Health Technology Assessment (HTA) Policy and Methods Review – Consultation One

The Australian Government agreed to support the HTA policy and Methods Review (HTA Review) as one of the main commitments under the 2022-27 Strategic Agreement between the Commonwealth and Medicines Australia. A Reference Committee was established and will oversee a series of consultations. Written submissions to the first consultation closed on 6th June 2023.

Consultation 1 aimed to *"gather evidence or examples in relation to the objectives of the HTA Review, not previously considered through other recent stakeholder consultation relating to HTA."* It specifically asked for input related to the following:

- how the existing processes work effectively
- may act as current or future barriers to earliest possible access
- may act as current or future barriers to equitable access
- detract from person-centredness
- may be creating perverse incentives.

Cancer Council along with the Cancer Nurses Society of Australia, the Clinical Oncology Society of Australia, the Medical Oncology Group of Australia and the Private Cancer Physicians of Australia, made a joint submission to this consultation. As an outcome from the HTA Review, we would like the Australian Government and regulators to play an active, rather than passive role in enabling Australian's timely and affordable access to safe and effective medicines and health services supporting best cancer care. Our submission highlighted several opportunities to reform Australia's HTA processes to improve timely and equitable access to essential cancer medicines, medical devices and health services, and create flexibility in the system to assess applications for new and emerging cancer medicines.

The main points in our submission included:

- Introducing policy to enable the Australian Government Department of Health and Ageing and the Pharmaceutical Benefits Advisory Council to proactively identify therapeutic products for reimbursement, and for therapeutic products already listed on the Australian Register of Therapeutic Goods, initiating a review to subsidise products that address a significant unmet need.
- Introducing a mechanism for the PBAC to make recommendations for immediate access for medicines that substantially improve survival while the final price is being negotiated.
- For therapeutic products already listed on the Australian Register of Therapeutic Goods, the Department of Health and Ageing and PBAC should be able to request that the Therapeutic

Goods Administration review and extend a product's indication where it may address a significant unmet need.

- Consider a single approval entity or review to facilitate streamlining of approval processes, and processes for extending indications between the Medical Services Advisory Committee and PBAC processes.
- Requiring co-dependent technologies associated with the improved health outcomes to be assessed at the same time as the medicine or medical service for which its use is associated.
- Exploring the feasibility of introducing a fast-tracked pathway to assess evidence to extend the use of a targeted medicine to other diseases.
- All submissions for funding of new technologies should demonstrate evidence of clinically relevant benefits and patient relevant outcomes, such as improvement in overall survival and quality of life. Regulators should encourage evidence of additional patient relevant outcomes to be submitted such as patient preferences for one treatment over another, ability to return to work or other meaningful activity, and beneficial effects on family and/or carers.
- Identifying opportunities for patient outcomes from clinical trial data to be presented to the PBAC in a clinically meaningful way. Inviting clinical trial participants to speak directly to the PBAC about their experience, and other opportunities to improve patient engagement with the HTA process such as introducing a more person-focused online submission process which has standardised questions to capture the elements of their experience patients want to share.
- Greater use of Managed Access Programs, or similar risk-sharing arrangements between a product's sponsor and the Australia Government, for products aimed to fulfill a significant unmet need and where evidence is promising but remains uncertain.
- Considering the feasibility of publicly-funded comprehensive genomic profiling for people diagnosed with cancer to provide patients and doctors with information to direct care earlier and avoid the need for single gene tests.
- Explore the appropriateness and impact of capped funding programs, and policies to drive the uptake of biosimilar medicines including ensuring patients and their healthcare professionals are educated and incentivised to opt for the more affordable biosimilar medicine, when it is appropriate.

Information about the progress of the consultation, can be found on the consultation's webpage.