Medicines Australia | Better health through research and innovation

The patient access gap

October 2022

Speed up access to new medicines and medical technologies to reduce the Australian patient access gap

- The average time it takes for an innovative medicine to go from registration to funding in Australia is 391 days, compared to 101 days in Japan, 121 days in Germany and 167 days in the UK. This means Australian patients are waiting seven to ten months longer for new medicines to become available on the Pharmaceutical Benefits Scheme (PBS).
- Australia should strive to reimburse innovative medicines within three months of regulatory approval. This would place Australia in the top five OECD nations for patient access and deliver widespread health outcomes.
- The 2022 Independent Health Technology Assessment (HTA) Review is a critical opportunity to introduce bold reforms that can address the Australian patient access gap and introduce KPIs for patient access to measure the success.

The issues: the Australian patient access gap

Australian patients are waiting longer to access medicines than patients in other OECD countries. For some patients, this will mean missing out on, or delaying access to, potentially lifesaving and life-changing therapies[1].

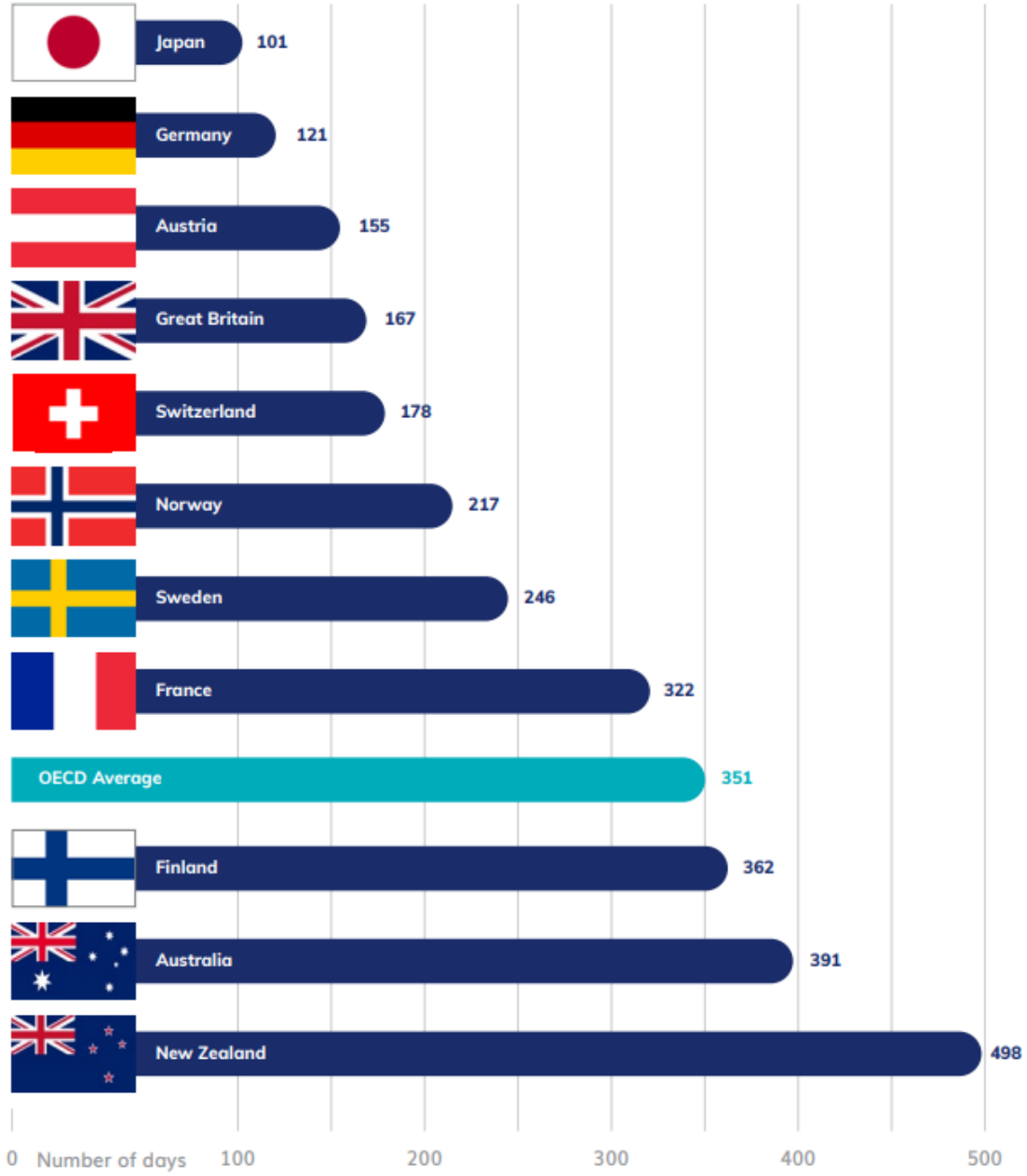
Funded access through the PBS is required for most patients to access innovative medical technologies reliably and affordably.

The Australian patient access gap is the time from when an innovative medical technology (including medicines and vaccines) is registered with the TGA to when it is subsidised and becomes available to patients on the PBS.

1 Linhorst, J, Facilitating Access to Oncology Medication. Pharmacy Times Oncology Edition, December 2021, 3(6) https://www.pharmacytimes.com/view/facilitating-access-to-oncology-medication

Figure 1 shows that the average patient access gap in Australia, 391 days, is longer than the OECD average (351 days) and well below the top five[2].

Figure 1: Average patient access gap in Australia and comparable OECD countries (2014-2019)



Source: Medicines Australia 2020 Medicines Matter: Australia's Access to Medicines 2014-2019, Figure 4 [2]

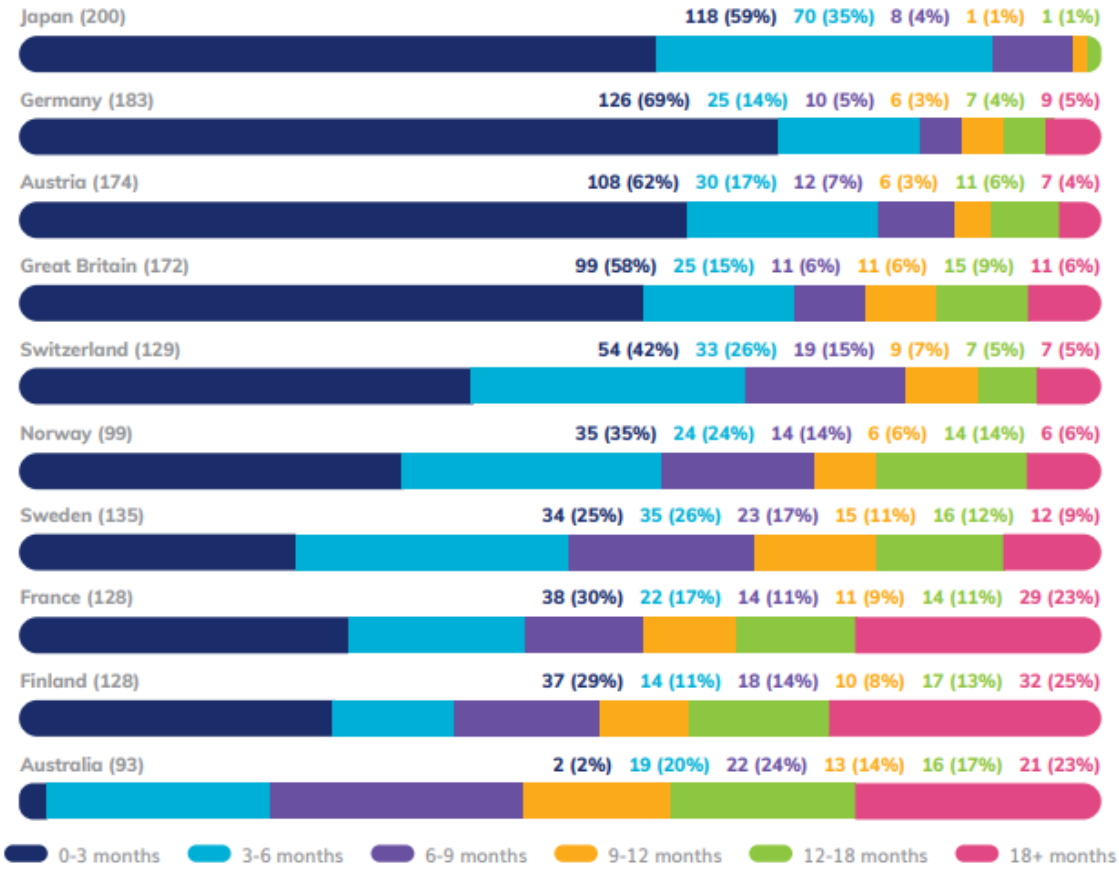
2 Medicines Australia, Medicines Matter: Australia's Access to Medicines 2014-2019, Medicines Australia, Australia, 2020 http://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/Medicines-Matter-Access-Report.pdf

NOTE: This Discussion Paper is not a final position paper. It has been developed as a conversation starter and to support discussion and feedback

On average, more than 60% of medicines in countries including Germany, France, Japan, and the UK are reimbursed within six months, compared to only 22% of medicines in Australia (Figure 2).

Incremental reforms over the past 10 years, including reforms introduced through the current and previous Strategic Agreements between Medicines Australia and the Australian Government, have aimed to reduce the

Figure 2: Time from registration to funded access, selected OECD countries (2014-2019)



Source: Medicines Australia 2020 Medicines Matter: Australia's Access to Medicines 2014-2019

Australian patient access gap. These include the Therapeutic Goods Administration (TGA) / Pharmaceutical Benefits Scheme (PBAC) Parallel Process (2011)[3] and early re-entry pathways (2021). While a medicine can achieve reimbursed access within 60 days of TGA registration in theory,[4] very few medicines achieve this in practice.

Further improvements are needed to address underlying issues. Multiple resubmissions for HTA are the biggest contributor to the patient access gap. An analysis of medicines that were recommended by the PBAC in the year to March 2022 took approximately 600 days (on

3 Amgen Supplementary Submission to the Inquiry into approval processes for new drugs and novel medical technologies in Australia Inquiry into approval processes for new drugs and novel medical technologies in Australia Submission 82 -Supplementary Submission [Internet]. 2021 [cited 2022 May 6].

4 TGA & PBAC Parallel Process & Requirements: https://www.pbs.gov.au/info/publication/factsheets/shared/tga-pbac-parallel-process

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average) to be approved. Each medicine required multiple submissions[5]. The increasing complexity of innovative medical technologies is expected to challenge HTA and may exacerbate the Australian patient access gap.

The Strategic Agreement outlines a shared commitment to "ensure access for Australian patients to the rapid advances in modern, and emerging, technologies, therapies and vaccines, and to address the complexities of enabling access for therapies to treat rare diseases". The 2022 independent HTA review is an important opportunity to introduce bold reforms to address the Australian patient access gap.

Feedback

Do you have any thoughts on the policy ideas in these papers? We'd love to hear your feedback! Please let us know at this email address: HTA-Reform@medicinesaustralia.com.au.

5 Miller, D, Commercial Eyes Analysis - Presented by Douglas Miller at ARCS 2022 Conference, ARCS, Australia, 2022

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