

16 January 2025

Budget Policy Division
Treasury
Langton Cres
Parkes ACT 2600

Via email: PreBudgetSubmissions@treasury.gov.au

Dear Budget Policy Division,

Re: 2025-26 Pre-Budget Submissions

Thank you for the opportunity to put forward a 2025-26 Pre-Budget Submission that advocates for reform to Australia's Pharmaceutical Benefits Scheme (PBS) to ensure timely access to life-saving and life-changing medicines for all Australians.

Medicines Australia and its members are seeking to continue our collaborative and effective partnership with the Australian Government to ensure Australia's PBS continues to meet the needs of Australian patients. The PBS is an essential part of our health system and is instrumental in realising the vision of our *National Medicines Policy* (NMP) to achieve the world's best health, social and economic outcomes for all Australians.

Medicines Australia commends the Government for releasing the [final report of the Health Technology Assessment Policy and Methods Review](#) (HTA Review), a consensus view of reform which outlines 50 recommendations endorsed by the Department of Health and Aged Care, the PBAC, clinicians and patients, via the HTA Review Reference Committee.

Australia's HTA system has not been comprehensively reviewed or reformed for 30 years. We now have a once-in-a-generation opportunity to set the PBS up for the next 30 years. The report acknowledges there is urgent need for system reform, with patients experiencing profound negative consequences caused by delays in access to new treatments. It is the last in a long series of consultations about access to medicines, and stakeholders are now expecting their input will be translated into reform.

Medicines Australia and its members support the implementation of all recommendations as a package of reforms that will work synergistically to achieve an ambitious but achievable aim of ensuring Australians have access to innovative medicines within 60 days of TGA registration. Importantly, there are priority recommendations that can be implemented to have an immediate impact. These are discussed in more detail below.

HTA reform will be further supported by the other policy initiatives that are part of Medicines Australia's Strategic Agreement with the Commonwealth. Industry has delivered billions of dollars in budget savings through successive Strategic Agreements that are forever embedded in the system. They provide enduring savings that are reflected in the New Medicines Funding Guarantee. The savings agreed to were: 2010 (\$1.9 billion), 2015 (\$6.5 billion), 2017 (\$1.8 billion) and 2022 (\$1.9 billion). These savings were in return for agreed policy initiatives to provide business stability and predictability to encourage the industry's ongoing investment in the Australian economy. These policy initiatives include the HTA Review. There are outstanding clauses of the Strategic Agreement, given in detail below, that must be implemented to support the HTA recommendations and achieve fundamental reform of the PBS to ensure its future sustainability, so that it can deliver the world's best health, social and economic outcomes for all Australians.

RECOMMENDATIONS

To achieve whole-of-system reforms to ensure Australians have equitable and timely access to new medicines, Medicines Australia recommends the Government:

1. Implement the roadmap of HTA reforms in accordance with the advice of the HTA Implementation Advisory Group, funded over the forward estimates as appropriate, starting with priority recommendations that will have an immediate impact.
2. Implement all remaining clauses of the current Strategic Agreement between Medicines Australia and Commonwealth (2022-2027).

These recommendations are discussed in more detail below, including costing implications.

1. HTA REFORMS THAT CAN BE IMPLEMENTED FOR IMMEDIATE IMPACT

The HTA Review recommendations will need to be phased over three years as many of them require co-design work with a broad range of stakeholders, however there are several that can be implemented quickly to speed up medicines access for patients.

Overarching Recommendations for all HTA funding and assessment processes (Recommendation 3)

The following principles can be adopted by the HTA Implementation Advisory Group to guide their work, namely that the restructuring and development of HTA funding and assessment pathways and processes should be:

- Proportionate and fit-for-purpose
- Streamlined and simple
- Unified and consistent.

Jointly Owned Performance Targets (Recommendation 15)

The performance targets outlined in the HTA Review Report can be adopted straight away, together with the KPIs for reducing time to PBS listing that are outlined in the Strategic Agreement between Medicines Australia and Commonwealth. The work already done on these KPIs by the Access to Medicines Working Group can be leveraged, and they will provide a baseline for measuring the impact of HTA Reforms.

Improving Consumer Involvement (Recommendation 25)

The work already done to co-design an Enhanced Consumer Engagement Process can be leveraged for early implementation of this recommendation, as outlined in the [Enhance HTA Report](#).

Discount Rate Reduction (Recommendation 39)

The PBAC Guidelines can be updated to reduce the discount rate to 3.5% for health technologies with upfront costs and benefits that accrue over a long period of time, such as gene therapies and some vaccines. This will help to ensure the full value of medicines and vaccines is recognised and maintain Australia's status as a first launch country. Medicines Australia notes that while a 3.5% discount rate is a step in the right direction, a discount rate of 1.5% is needed to fully value the medicines and vaccines provided to Australians, and will continue to advocate for further reductions. This does not need costing in the forward estimates as it will be prospectively applied to medicines that have not yet applied for funding on the PBS, and future medicines are not costed in the budget forward estimates.

Comparator Selection (Recommendation 40)

The PBAC Guidelines can be quickly and easily updated to clarify what alternative therapy should be selected as the main comparator in submissions for health technologies with multiple alternative therapies. This will help to ensure patient choice and access to the latest medicines and that the full value of medicines is recognised, and maintain Australia's status as a first launch country. An early change to the Guidelines is required to test whether this approach will lead to change and will determine whether legislative change will be required to achieve the outcomes desired by the HTA Review Reference Committee. Cost minimisation submissions are cost neutral by definition, hence there is no budget impact over the forward estimates from this recommendation.

Streamlined pathway for submissions using cost-minimisation analysis (Recommendation 7)

A streamlined pathway could be designed and implemented reasonably quickly, which would immediately free up resources for more complex submissions, hence providing efficiencies to the system. It would also speed up access, provide greater choice for patients and clinicians, and reduce the risk of shortages.

Delink the TGA Delegate's Overview from the PBAC Process (Recommendation 8)

This recommendation can be implemented quickly through an update to the PBAC Guidelines and will enable full parallel processing of TGA and PBAC submissions, speeding up the time to access for Australian patients.

Bridging Fund (Recommendation 20)

Work on co-designing a bridging fund should begin early, as this will support earlier access for patients with no other treatment options. Modelling undertaken by Medicines Australia suggests that a capped fund would require an annual investment of \$500 million, noting that the expenditure cap would not be reached until the fifth year of the program.

2. IMPLEMENT ALL REMAINING CLAUSES OF THE CURRENT STRATEGIC AGREEMENT BETWEEN MEDICINES AUSTRALIA AND THE COMMONWEALTH (2022-2027)

Important clauses of the Strategic Agreement have yet to be fully implemented, and these must remain a focus of the Access to Medicines Working Group.

- **5.2 Discount Rate:** See HTA Recommendation 39 above
- **6.6 Lowest Cost Comparator:** See HTA Recommendation 40 above.
- **6.8 Exchange and Sharing of Information:** This was piloted for the November 2024 PBAC meeting, with eight member companies participating. The Department will do an evaluation in early 2025 and the process should be modified as appropriate and then fully implemented.
- **6.9 Cost Recovery:** The cost recovery time and motion study is complete but analysis is ongoing. It is intended to feed into the 2025-25 Cost Recovery Implementation Statement (CRIS) but is behind schedule. This must be completed on time so companies have sufficient opportunity to do business planning for any updates to the CRIS.
- **7.2 Risk Sharing Arrangements:** Medicines Australia has been working with the DoHAC to align on principles via the Access to Medicines Working Group. A roadmap for short- and long-term reforms is now being prepared. This must be implemented to provide policy certainty for all parties
- **Appendix 3. Performance Measures for Reporting:**
 - **KPIs 1. Reduce time to PBS listing:** a set of baseline metrics will be endorsed by the Access to Medicines Working Group early in 2025. A baseline measurement must be taken to assess the impact of HTA Reforms over the longer term. (The ANAO Audit of the

Administration of the PBS¹ adds weight to the argument for KPIs, finding that the current single external performance measure for the PBS does not provide meaningful performance information to the Parliament or the public.)

- **KPIs 3. Enhanced reporting on investment in F1 medicines:** The DoHAC is aiming to publish the PBS expenditure and prescriptions report by the end of December which is expected to include PBS expenditure broken down by formulary and subsidy component (AEMP and fees and mark-ups).

NATIONAL WELLBEING FRAMEWORK

Our recommendations will support three of the wellbeing themes and multiple indicators from the Measuring What Matters framework:

- **Healthy:** timely access to safe and cost-effective innovative medicines, biotherapeutics and vaccines is vital for Australians to continue to seeing improvements in life expectancy and quality of life. Improved access to innovative therapeutics will also support greater gains in mental health and prevention and treatment of chronic conditions. Investing in innovative medicines reduces premature mortality and saves hospitals money by reducing the length of hospital stays².
- **Sustainable:** an effective and efficient HTA system will send a signal to international and local suppliers of innovative therapeutics that Australia is an available market, therefore supporting improvements in Australia's economic resilience ranking. Fiscal sustainability is also a key feature of the PBS as explained above.
- **Prosperous:** as demonstrated during the COVID-19 pandemic, investment in medicines is a key driver for the economy and productivity. COVID-19 vaccines, for example, are estimated to have reduced the impact of the pandemic on the economy to an estimated \$214 billion, resulting in a positive incremental benefit of \$181 billion³. Additionally, a well-functioning HTA system will promote downstream benefits of local innovation in the entire life sciences industry and supply chain.⁴

Medicines Australia looks forward to continuing to work collaboratively and transparently with the Government on a range of issues relating to the health of Australians and the industry, including the implementation of the Strategic Agreement, TGA funding, the Clinical Trials National One Stop Shop, tax reform, climate change, government procurement, and a high-level government-industry forum.

Yours sincerely,



Elizabeth de Somer
CEO
Medicines Australia

¹ <https://www.anao.gov.au/work/performance-audit/administration-of-the-pharmaceutical-benefits-scheme/> Accessed 16/01/2025

² F. Lichtenberg, *The Effect of New Medicines Provided by the PBS on Mortality and Hospital Utilisation in Australia, 2002-2-19, 2023* <https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/06/From-Hospital-Beds-to-Healthy-Lives-The-Impact-of-Innovative-Medicines.pdf> Accessed 16/01/2025

³ N. Fox, P. Adams, D. Grainger, J. Herz, C. Austin. *The Value of Vaccines: A Tale of Two Parts, 2022* <https://www.mdpi.com/2076-393X/10/12/2057> Accessed 16/01/2025

⁴ Commonwealth Government. *Measuring What Matter July 2023.* <https://treasury.gov.au/publication/p2023-mwm>. Accessed 16/01/2025

ABOUT MEDICINES AUSTRALIA

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.