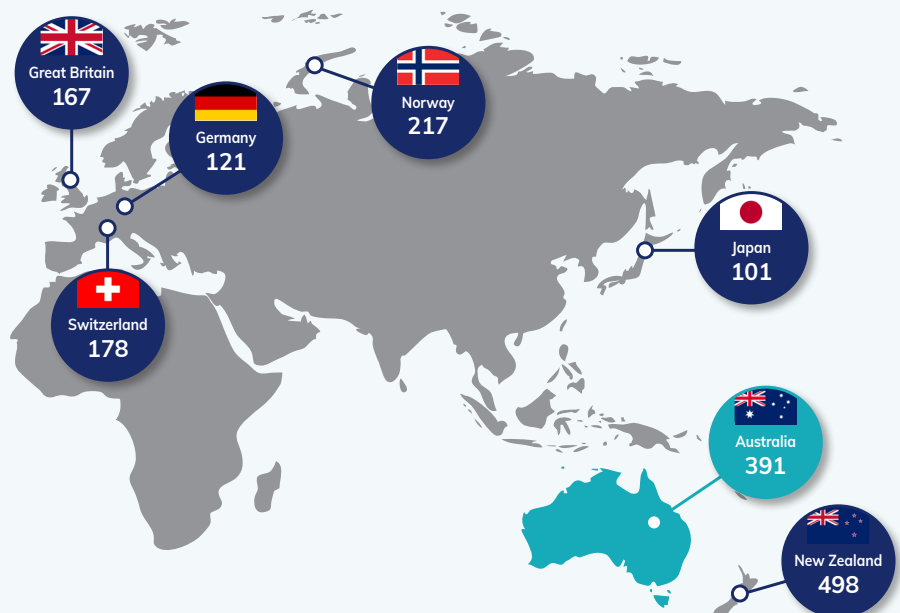
The implementation of both the TGA Priority Review and Provisional Registration Pathway in Australia have helped reduce the evaluation and approval time for the TGA.

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.

### It however, takes longer to achieve reimbursement in Australia than comparable OECD countries

The analysis also calculated the average number of days it took for a medicine to achieve public reimbursement from registration between 2014 and 2019.

Japan, Germany, Great Britain and Switzerland are all able to complete this process in under 200 days, compared to almost 400 days in Australia.



## While timeframes from registration to reimbursement are getting shorter there is room for improvement

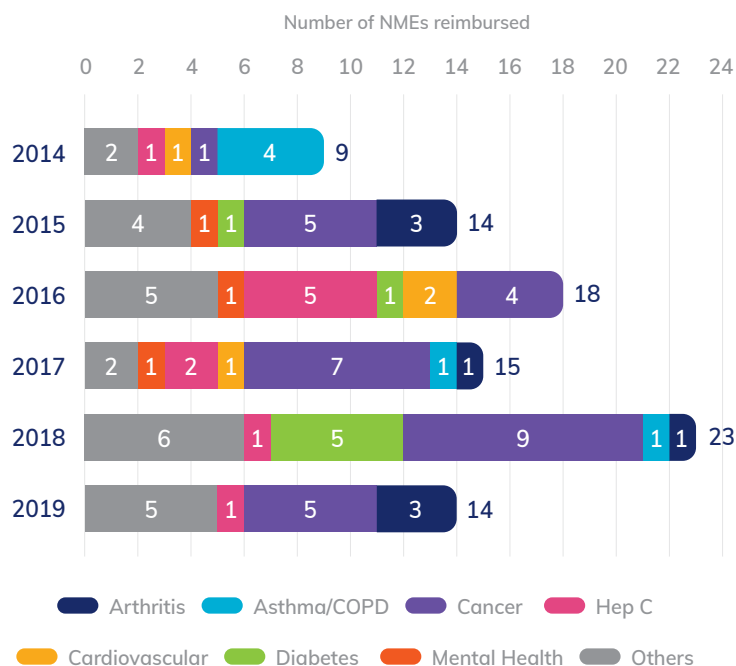
- **60%** of new medicines achieve PBS reimbursement in Australia within 12 months of submission to the PBAC.
- However, of the 10 OECD countries assessed, on average, more than **60%** of medicines are reimbursed within 6 months, in comparison to **Australia's 22%**.
- Australia's average time-to-reimbursement on the PBS has **shortened by 10 days** from previous analyses.
- Many new medicines are complex oncology products which have some of the **longest listing times**.

## Access to medicines requires further focus and improvement

- Of the 96 new molecular entities that are registered but not reimbursed in Australia, one third have been **launched privately** and the remaining two thirds still require reimbursement outcomes.
- There are **33 medicines that are not currently on the PBS** that have been reimbursed in at least one other comparable OECD country.
- Medicines Australia is actively working with the Government to **address these areas of concern**.

## Number of reimbursed New Molecular Entities (NMEs) per year and per therapy area (2014-2019)

The average time-to-reimbursement for arthritis, cancer and mental health have shortened significantly by at least a month.



## The time to listing from registration 2014 to 2019

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

