

April 2024

Health Technology Assessment Co-design Working Group  
C/o Department of Health and Aged Care  
GPO Box 9848  
Canberra ACT 2601

Via email: [HTAconsumerengagement@health.gov.au](mailto:HTAconsumerengagement@health.gov.au)

Dear Health Technology Assessment Co-design Working Group

## Re: Co-design of an Enhanced Consumer Engagement Process

Thank you for the opportunity to provide a submission as part of the consultation for the *Co-design of an Enhanced Consumer Engagement Process*.

For over 45 years, the Leukaemia Foundation has provided a variety of supports and services, and funded life-changing research. We provide evidence-based policy advice and amplify the voices of those affected by blood cancer.

We welcome this work on an Enhanced Consumer Engagement Process and thank the Co-design Working Group for helping ensure Australia's HTA system better captures the perspectives of consumers and patients in the HTA process.

Healthcare policy settings and funding arrangements (including those between the Commonwealth and the States and Territories) impact patients because they heavily influence which services patients can access, where they can access them, and at what cost.

While Australia has a robust health system and HTA processes, consumer involvement in HTA is reduced by opaque processes and difficult-to-understand HTA procedures (including lack of transparency; difficult-to-access information; limited stakeholder involvement; and a lack of clear decision criteria).

This submission makes suggestions for HTA system improvements and discusses key recommendations proposed by the Working Group.

Thank you for your consideration of the issues highlighted in this submission. We would be happy to discuss further and can be contacted at [ctanti@leukaemia.org.au](mailto:ctanti@leukaemia.org.au).

Sincerely,



**Chris Tanti**  
Chief Executive Officer

## 1. Overarching comments

### *Importance of consumer-centricity*

The Leukaemia Foundation reinforces that the centrality of patients' needs and perspectives should be integral to policy frameworks and funding arrangements – including HTA.

All parts of our healthcare system, and associated funding arrangements, need to support the fundamental right of patients and taxpayers to have access to medicines and healthcare interventions funded by taxpayers.

Consumer centricity provides the important perspective of people who use the health system. Involving consumers (patients, their families/caregivers, and consumer organisations) in HTA processes guarantees that the guidance offered reflects the needs of individuals dealing with health conditions.

Such participation provides valuable insights into the actual advantages of health technologies, explaining their usefulness (or lack thereof), their effect on daily life, and the most effective ways to access them.

For example, the use of Patient Reported Outcomes (PROs) allows the lived experience of patients to be better reflected in healthcare decisions. Specifically, they can:<sup>1</sup>

- Improve effectiveness and efficiency of patient and clinician engagement
- Monitor, evaluate, benchmark and improve the development of support services
- Inform government investment decisions.

Further, patient-centricity in healthcare policy, practice and funding is becoming increasingly entrenched and mandated. Recent examples include:

- The National Medicines Policy (NMP) – "The NMP acknowledges the fundamental role of consumers in achieving the policy aim by placing the individual at the centre, and by focusing on and responding to the needs of Australia's diverse population."<sup>2</sup>
- The \$2.2 billion package of measures announced (28 April 2023) at National Cabinet, where National Cabinet articulated their shared vision for 'a patient-centred and sustainable Australian healthcare system.'<sup>3</sup>

The importance of consumer-centricity should remain a fundamental part of HTA processes – but there are significant opportunities to further strengthen what this looks like in practice.

### *Opaque processes and difficult-to-understand HTA procedures*

Transparency and accountability are crucial to maintaining the social contract underpinning public funding.

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<sup>1</sup> [https://www.leukaemia.org.au/wp-content/uploads/2023/02/Leukaemia-Foundation\\_Final-Report\\_State-of-the-Nation-Blood-Cancers-in-Australia-Report-2023.pdf](https://www.leukaemia.org.au/wp-content/uploads/2023/02/Leukaemia-Foundation_Final-Report_State-of-the-Nation-Blood-Cancers-in-Australia-Report-2023.pdf)

<sup>2</sup> *National Medicines Policy*, <https://www.health.gov.au/sites/default/files/2022-12/national-medicines-policy.pdf>

<sup>3</sup> *National Cabinet Statement*, <https://www.health.gov.au/news/national-cabinet-statement-on-a-better-future-for-the-federation>

From work undertaken to develop the *National Strategic Action Plan for Blood Cancers, State of the Nation 2023* and our ongoing engagement with patients and HTA systems, the Leukaemia Foundation reiterates the following HTA features that represent opportunities for improvement:

- *Lack of transparency*: Lack of clear and accessible information about the decision-making criteria, methodologies, and evidence considered.
- *Difficult-to-access information*: Relevant documents, reports, and data related to HTA processes are often not easily accessible to the public (inclusive of complex terminology), making it difficult to gain a comprehensive understanding of the assessment process. Pragmatically, HTA-related websites are often very difficult to navigate.
- *Limited stakeholder involvement*: In part due to the two points above, involvement of patients can be limited.
- *Inconsistent communication*: Communication of HTA findings and decisions to the public and stakeholders can be inconsistent, making it hard for individuals and organisations to stay informed about the assessment process and outcomes.
- *Complex evidence evaluation*: The evaluation of clinical and economic evidence can be complex and requires specialised knowledge.
- *Lack of clear decision criteria*: The criteria used to make HTA decisions are not clearly defined or communicated.

In the Leukaemia Foundation's view, these current characteristics of Australia's HTA system rank as some of the biggest challenges requiring change. These themes are picked up in our comments below in relation to the consultation paper's specific proposed recommendations.

We support efforts to make the processes more streamlined and with enhanced clarity. The map of proposed recommendations to enhance consumer engagement Figure 2 of the *March 2024 Co-design Project report* is an important step in the right direction.

## 2. 'System-wide' recommendations

### *Single Digital Portal (Working Group Recommendation 2)*

We strongly agree that "it is challenging to locate and navigate information and resources to support consumer engagement across different Departmental websites." We welcome the recommendation for a single digital portal (Recommendation 2) to provide a 'one stop shop' where consumers can access resources that enable their engagement across the health technology pathway.

As it currently stands, significant website improvements are required. Relevant documents, reports, and data related to HTA processes are often not easily accessible to the public (inclusive of complex terminology), making it difficult to gain a comprehensive understanding of the assessment process.

A single, well-designed portal with plain language would increase the accessibility of current HTA engagement processes and support greater transparency of those processes.

### *Plain language communications (Recommendation 3)*

We support the plain language recommendation as we strongly agree that 'clear, plain language communication is an essential part of enhancing consumer engagement'.

Plain English summaries, including of medical content, are important for consumers to ensure they are supported in their understanding of the issue.

Currently, HTA documentation can be hard to understand and is often not easily accessible to the public. In addition to being a deterrent to engagement, this also makes it difficult to gain a comprehensive understanding of the assessment process. We do appreciate the recent development in the PBAC's Public Summary Documents, which make it clear when the medical/clinical need under consideration has been satisfied.

Further, while training can be useful (Recommendation 4 – "Establish stakeholder training and resources for government, industry, and consumers"), it should not be used to absolve relevant entities of the need to provide information in plain language, make this information easily accessible, and on a clear schedule.

### *Consumer engagement framework (Recommendation 1)*

The Leukaemia Foundation supports the proposal for a "Consumer engagement framework" (Recommendation 1) to embed consumer engagement into government strategies, implementation planning and evaluation activities. This is an important means of facilitating consumer involvement and helping ensure it is integrated into policy, projects and funding.

The scope would need to be very clear – including which aspects of HTA it encompasses, and whether it extends beyond HTA.

The Framework would need to have broad alignment with other consumer engagement frameworks. This may include the NHMRC's consumer engagement framework and the National Preventive Health Strategy 2021–2030 (in terms of principles and approach to consumer engagement, etc), and that Strategy's "policy achievement" goal that "Partnerships with the community are strengthened and informed by a national consumer engagement strategy that prioritises co-design approaches."<sup>4</sup>

The Framework should address differing cycles between the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC), and also encourages a more engaging approach to consumer involvement. This engagement should be interactive, allowing patient groups to be active participants in discussions rather than passive recipients of decisions. Such involvement is essential throughout the entire process of listing therapies, ensuring that patient perspectives are considered at every stage.

### *Consumer identification and development (Recommendation 6)*

We support this initiative in principle, but believe it is important to clarify the scope and application of this recommendation. Specifically, clarification is required regarding whether the dissemination

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<sup>4</sup> National Preventive Health Strategy 2021–2030, p.40:  
[https://www.health.gov.au/sites/default/files/documents/2021/12/national-preventive-health-strategy-2021-2030\\_1.pdf](https://www.health.gov.au/sites/default/files/documents/2021/12/national-preventive-health-strategy-2021-2030_1.pdf)

of targeted information will be limited to specific applications relevant to a disease area, and how frequently and to which organisations this information will be provided.

We also emphasise the need for transparency and the establishment of appropriate safeguards to protect consumers and consumer groups. This would help ensure they do not inadvertently compromise themselves or prejudice their position, particularly concerning existing requirements, such as the Medicines Australia Code of Conduct. Implementing clear guidelines and protections will help maintain the integrity of the engagement process and safeguard the interests of all parties involved.

### **3. Timing-specific recommendations – Before, during and after HTA committee consideration**

The consultation document proposes recommendations described as 'Pre-HTA enhancements', 'HTA Process Enhancements', and 'Post HTA Enhancements'. We have focused primarily on "Consumer evidence in PBAC submissions" (Recommendation 13) and related recommendations.

We would like to see genuine consumer input embedded throughout the HTA process, where consumers are supported to give voice to their lived experiences. In addition to pro-active outreach to relevant organisations, multiple points of entry for consumer comments should be available.

HTA assessments should allow more flexibility in the evidence base, including greater acceptance of non-randomised evidence and the role of real-world data, and the lack of information about how elements (beyond clinical effectiveness, cost effectiveness and financial impact) such as patient and consumer input were being considered in HTA decision making.

We have advocated for the earlier input of consumers. In that context, we support earlier involvement in PICO.

The proposed checks to ensure that submissions made to PBAC (and other HTA committees) demonstrate consumer engagement and the inclusion of consumer evidence and experience (Recommendation 13) will need to be carefully implemented. Specificity will be required on which submissions are being referred to (consumer comment submissions, the application itself, new listings versus updated listings etc), and then what the expectation is of consumers and consumer organisations that these parties (e.g., a company writing an application/submission) need to undertake.

#### *Consumer-initiated submissions to PBAC (Recommendation 12)*

In principle, we support the idea of enabling consumer-initiated submissions as it potentially democratises the process and ensures that the needs and voices of patients and their advocates are directly heard. However, we have reservations about the practical implications of such a recommendation.

Our primary concern revolves around the question of "but what next?" Specifically, even if a consumer-initiated submission is successful, the availability of the drug or therapy in Australia ultimately depends on the pharmaceutical company's willingness to make a submission to the PBAC and to supply the product. This dependency could inadvertently maintain the status quo, where patient access to new treatments remains contingent upon industry priorities and timelines.

Further, there is the potential that a company might leverage consumer-initiated submissions as a means to circumvent the financial and administrative responsibilities associated with the application

process, including the payment of application fees. Such a scenario, however rare, could undermine the integrity of the submission process and potentially exploit patient groups and individuals advocating for access to treatments.

To address these potential challenges, we advocate for a clear and distinct pathway for consumer-initiated submissions that is separate from the current business-to-government system. This pathway must be transparent, with explicit guidelines to prevent any perception of it being a backdoor for pharmaceutical companies. Furthermore, the outcomes of these submissions should include firm recommendations for action by both the pharmaceutical company and the government to ensure that successful treatments become accessible. This may require introducing measures that compel action based on the recommendations made by the PBAC or the Medical Services Advisory Committee (MSAC).

#### 4. Implementation considerations for the proposed recommendations

The consultation document describes implementation considerations for the proposed recommendations. We have focused primarily on strengthening the use of consumer evidence and experience.

PROs are not adequately embedded in our healthcare system, including funding agreements and associated data gathering, measurement and reporting.

The NHRA Roadmap commits governments to striving to "promote the use of Patient Reported Measures to understand what patients value and improve patient experiences and outcomes."<sup>5</sup>

However, PROs need to be central to data collection and embedded more strongly into HTA. This should be mandated and codified. They can also be used to inform research directions by industry and clinicians and investment decisions by governments.

In the context of cancers, PROs support engagement during what can be an intense period of diagnosis and treatment. Furthermore, progress in the type and number of therapies available to treat cancer mean that some cancers are becoming long-term chronic conditions, instead of acute, life-threatening ones. This means treatment is required for longer, and the experiences of patients needs to be captured across a longer period.

Recognising the importance and value of PROs, the *National Strategic Action Plan for Blood Cancers* called for a national system for patient reported outcomes in blood cancer. This been adopted in the *Australian Cancer Plan*, which includes the following action (4.5.1):

- "Design and embed patient reported experience and patient reported outcomes into national performance monitoring and reporting for all providers, to assess services for all population groups and establish an evidence base."<sup>6</sup>

We support adding additional guidance on RWE and PROMs, on the condition this is developed with consumers. Further, the *National Strategic Action Plan for Blood Cancers* called for a national system for patient reported outcomes in blood cancer, and in that context we support consistency in the implementation of RWE/PROMs across HTA systems and processes.

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<sup>5</sup> <https://www.health.gov.au/sites/default/files/documents/2021/10/national-health-reform-agreement-nhra-long-term-health-reforms-roadmap.pdf>, p.18.

<sup>6</sup>

[https://www.canceraustralia.gov.au/sites/default/files/publications/pdf/2023\\_ACP%20Summary%20Report%20DIGITAL\\_V9.pdf](https://www.canceraustralia.gov.au/sites/default/files/publications/pdf/2023_ACP%20Summary%20Report%20DIGITAL_V9.pdf)

This is linked to recommendation 16 ("Consumer input feedback loop"). Feedback on the use of consumer input in decision-making is important and is currently lacking. We would like to see more transparency on how consumer comments are considered in HTA deliberations. For example:

- How are consumer comments weighted in the decision framework, compared to economic and other factors?
- Is all the effort we and other consumers put into providing perspectives from lived experience actually useful, and to what extent do these comments have any influence on the outcomes?

Finally, and very importantly the relationships, processes and movement of funds and funding accountability between Federal and State and Territory Governments require streamlining to improve efficiency. The current lack of coordination and data sharing between these levels of government creates barriers to access for patients, who are consequently denied timely access to essential therapies. This model of cost shifting is inconsistent with the NMP and the PBS and especially to Australian's expectations that all levels of government will work seamlessly to ensure timely access to innovative and life enhancing new treatments and care.

### ***About the Leukaemia Foundation***

The Leukaemia Foundation is the only national organisation that represents all Australians living with blood cancer – including leukaemia, lymphoma, myeloma, myeloproliferative neoplasms (MPN), myelodysplastic syndromes (MDS) and amyloidosis.

We provide the following free services to patients:

- Personalised information and support from highly trained Blood Cancer Support Coordinators for patients and their loved ones alongside a range of health and wellbeing services
- Accommodation near major hospitals around Australia and help getting to and from the many appointments that come with a blood cancer diagnosis
- Trusted information to empower people to navigate the road ahead, including critical education, support groups, booklets, newsletters, and online information

The Leukaemia Foundation's research program drives rapid advancements in blood cancer treatments, encourages the careers of promising scientists, and helps give Australians access to global clinical trials.