A joint submission to

The Health Technology Assessment (HTA) Policy and Methods Review – Consultation 2

26th February 2024

This submission has been prepared jointly between Cancer Council Australia (Cancer Council), the Cancer Nurses Society of Australia (CNSA), the Clinical Oncology Society of Australia (COSA), Private Cancer Physicians of Australia (PCPA) and Medical Oncology Group of Australia (MOGA).

Cancer Council is Australia's peak national non-government cancer control organisation and advises the Australian Government and other bodies on evidence-based practices and policies to help prevent, detect and treat cancer.

Cancer Nurses Society of Australia is the peak national body for cancer nursing and strives to promote excellence in cancer care through the professional contribution of cancer nurses.

The Clinical Oncology Society of Australia is the peak national body representing health professionals from all disciplines whose work involves the care of cancer patients.

Medical Oncology Group of Australia is the national, professional organisation for medical oncologists and the profession in Australia.

The Private Cancer Physicians of Australia is the peak body for private cancer physicians (Medical and Radiation Oncologists and Haematologists), dedicated to improving outcomes for all cancer patients, but particularly those seeking treatment in the private sector.

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Chapters we will be providing feedback on:

1. Transparency, communication, and stakeholder involvement in HTA
2. Health technology funding and assessment pathways
3. Methods for HTA for Australian government subsidy (technical methods)
4. Health Technology funding and purchasing mechanisms and decisions
5. Futureproofing Australia's systems and processes

Topics we will be providing feedback on:

1. Transparency, communication and stakeholder involvement in HTA
    - 1.1. Transparency and communication of HTA pathways, processes and decisions
    - 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA
    - 1.3. First Nations people involvement and consideration in HTA
    - 1.4. State and territory government collaboration in HTA
2. Health technology funding and assessment pathways
    - 2.1. Streamlining and aligning HTA pathways and advisory committees
    - 2.2. Proportionate appraisal pathways
3. Methods for HTA for Australian government subsidy (technical methods)
    - 3.1. Determination of the Population, Intervention, Comparator, Outcome
    - 3.2. Clinical Evaluation Methods
    - 3.3. Economic evaluation
4. Health Technology funding and purchasing mechanisms and decisions
    - 4.1. Approaches to funding or purchasing new health technologies
5. Futureproofing our systems and processes
    - 5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS
    - 5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system
    - 5.4. Mechanisms for continuous review and improvement
    - 5.5. Capacity and capability of the HTA system

1.1. Transparency, communication, and stakeholder involvement in HTA into account.
Overall, to what extent could the options (if implemented) address the issues that relate to them?

- We welcome increased transparency at every level of the HTA process and greater involvement with stakeholder consultation at every stage of the process.
- We support any measures that increase community member and healthcare professional engagement, ensuring that this occurs as early as possible and frequently throughout the process, and all outputs or decisions made because of that input are transparently shared with the community.
- Developing an engagement framework is important to ensure stakeholder involvement and communication is a transparent process and accessible to all who wish to be involved in the process.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Publish plain language summaries

- Increasing plain language communication will assist in stakeholder engagement in the HTA process and make the process easier for all individuals and organisations to engage.
- Accessible versions of the summaries in various communication modalities, such as audio or braille, should be available as requested by individuals and organisations to support their engagement to promote access and inclusion.
- Summaries should be co-designed with community members from different populations to ensure the content is accessible and in an appropriate format they understand. The content should reflect the information needs of specific populations to make informed decisions.

Improvements to the HTA webpage including the development of a dashboard

- Consideration should be given to improving the readability and accessibility of the content on the website for all stakeholders and populations.
- Consideration should be given to how the HTA webpage is promoted. Promotion of the website will increase awareness of where to find information, how to engage in the process and opportunities for input/participation. A campaign focusing on changes to the HTA process, including the focus on stakeholder engagement, and how to interact with the website and dashboards will help improve community engagement and make it more likely to be accessed.
- The website re-design must involve community members and healthcare professionals to ensure the dashboard is user-friendly for multiple audiences. Adoption of a human-centered design approach would consider the different information needs of user groups and increase accessibility.
- Consideration of the development of dashboards for different stakeholder groups would enable more targeted information to be provided based on user needs and involvement in the HTA process.
- Information and content on the website and its accessibility should be community-led and appropriate.

1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.
If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Develop an engagement framework

- Ensure the co-design of the framework with community members and groups, both those who are currently actively engaged in the HTA process and individuals and organisations with an interest in engaging in the HTA process. It is critical that both groups are engaged so they can provide insights into the current barriers and enablers of engagement and participation from their different perspectives to ensure the framework is able to accommodate the needs and interests of both groups.

- The implementation of this engagement framework needs to actively support community members and groups with an interest in participating in the HTA process, without putting an increased burden on them to fund and resource their own participation.
- The development of guidance for HTA staff on identifying appropriate community members or groups, including a process of accepting expressions of interest from individuals and organisations, to participate based on the specific needs of the HTA submission and ensuring support is provided to ensure equity in participation.

Strengthen consumer evidence

- Greater clarity is required around the implementation plan, including who is responsible for collecting RWE/RWD, how it is collated, how datasets are linked, and the accessibility of this data to stakeholders.
- It is important to ensure consistency in data collection across different state/territory and public/private healthcare systems to ensure dataset linkage is possible and collection is aligned with national standards.
- Greater clarity is required in understanding how HTA values different types of RWE/RWD, as this will inform research and development data collection and trial design, and investment in new models of evidence collection.
- Community member input should be sought in evaluating the value of different RWE/RWD.
- Incentives should be identified to ensure clinical trial design and post-marketing surveillance data collection includes RWE/RWD collection in a way that supports a HTA application to represent community experiences and outcomes.

1.3. First Nations people involvement and consideration in HTA into account.
If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

First Nations peoples partnership in decision making

- The Department should take a more proactive role in promoting representation to address the needs of Aboriginal and Torres Strait Islander people. This recommendation does not include a plan to address the need for greater representation of Aboriginal and Torres Strait Islander peoples in clinical trials and RWE/RWD collection.
- It is important to provide dedicated support and resources to enable Aboriginal and Torres Strait Islander people's involvement, as aligned with the priority of the Australian Cancer Plan due to the poorer cancer outcomes experienced by Aboriginal and Torres Strait Islander peoples compared to non-Indigenous Australians.
- The current lack of RWD/RWE outcomes data for Aboriginal and Torres Strait Islander peoples needs to be addressed to support the identification of their needs, including participation in clinical trials, and the horizon scanning process.

Dedicated resource for HTA submissions and education

- Key to achieving this will be adequate funding, support and resourcing for Aboriginal and Torres Strait Islander peoples and representative organisations to help support community awareness and participation in the HTA process.

1.4. State and territory government collaboration in HTA into account.
If you would like to expand on your answer above you can do so below:

- We welcome this priority as it recognises that HTA decisions impact patients regardless of where they live and which funding source (public or private) is utilised to pay for access to technologies.
- It is important to recognise that funding of HSTs is challenging where there is overlap between Commonwealth and state and territory government systems in the private and public sector.
- Early engagement is needed with state and territory governments and federal funding pathways to understand the impact of these new technologies on the overall health economy and as it pertains to assessing the relative value.
- This recommendation will start to address challenges of inequity of access due to discrepancies in the state and territory health service funding of new technologies. Reform of the current model of funding should be considered where it is a barrier to equity of access to new technologies.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Development of central standardised data sharing system for utilisation and outcome data

- Consideration is needed on how data is collected across different states and territories and healthcare systems to ensure standardisation of data collection, access, use, privacy, and protection.
- Community organisations and members should be involved in discussions and co-design of this framework.
- More information is needed on the implementation in terms of who and how this process will be managed to ensure responsible management of centralised data.

Increase opportunities for consultation and work-sharing

- Consideration is needed into how this will be achieved without impacting timelines to access new technologies, and the levels of resourcing that will be required for states and territories to efficiently engage and consult in the process without negatively impacting timelines.

Health technologies that are jointly funded by the Commonwealth and state and territory governments (such as high cost, Highly Specialised Therapies (HSTs) delivered to public hospital inpatients)

- If this results in improved equity of access and reduced timeframe for HSTs being accessible once approved by the HTA then we support this option.
- There will need to be consideration given to the need for funding and resourcing to support healthcare professionals to ensure they are adequately prepared for the implementation of new technologies that will reform clinical practice.

2.1. Streamlining and aligning HTA pathways and advisory committees into account.
Overall, to what extent could the options (if implemented) address the issues that relate to them?
If you would like to expand on your answer above you can do so below:

- We would support streamlining and aligning to produce a unified HTA pathway if this is adequately funded and resourced to ensure that the revised process improves the timeliness of access to new technologies.
- More clarity is needed on whether there will be multiple advisory committees to manage this process and how they will ensure consistency in their approach and decision-making across the organisation.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Pathway for drugs for ultra-rare diseases (Life-Saving Drugs Program (LSDP))

- Greater clarity is needed on the composition of the LSDP Review Expert Panel and how other experts will be convened to ensure specific expert advice is available for new technologies.
- It is important to demonstrate that incorporating this pathway into the PBAC process would not disadvantage community members by creating inequity or preventing timely access.

Expanding role of PBAC

- While this is only a short-term solution, more information will be needed to ensure adequate resourcing and processes are in place to deliver improvements in the timeliness of approvals.
- The implementation of this process will need greater clarity on the required legislative reform and timeline to achieve this will impact the achievability of improving the timeliness of approvals as a short-term solution.
- Greater clarity is needed on how the implementation of this process will impact outcomes, including the measurement of key performance indicators and how stakeholders will be engaged in a review of the effectiveness of this short-term arrangement before a single HTA pathway is implemented.

Unified HTA pathway for all health technologies with Commonwealth funding

- The implementation plan should be designed with proper consultation with the community and stakeholders, and adequately resourced and funded to ensure it meets the goals of all stakeholders.
- A process of continuous review and improvement should be planned with oversight and transparency for stakeholders to ensure it is meeting its goal of improving timeliness and equity of access.
- Greater clarity is sought to understand the new structure of the single HTA, including the setup and composition of expert advisory committees to inform the review process.

2.2. Proportionate appraisal pathways into account
Overall, to what extent could the options (if implemented) address the issues that relate to them?
If you would like to expand on your answers above you can do so below:

- It is encouraging that options are being considered to improve timely access to new technologies and adequate funding and resourcing are required to ensure the implementation achieves its goals.
- While streamlining the HTA process would in principle improve timelines to access, the specifics of the implementation of each option would need to be well-considered before being implemented and an evaluation period, with key metrics, defined to ensure it achieves the goal. The possible advantages of one option over another should be evaluated with significant stakeholder input to ensure there are no unintended consequences.
- Greater clarity is needed on how clinical need is defined; this appraisal should also consider community needs and be developed in consultation with all stakeholders to define value as it relates to society and public health.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Triaging submissions

- Consideration of seeking greater international expert input from individuals with technical expertise and experience with new and co-dependent technologies that weren't developed or trialled in Australia, when there is a lack of local experience and expertise.
- The process of developing a decision tool for triaging submissions will need to consider the complexity of targeted/personalised technologies that target specific genetic markers across different cancer types, the need for treatment sequencing to guide optimal therapy, and co-dependent health technologies to support the successful implementation of treatment in practice.
- Clarity and transparency are needed on the guidelines provided for the assessment and rating of submissions to ensure that this will not detrimentally impact access to HCUT therapies and co-dependent technologies, which are more difficult to review and require more resources.
- Community members must be involved to provide input into how submissions are assessed for triaging.

Decouple the requirement for the TGA Delegate's overview to support PBAC advice

- A significant challenge to the existing HTA process is that the product under review for reimbursement can only be considered for the indication for which it is listed on the Australian Register of Therapeutic Goods (ARTG). This recommendation may help to streamline the HTA process and enable earlier access.

Case manager

- There is a need for more clarity on how this would be different to the current case management approach and improve timelines to approval, along with their role in liaising with other stakeholders (not the sponsor) involved in the submission to navigate the complexities of the system.

3.1. Determination of the Population, Intervention, Comparator, Outcome into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
If you would like to expand on your answer above you can do so below:

- Increasing early stakeholder input and transparency around how this input is utilised to provide context to the PBAC on the value of new technologies to both community and healthcare professionals.
- A shared understanding of the importance of the advice provided by stakeholders to the HTA, the priorities and overall aims of the HTA process is needed.

3.2. Clinical Evaluation Methods into account.
If you would like to expand on your answer above you can do so below:

- We support changes to the HTA that streamline the process and allow decisions to be made about companion diagnostics and genomics alongside medications that target biomarkers, especially if that leads to improved timelines and equity of access.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Methods for the assessment of nonrandomised and observational evidence

- This is important to support greater use of RWD/RWE. Implementation requires reliance on local and international cancer data to demonstrate improved outcomes based on community experience.

Methods for the assessment of surrogate endpoints

- This form of data is relevant for rare and less cancers when the burden of evidence is high due to the small numbers of people impacted. This may also increasingly be the case for more common cancers with rare sub-types defined by their genetics.
- This is important to increase the use of RWD/RWE data. All submissions for funding of new technologies should demonstrate evidence of clinically relevant benefits and community-relevant outcomes, such as improvements in quality of life.
- Consideration should be given to providing clarity and guidance to sponsors on how the HTA values different types of surrogate endpoints used in clinical trials and the importance utilise co-designing with the community to ensure that the data collected reflects their real-world needs and outcomes.

Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors

- There should be a plan for this framework to be regularly reviewed and assessed as new technologies are developed this will lead to new methods of data collection and RWE/RWD endpoints to be considered.
- Community members and groups should be involved in the design of methodologies to ensure they reflect real-world situations and outcomes that are relevant.

Develop an explicit qualitative value framework

- There should be a plan for this framework to be regularly reviewed and assessed as new technologies are developed this will lead to new methods of data collection and RWE/RWD endpoints to be considered.
- Community members and groups should be involved in the design of methodologies to ensure they reflect real-world situations and outcomes that are relevant.

Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)

- Consideration should be given to the opportunity for evidence to be submitted for technologies that target specific genetic markers across different cancer tumour types, and consideration given to the weighting of the evidence based on the overall population's unmet need.
- This guidance should align with the National Health Genomics Policy Framework for the integration of technology into the healthcare system.

Pharmacogenomic technologies

- Consideration should be given to the impact of the implementation of next-generation sequencing or genomic profiling in terms of funding and resourcing services to provide access to these technologies

across states and territories to ensure access they are evaluated in terms of the ability of the technology to be adopted into clinical practice to assist clinician decision-making.
- Guidance should be given on the need to factor in the cost to the health service to fund and resource education and training of healthcare professionals to implement the technology in practice to ensure equity of access to the technology across states and territories.

3.3. Economic evaluation into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
If you would like to expand on your answer above you can do so below:

- We would welcome any changes that ensure appropriate estimation of the value of novel technologies to community members beyond just the health benefits to ensure they receive patient-centred care.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Valuing overall
- These workshops must be conducted with community members and healthcare professionals to determine how these stakeholders value quality-adjusted life years (QALY) and alternative measures.
- To enable a comprehensive view of value, appropriate assessment of societal benefits must be considered in addition to the clinical benefit of the technology.

4.1. Approaches to funding or purchasing new health technologies into account.
If you would like to expand on your answer above you can do so below:

- We welcome recommendations that will enable managed access and mechanisms to allow earlier access to medicines while the final price is being negotiated between the sponsor and the Australian Government.
- The provision of interim bridging funding and mechanisms to allow assessment of value post-listing could be of important to enable earlier access and the incorporation of RWD/RWE as it becomes available. However, details about the planned implementation are needed before we can assess its impact and risk mitigation plans should be put in place for the risk that a technology is removed after initial listing should be considered and weighed against the short-term benefits of earlier access.
- There needs to be transparency around the process for re-assessment and clear communication to stakeholders around the timeline for re-assessment.
- There is a need for a clear definition of “promising therapies” or “time critical” and how this is assessed to determine whether new medications are worthy of an accelerated pathway.

5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS into account.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Proactive submission invitation and incentivisation

- We welcome this recommendation to incentivise sponsors to apply for HTA review when there is a lack of commercial incentives for a sponsor to register or apply for reimbursement of their therapeutic product, especially for new indications.
- Currently there are limitations on access to data, funding or resources that impact the ability of non-commercial sponsors to complete the HTA application, more support for this pathway should be considered, especially in cases of identifying a medicine suitable for repurposing.

5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
If you would like to expand on your answer above you can do so below:

- We welcome this recommendation to ensure the HTA is taking a proactive approach to identifying technologies that would fulfil a significant unmet need for Australians. Regulators can then play an active, rather than passive role, in enabling Australian's timely and affordable access to safe and effective medicines and technologies.

If you would like to expand on any of your answers above relating to a specific Option, you can do so in the table below:

Horizon scanning for advanced therapies (including high cost, HSTs funded through the NHRA) and other potentially disruptive technologies

- Consideration should be given to the need for a molecular tumour board to discuss complex results from genomic sequencing and how this could potentially guide the use of therapy in practice and bridge the gap between health technology development and successful implementation.

Horizon Scanning to meet priority areas (including addressing equity and HUCN)

- Consideration should be given to identifying priority areas based on high unmet therapeutic needs and situations where there is a need to repurpose medicines and have alternative medicines available to mitigate medicines shortage situations.
- Consideration should be given to the process and support needed to enable non-commercial sponsors to be involved in submitting HTA applications when a sponsor-initiated application is not available.

5.4. Mechanisms for continuous review and improvement into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?
If you would like to expand on your answer above you can do so below:

- We welcome this recommendation to ensure any options implemented are reviewed periodically to determine if they are achieving their objectives. More information is needed on the timelines for review, key performance indicators assessed, and who will be involved in reviewing and providing suggestions for improvement.
- This phase of implementation is key to ensuring the options are achieving their aim of ensuring timely access to new technologies for all Australians without associated financial burden. How this aim is measured and by whom is important to ensuring stakeholders feel this review has achieved the necessary reform and ongoing stakeholder engagement and consultancy is key.

5.5. Capacity and capability of the HTA system into account.

If you would like to expand on your answer above, you can do so below:

Improve HTA capacity and workforce in Australia

- This will be important to ensure sufficient funding and resource allocation to implement the options proposed and within a timeframe that can achieve reform in the short- and long term. It is key to ensure that the changes implemented do not worsen timeframes for review.
- Key to implementing any of these reforms is an adequately trained workforce who can successfully liaise with all stakeholders at all levels of engagement to make the rollout a smooth process.