Medicines Australia

# Inquiry into approval processes for new drugs and novel medical technologies

## House of Representatives standing committee on health, aged care and sport

### Medicines Australia's recommendations for regulation and reimbursement

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

COVID-19 has established without question that Australia's overall health and economic indicators are inextricably linked. Medicines Australia's members have helped ensure timely access for all Australians to medicines and therapeutics throughout the challenges of the pandemic. Every innovative medicine made available in Australia generates a significant return on investment to the patient, the community, the economy and the Government.

Health Technology Assessment (HTA) introduced in 1992 saw Australia lead the way in introducing many therapeutic advances. HTA provides policy-makers, funders, health professionals and health consumers with the necessary information to understand the benefits and comparative value of health technologies and procedures. This information is then used to inform policy, funding and clinical decisions, and assist with consumer decision-making.

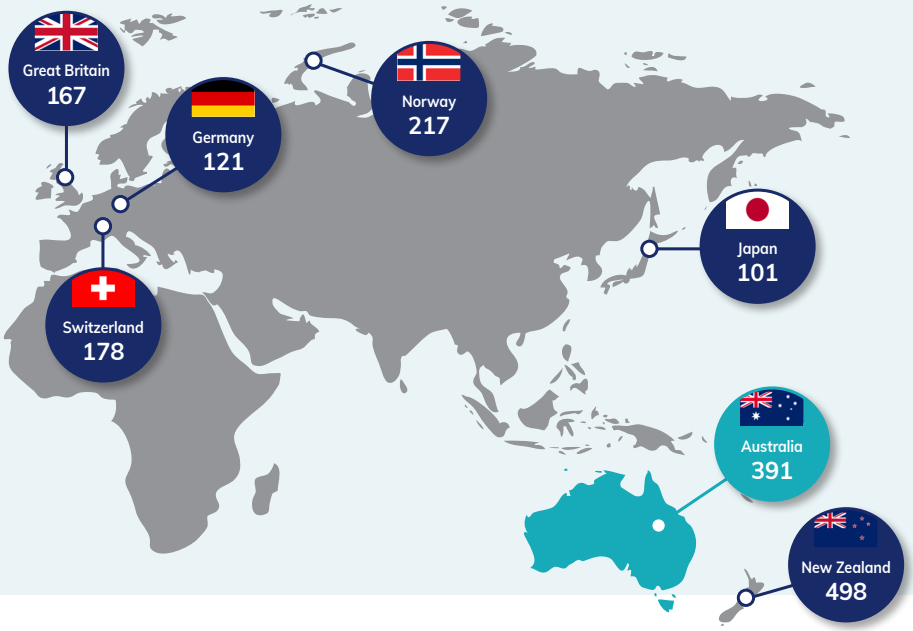
There have been dramatic shifts in life expectancy and quality of life to people with cancer, hepatitis, HIV and many chronic diseases.

| Comparison of key metrics for the U.K. and Australia HTA Systems | UK | AUS |
|---|---|---|
| % of New Molecular Entity reimbursed 2012–2017. | 84.3% | 46.4% |
| Avg time from registration to reimbursement. | 128 days | 420 days |
| % of major submissions recommended after 1st consideration (data from 2019). | 90% | 39% |
| Cost per major submission, as of 1 July 2020. | $227,027[1] | $335,170[2] |

1. Fee for large companies - £126,000 converted to AUD. Fee for small companies - £31,500.
2. Fee for all companies - includes pre-submission meeting, intent to apply, notice of intent and new deed pricing pathways.

HTA has not evolved as rapidly as global advances in science and technology. Australia is no longer in the forefront of access to medicines – there are numerous examples of medicines taking too long to be reimbursed, in some cases years.

For example, cancer treatment Folotyn took 1144 days from registration to reimbursement; while cardiovascular treatment Adempas took 1,007 days.




## Regulation recommendations

- Streamline evaluation processes across all independent and government advisory bodies.
- Enable joint pre-submission advice framework (to TGA, PBAC, MSAC, ATAGI) to improve alignment of end-to-end process.
- Update TGA regulatory processes to include expedited pathways for cell therapies mirroring pathways for prescription medicines, including priority review and provisional determination.
- Statutory 30-day review timeframes and monitoring mechanisms for Clinical Trial Exemption (CTX) review.

## Reimbursement recommendations

- Modernise the HTA evaluation process to better capture the impact of the social and economic contribution of medicines.
- Ensure consistency and alignment across all HTA processes.
- Work with industry to establish and introduce flexible assessment models and funding mechanisms recognising innovation and new technologies.
- Enable consumers, patients and patient groups to provide relevant input for individual technologies through patient-led initiatives.
- Establish a new oversight committee to independently supervise the post-PBAC price negotiation process to ensure appropriate risk sharing.
- Reinstate annual dialogue between industry (represented by Medicines Australia) and the PBAC to resolve issues of relevance for a 21st Century HTA process.

Timeliness of **access to new medicines** is one of the keys to making Australia's regulatory and reimbursement process fit for purpose in the 21st Century world of personalised medicine using **individualised molecular diagnostic tests** and **targeted therapies** to get the right treatment to right patient at the right dose first time.

MA's members contribute approximately **$9 billion to the Australian economy**, directly and indirectly supporting the employment of **23,000 Australians**.

**Domestic manufacturing** of pharmaceutical products generate **$1.6b in exports**.

Our members initiate **1,000 clinical trials** annually **helping 33,000 Australians** get early access to emerging therapies.

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