Medicines Australia

Achieving Timely Access for Australian Patients with an Independent HTA Review

Given advancements in scientific research and development, and the pace of change in technology, the current Inquiry into approval processes for new drugs and medical technologies is both timely and critical. It has prompted a significant community response, with a total of 193 submissions being published on the Inquiry website as of June 2021.

Common Opportunities Raised Across All Submissions:

- Patients can be **better engaged** in approval processes
- Approval processes can be streamlined for **innovative medicines**
- Approval processes simplified for **rare diseases**
- **Innovative medicines** better positioned to reap benefits and value
- Reposition **Australia as world leader** for time to access new medicines
- Expand access to **clinical trials**

Reforms Being Sought

- **Early and meaningful patient engagement:** All Australian patients, their families and carers deserve to have their voices heard and should have a consistent opportunity to contribute to the HTA process. Early and meaningful patient engagement will help expedite treatment access.
- **A flexible, transparent HTA system that is responsive to new innovative medicine:** By adopting some of the relevant features of international HTA frameworks, Australia can minimise duplication of effort in the registration process and future-proof the reimbursement system.
- **Equity of access for patients living with a rare disease/cancer:** Continuous improvements to the HTA system are needed to address the rapid advances in emerging technologies and the complexities of enabling access for therapies to treat rare diseases and cancers.
- **Greater consideration of the value new innovative treatments deliver to patients:** Every innovative medicine made available in Australia generates a significant return on investment to the patient, the community and the economy. It is critical HTA processes take a broader range of values into account.
- **Reduce the time from TGA registration to reimbursement:** Timely access to innovative medicines for Australian patients should be a priority for decision makers. Currently Australian patients are waiting longer than patients in other parts of the world to get subsidised access to some new innovative medicines.[1]
- **Facilitate increased investment in, and streamlined access to, local clinical trials:** Current regulatory and reimbursement processes, along with existing R&D policies, have led to a number of global pharmaceutical companies choosing not to invest in local clinical trials and research. A streamlined, harmonised clinical trials environment would facilitate the establishment of more clinical trials across Australia.

An Independent HTA Review is a Possible Solution

In the view of industry, an independent review of Australia's Health Technology Assessment (HTA) processes would address the majority of the issues raised in submissions to the Inquiry.

What is HTA

HTA refers to a range of processes that use scientific evidence to assess the quality, safety, efficacy, effectiveness and cost effectiveness of health products and services. In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC), an independent body appointed by Government, assesses medicines for reimbursement by the Commonwealth via the Pharmaceutical Benefits Scheme (PBS). HTA was introduced in Australia in 1993, but has not kept pace with advancements in scientific research and technological developments.

What Could an Independent HTA Review Achieve

An independent review of Australia's HTA processes would help to ensure that they provide rapid access to new technologies such as precision medicines, and curative therapies such as CAR-T. It would do this by considering the patient's perspective on new medicines, helping to ensure that the medicines most valued by patients for their health outcomes are made available by the Government in a timely manner.

The UK's HTA Review

The UK's National Institute for Health and Care Excellence (NICE) is currently reviewing their HTA processes, to ensure that there is rapid access to clinically and cost effective health technologies vital to patients.[2] NICE has already identified potential areas for change within its consultation document, including incorporating severity of disease, health inequalities and a 'refined' approach to uncertainty and innovative technologies within its methodologies for evaluation. NICE said there is also a 'case for change' regarding how it values costs and health effects for health technologies.[3]

1. Medicines Australia. Medicines Matter: Australia's Access to Medicines 2014-2019. November 2020.
2. https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/chte-methods-consultation
3. http://www.pmlive.com/pharma_news/nice_launches_consultation_on_its_methods_of_drug_evaluation_1356330?SQ_DESIGN_NAME=2&