

[REDACTED]

16 February 2024

Office of Health Technology Assessment  
Consultation Hub

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Dear Sir/Madam

## Re: Health Technology Assessment Policy and Methods Review - Consultation 2

[REDACTED] welcomes a review of the HTA and the chance to provide stakeholder feedback and acknowledges the breadth of work being undertaken by the Review Committee. It is also acknowledged the Review Committee has considered many of the recommendations made by stakeholders, [REDACTED] to improve the HTA pathway process for improved equity and timeliness of access to new technologies for the Australian [REDACTED]

The key concerns highlighted [REDACTED] with the current process that lead to barriers, inequality and lack of person centeredness were:

- Lack of understanding of the process by stakeholders (addressed in proposal 1.1 - 1.3),
- Long lead time for approvals and subsequent listings (addressed in proposal 2.1 - 2.2) ,
- Lack of transparency and broad stakeholder engagement (addressed in proposal 1.4 & 5.4)
- Financial criteria review (addressed in proposal 1.4)

Many of the proposals outlined in Consultation 2 provide improvements to assist in removing these barrier in the HTA Process.

### Transparency, Communication, and Stakeholder Involvement in HTA

In previous feedback submissions, [REDACTED] advocated for improved transparency, communication and stakeholder involvement in the HTA pathways. This is particularly important for smaller population subgroups within the Australian context, such as Aboriginal and Torres Strait Islander peoples and/or rural and remote populations. These populations are often at higher risk of worse health outcomes than their urban counterparts and, as they are a small cohort, with needs that differ to urban population due to different geographical requirement and disease burdens, risk being overlooked when technologies are assessed and a lack of access to specialist services that may be required to deliver the technologies.

The introduction of plain language summaries aimed at consumers, improved HTA webpage content and navigation should help to address some of the issues regarding ensuring appropriate stakeholder engagement and understanding that were identified in the current process. Furthermore, the improved transparency in decision making will help improve understanding by consumers, clinicians and in particular, will also assist jurisdictional Medicines and Therapeutics Committees in their own decision making with the addition of a central standardised data sharing systems

The establishment of a First Nations Advisory Committee to enable partnership in decision making is welcomed [REDACTED]. It was recognised that the current system results in in-equity for patients who access medicines under various Commonwealth program rules and that an advisory role of

this capacity could be beneficial in ensuring HTA meets the needs of Aboriginal and Torres Strait Islander peoples. However, it not clear from the options listed in consultation paper 2, how the use of the stakeholder engagement and input will be considered in decision making and the impact this will have on the assessment pathway and [REDACTED] welcomes an opportunity to be involved in the further development of this process.

Furthermore, to prevent risk of complicating consensus-building with a wider stakeholder engagement, developing structured processes for engaging with stakeholders would help streamline input and ensure that diverse perspectives are efficiently integrated into decision-making. In addition, by maintaining transparency about the HTA process and decisions and communicating effectively with all stakeholders, this will build trust and facilitate smoother implementations of changes.

**Recommendation:**

- Provide further detail regarding how the use of the stakeholder engagement and input will be considered in the decision making and the impact this will have on the assessment pathway.
- Provide further detail regarding how early access, real world data and delisting of products will be considered and risk mitigated.
- Request to be involved in the development of structured processes for engaging with stakeholders.

**Health Technology Funding and Assessment Pathways**

As outlined in the previous feedback submission, timeliness and equitable access to medicines are a key objective [REDACTED]. The suggested proportionate appraisal pathways is considered a positive proposal to improve timeliness of access to medicines, particularly those considered low risk. This relies on ensuring that committee members have adequate understanding and expertise to ensure appropriate triaging. This proposed system would rely on therapies meeting High Unmet Clinical Need (HUCN) and High Added Therapeutic Value (HATV). However, there is no detail in the proposal as to the criteria for medicines to meet the criteria of HUCN or HATV. There is concern that different sectors of the public, drug sponsors and government may have different considerations as to the criteria and value for HUCN and HATV. These definitions should be robust and created in consultation with stakeholders to ensure they are appropriate and fit for purpose.

The potential for development of a single HTA advisory committee comprising the necessary expertise to assess all applications seeking public funding would assist in reducing confusion of application pathways and streamline processes. However, there is concern regarding the capacity of a single committee to consider all applications as well as having appropriate skill-mix to consider the vast array of technologies that exist. This broad range of expertise may require HTA committees to draw on a wider pool of expertise, posing challenges in ensuring that the committee has access to the necessary specialized knowledge for all types of technologies it would assess. This could be addressed by adopting a flexible approach to committee composition, where experts can be brought in on an ad-hoc basis for specific assessments to ensure access to the necessary specialized knowledge, in addition to collaborations and partnerships with academic institutions, international bodies, and other expert groups could provide access to additional expertise.

There is a risk that a single committee may also create bottlenecks and may reduce timeliness of applications to progress through the pathway. It is recognised that this potential increase in workload could be managed by efficiency improvements (implementing more efficient processes and decision-making frameworks to avoid significantly delaying assessments) and leveraging technology and data analytics to streamline data analysis and support more informed decision-making. Further details regarding this proposal would be required to ensure that, operationally, it could meet the intent of improved efficiency and ultimately timely access to medicines.

There is lack of detailing [REDACTED] regarding the consideration of the impact of on hospital budgets arising from PBS listing of new treatments either via requirements for commencement in hospital or arising from treatment of side effects requiring admission. Inpatient use of medicines in public hospitals is generally funded through state and territories. Although PBAC does not explicitly consider medicines used in public hospitals, there have been some PBAC recommendations for medicines which require initiation in hospital. It could be considered that with appropriate jurisdictional engagement and feedback during the process these considerations would be taken into account during the assessment process.

**Recommendation:**

- Ensuring appropriate and broad stakeholder engagement in the development phase of building the new systems to ensure definitions, criteria such as HUCN or HATV etc are appropriate and fit for purpose
- Provide further details regarding implementation and operational aspects of a single HTA committee proposal
- Ensure the HTA advisory committee and HTA processes are adequately resourced, both financially and in terms of human capital, to handle its expanded role and mitigate risks of delays (demonstrating long-term cost saving and health benefits as a result of HTA process should easily justify the investment).

**Future Proofing Australia's Systems and Processes**

A coordinated approach to horizon scanning of new technologies is welcomed [REDACTED]. It is considered that individual jurisdictions have limited resources and means to conduct ongoing horizon scanning. To reduce duplication of effort, it would be ideal for the HTA advisory committee to include horizon scanning details on their website to allow jurisdictions, patients, clinicians and Medicines and Therapeutics Committees improved decision making and understanding of future changes to the medicine landscape to allow for pro-active rather than reactive integration into health care systems and budgets.

It is acknowledged that Health technologies and their assessment methods are constantly evolving at a significant rate and must be reviewed and updated regularly. This HTA review proposal constitutes a significant change to the current process and there is likely to be teething problems and opportunities for learning. As such, the program of continuous review and improvement is essential with mechanisms to ensure review and quality improvements as the system progresses to prevent unintended consequences of the new processes. It is considered that regular process review and stakeholder feedback opportunity is appropriate as an ongoing aspect of this constantly evolving landscape.

**Recommendation:**

- Include details of the proposed approach to horizon scanning as part of the transparency process to prevent duplication of work and assist in healthcare systems to be improve pro-active activities.
- Ensure ongoing stakeholder feedback opportunities at regular intervals to continue to address issues and maintain quality improvement of HTA pathways.

Thank you again for the opportunity to provide input to the Health Technology Assessment Policy and Methods Review [REDACTED] look forward to further opportunities for input as the review progresses.

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