

## Fact sheet 3 - Strategic Agreement with Medicines Australia – Health Technology Assessment Policy and Methods Review

The Australian Government and Medicines Australia have the shared goals of:

- Reducing time to access to emerging treatments for Australian patients so that they can access new and innovative health technologies as early as possible; and
- Maintaining the attractiveness of Australia as a first-launch country for new medicines;
- Building on Australia's status as a world leader in providing patients affordable access to healthcare.

The Australian Government has agreed to support an independent review of Health Technology Assessment (HTA) current policy and methods used by the Pharmaceutical Benefits Advisory Committee (PBAC) to assess new medicines for listing on the Pharmaceutical Benefits Scheme (PBS), contemporary research, and relevant methodologies and purchasing practices used by comparable international jurisdictions.

The HTA review is a mutual acknowledgement by the Government and the medicines industry that medical technology is progressing rapidly and a step-change is required to keep pace with advances in science as well as continuous evaluation and improvement to help ensure access as early as possible to the most effective medicines for all Australians.

The review will consider a number of important areas including:

- selection of comparator(s)
- methods for evaluating rare diseases for reimbursement and alternative funding pathways if required
- methods for evaluating new and emerging technologies (including cell and gene therapies, and other precision-based medicines) and the suitability of existing funding pathways as required
- methods for evaluating all new medicines and vaccines
- use of real-world evidence including from sources other than randomised controlled trials
- managing clinical, economic, financial and other uncertainty
- the feasibility of international work-sharing for reimbursement submissions

The review will be overseen by a Committee that is independently chaired, and includes a patient representative, a member nominated by Medicines Australia, a Government Nominee, the Chair of the PBAC and the independent Chair. The Chairperson and membership of the HTA Review Reference Committee will be approved by the Australian Government.

The HTA policy and methods review will be conducted during the first year of the Agreement (2022-23 financial year) with milestones for implementation of recommendations. The Minister will also seek early advice from the PBAC as to whether the base case discount rate currently outlined in the PBAC guidelines aligns with international best practice.

The review will support the continuous improvement of Australia's HTA process and access to the most effective medicines for Australians, in parallel with the review of the National Medicines Policy, and informed by submissions to the inquiry into approval processes for new drugs and novel medical technologies in Australia that was conducted by House of Representatives Standing Committee on Health, Aged Care, and any recommendations arising from that inquiry.

The review will also help ensure Australia is a global priority for launching new medicines and that delays in accessing innovative therapies for patients are reduced. This is important in the rapidly evolving international environment.

### **Why is this important?**

Health Technology Assessment refers to the processes and mechanisms based on scientific evidence used to assess the comparative quality, safety, efficacy, effectiveness and cost-effectiveness of health technologies.

For medicines on the PBS, this process is overseen by the PBAC who consider effectiveness and cost of new medicines when determining whether to recommend to the Minister that they should be listed on the PBS.

It is important to ensure that they are continually evaluated and updated so that they remain fit for purpose and deliver best value for the community.

**Who will benefit?**

Australian patients who will continue to benefit from access to affordable breakthrough, innovative medicines as early as possible.

The medicines industry who will benefit from stability and certainty for investment in new medicines and assessment processes that remain world class and keep pace with rapid advances in medicine enabling them to be marketed and funded in Australia as they emerge.

The Australian economy will benefit from improved health outcomes, and continued investment in research and innovation.