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Accelerated access to innovative medicines

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Accelerated Access: a proposal for improving Australia's patient access gap

- Bold reform of the reimbursement system for innovative medical technologies is required to reduce Australia's patient access gap: the time between TGA registration and funded patient access.
- Accelerated access could be achieved by prioritising patient access through interim access arrangements, while rigorous health technology assessment (HTA) is conducted.
- This would recognise the value of health technologies throughout the life cycle, ensuring that innovation is rewarded and incentivised, and that savings are delivered to taxpayers as technologies mature, maintaining sustainable expenditure on the PBS.

A Possible Solution for Accelerated Access

The reforms proposed below aim to increase the speed of patient access to new medical technologies by up to 10 months, compared with the existing PBS (Pharmaceutical Benefits Scheme) listing process. Faster access could mean saving lives and improving quality of life for Australians. The proposed reforms retain the best elements of our existing reimbursement system while addressing aspects of the system that cause delays.

Broader application of the reforms could include a similar pathway for faster access to any medical technology that offers superiority over standard clinical practice.

The proposed reforms include:

1. Earlier, more meaningful engagement between the sponsor and PBAC prior to submission lodgement and during the evaluation period, so that the requirement for resubmissions is minimised.
2. Earlier initiation of the HTA process to align with the TGA application, thereby delinking the existing TGA–PBAC processes from the requirement to receive the TGA Delegate's overview.
3. Introduction of an interim funding period for new technologies, which would enable patients to access these technologies at the time of TGA registration.
4. A structured process for pricing negotiations, funding reconciliation and potential delisting arrangements, should the PBAC and sponsor be unable to reach a funding agreement.

The reforms would be enabled through:

- Process improvements, including more meaningful engagement between the PBAC, PBAC executive, sponsors, consumers, and other stakeholders throughout the evaluation period.
- Technical changes to the HTA evaluation process, including use of the clinical comparator, consideration of the full scope of value, and broader acceptance of real-world evidence, to ensure that an appropriate value is placed on new medical technologies.
- Management of uncertainty in decision making in a manner that prioritises earlier patient access and reflects true risk-sharing between the sponsor and payer.
- Better alignment and streamlining of processes across HTA agencies and programs, including the MSAC, PBAC, LSDP and ATAGI.

The Proposed Accelerated Access Reforms in Detail

1. EARLIER, MORE MEANINGFUL ENGAGEMENT BETWEEN STAKEHOLDERS PRIOR TO SUBMSSION, AND DURING THE EVALUATION PROCESS

This is a critical step to reduce uncertainty and avoid the need for arbitration or delisting at the end of the process.

Pre-submission meetings

Optional pre-submission meetings would continue; however, there could be an option to improve on these by including an endorsement of the PICO and economic model parameters (akin to the existing MSAC PASC process) with the aim of reducing the need for resubmissions resulting from lack of agreement on these elements of the submission.

A further option is for a pre-ESC workshop to enable the development of a *plausible base case* assessment of cost effectiveness.

In addition, the Strategic Agreement states that the Commonwealth and Medicines Australia agree to work together to co-design a trial to facilitate the exchange of information between the Responsible Person and evaluators during the process of a particular PBAC submission. This would provide an opportunity to address any areas of uncertainty identified by the evaluators at an early stage.

2. DELINK THE PBS PROCESS FROM THE TGA DELEGATE'S OVERVIEW TO ALLOW EARLIER HTA EVALUATION

Reimbursement application and evaluation process

Under the proposed reforms, a sponsor would lodge a Category 1 or Category 2 PBAC submission via a revised TGA/PBAC process in which TGA and PBAC submissions could be lodged simultaneously. This would delink the current requirement to wait for the TGA Delegate's Overview before submitting to the PBAC. The PBAC submission would include a full HTA assessment, including a cost-effectiveness analysis. Current processes for evaluation of applications prior to PBAC consideration could continue, but would incorporate any improvements to the process and HTA technical considerations.

3. REIMBURSED ACCESS VIA AN INTERIM FUNDING ARRANGEMENT FROM THE TIME OF REGISTRATION OF THE MEDICINE

Medicines would be reimbursed on an interim funding basis from the time of TGA registration (that is, entry onto the Australia Register of Therapeutic Goods) at the list price proposed in the initial submission. A deed of agreement between the sponsor and the Government covering the interim funding period would be required. The PBS special pricing arrangement (SPA) policy would apply, whereby the Department of Health pays the list price and the sponsor rebates the difference between the submission list price and the agreed net price.

The method to agree the net price during the interim period requires more consideration, but could be fixed (for example, a mandatory proportional discount); as per the sponsor's initial submission (noting that the value has been assessed but not yet agreed); or as agreed between both parties. A similar agreement would apply for Managed Access Program or LSDP medicines. The interim funding process would continue until: 1) a positive PBAC recommendation is obtained; 2) the sponsor withdraws from interim funding; or 3) for a maximum period of 5 years.

An important consideration with interim funding is ensuring the appropriate patient consent. Informed patient consent would be required to demonstrate understanding that they are receiving a medicine under an interim mechanism. A model exists for this in the current system as part of the informed consent for medicines listed under Managed Access Programs.

4. A STRUCTURED PROCESS FOR PRICING NEGOTIATIONS, FUNDING RECONCILIATION AND POTENTIAL DELISTING ARRANGEMENTS

Once a positive PBAC recommendation is achieved, price reconciliation would occur whereby the Government reimburses the sponsor if a higher price is recommended, and the sponsor reimburses the Government if a lower price is recommended. The timeline for this process could be mandated (for example, 6 months from final cost-effective price determination).

An independent mediation/arbitration mechanism may be needed to enable dispute resolution in cases where the sponsor and the Government were unable to negotiate a final price during the interim funding period.

If dispute resolution is unsuccessful or PBS listing does not occur within the maximum duration for interim funding, the medicine may be delisted.

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.