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| Consultation Document | | |
| Co-design Project:  Enhanced Consumer Engagement Process  March 2024 |  | |
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# About this document

This document presents the proposed recommendations of the Co-design Working Group (CWG) for the Enhanced Consumer Engagement Process. This co-design project aims to:

*Develop a report with recommendations, for the consideration of the Minister for Health and Aged Care, on the design and implementation of the Enhanced Consumer Engagement Process for Health Technology Assessments relevant to the Pharmaceutical Benefits Advisory Committee, as per the 2022-2027 Strategic Agreement between the Commonwealth and Medicines Australia.*

Importantly, the co-design project presents an opportunity to respond to the commitments set forth in the [2022-2027 Strategic Agreement between the Commonwealth and Medicines Australia](https://www.pbs.gov.au/info/general/medicines-industry-strategic-agreement) with regard to enhancing consumer engagement in health technology assessments (HTA) overseen by the Pharmaceutical Benefits Advisory Committee (PBAC). At the same time, the project seeks to align with broader reforms, including the [HTA Policy and Methods Review](https://www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review), to ensure that recommendations also enhance consumer engagement across the entire health technology pathway (i.e., from clinical research through to post-market reviews), and may be transferrable to other HTA committees.

The CWG developed the proposed recommendations through co-design activities undertaken between October 2023 and February 2024. These processes were facilitated by contracted researchers from The University of Melbourne. The project is managed by the [Consumer Evidence and Engagement Unit](https://www.health.gov.au/contacts/hta-consumer-evidence-and-engagement-unit-hta-co-design-working-group-secretariat) (CEEU) in the Office of Health Technology Assessment (OHTA), Department of Health and Aged Care (the Department)

The proposed recommendations are a work in progress and not yet finalised. The CWG are seeking input from consumers and other stakeholders to inform further development of the proposed recommendations and subsequently prepare and submit a final report to the Minister for Health and Aged Care.

Please visit the [Terminology section](#Terminology) for definitions of key terms and acronyms described throughout the report.

If you would like more information about HTA processes please visit the resources on the [project webpage](https://www.health.gov.au/our-work/co-design-of-an-enhanced-consumer-engagement-process).

## How to provide input

A survey is available to provide your opinions about the information described in this consultation document.

You may complete the survey anonymously or have the option to provide your name or the name of your organisation if you wish to be acknowledged as a contributor to the consultation.

You also have the option to upload a written submission at the end of the survey instead of, or in addition to, answering questions in the survey itself.

The survey is securely managed by The University of Melbourne researchers contracted to facilitate the co-design project. The results of the survey will be analysed and reported back to the CWG to support their ongoing co-design work.

Please review this document carefully and consider your own feedback before responding to the survey.

The survey will be open from **1 March 2024 to 2 April 2024.**

**Please return to this** [**webpage**](https://www.health.gov.au/resources/collections/co-design-of-an-enhanced-consumer-engagement-process-for-health-technology-assessment-consultation) **to access the survey**

## Contact

For inquiries about this co-design project, please contact [HTAconsumerengagement@health.gov.au](mailto:HTAconsumerengagement@health.gov.au)

# Terminology

## Key Terms

|  |  |
| --- | --- |
| Application and Submission | Application refers to a general request made to the Department, which might include a request to list a generic medicine, or to change details of a listing that doesn’t require PBAC recommendation. Application also refers to an application made by the medicines/pharmaceutical industry for consideration by the TGA. Submission is an application made for consideration by the PBAC (or other HTA committees) to list a medicine or change a medicine listing. |
| Consumer | Patients, their families, carers, and consumer organisations. |
| Consumer evidence and experience | May entail consumer input into Population, Intervention, Comparator, Outcome (PICO) scoping, Patient Reported Experience Measures (PREMS), Patient Reported Outcomes Measures (PROMS), qualitative studies, health equity studies, and Real-World Evidence (RWE). |
| Health technology | A broad term encompassing medical tests, medical devices, medicines, vaccines, blood and human tissue products, procedures, programs, or systems involved in health care. |
| Health technology assessment | A process to make decisions about which health technologies will be subsidised. |
| Health technology pathway | End-to-end system whereby a health technology generally goes through a lifecycle from the clinical research stage through to TGA applications and registration, then HTA decision-making to recommend subsidisation (via PBAC, MSAC or other committees), before Ministerial approvals for positive recommendations to be listed via a funding scheme, and finally post-market reviews after a health technology is made available to the public. |
| Horizon scanning | A process that systematically identifies, assesses, and plans for the potential impact of new and emerging health technologies. |

## Acronyms

|  |  |
| --- | --- |
| CCC | Consumer Consultative Committee |
| CEEU | Consumer Evidence and Engagement Unit |
| CWG | Co-design Working Group |
| DCAR | Department Contracted Assessment Report |
| DHAC | Department of Health and Aged Care or ‘the Department’ |
| ECEP | Enhanced Consumer Engagement Process |
| HTA | Health Technology Assessment |
| MBS | Medicare Benefits Schedule |
| MDHTAC | Medical Device and Human Tissue Advisory Committee |
| MSAC | Medical Services Advisory Committee |
| NDSS | National Diabetes Services Scheme |
| OHTA | Office of Health Technology Assessment |
| PBAC | Pharmaceutical Benefits Advisory Committee |
| PBS | Pharmaceutical Benefits Scheme |
| PICO | Population, Intervention, Comparator, Outcome |
| PL | Prescribed List of Benefits for Medical Devices and Human Tissue Products |
| PREMS | Patient Reported Experience Measures |
| PROMS | Patient Reported Outcome Measures |
| RWE | Real World Evidence |
| TGA | Therapeutic Goods Administration |

# Project Background

Consumer perspectives are important when determining whether access to a new health technology (e.g., medicines, vaccines, nutritional products, and co-dependent technologies) should be subsidised. This is particularly so if a new medicine is a breakthrough technology that promises to address an otherwise high unmet clinical need. Enhancing consumer engagement will help inform decision-making in [Health Technology Assessment](https://www.health.gov.au/topics/health-technologies-and-digital-health/health-technology-assessments) (HTA) processes by embedding consumer experience and evidence across the end-to-end health technology pathway, including in submissions to HTA committees.

While the visibility of consumer engagement has increased over the years, recent reviews and consultations confirm that further efforts to improve engagement in HTA processes are both warranted and sought after by the Department, the medicines industry, and consumers alike. Indeed, the importance of enhancing consumer engagement in HTA processes is one of the key commitments embedded in the [2022–2027 Strategic Agreement between the Commonwealth Government and Medicines Australia](https://www.pbs.gov.au/info/general/medicines-industry-strategic-agreement). The Strategic Agreement includes a project to “co-design and agree upon an Enhanced Consumer Engagement Process, for consideration by the Minister for Health and Aged Care, to capture consumer voices in respect to applications to list new medicines on the Pharmaceutical Benefits Scheme (PBS).”

The project commenced in late 2023 with the establishment of the Co-design Working Group (CWG) consisting of consumer, government, and medicines industry representatives. The CWG is facilitated by researchers from The University of Melbourne. The project is managed by the [Consumer Evidence and Engagement Unit](https://www.health.gov.au/contacts/hta-consumer-evidence-and-engagement-unit-hta-co-design-working-group-secretariat) (CEEU) in the Office of Health Technology Assessment (OHTA), Department of Health and Aged Care (the Department)

The purpose of the project is to:

*Develop a report with recommendations, for the consideration of the Minister for Health and Aged Care, on the design and implementation of the Enhanced Consumer Engagement Process for Health Technology Assessments relevant to Pharmaceutical Benefits Advisory Committee (PBAC), as per the 2022-2027 Strategic agreement between the Commonwealth and Medicines Australia.*

The scope includes:

* submissions to list new health technologies (single or class) on the Pharmaceutical Benefits Scheme, (i.e., medicines, vaccines, nutritional products, codependent technologies)
* changes to early stages of the HTA pathway
* clarifying the relationship with horizon scanning information
* understanding where conflicts of interest may need to be managed.

Importantly, while the purpose and scope focus on enhancing consumer engagement in relation to PBAC, the co-design project presents an opportunity to align with broader reforms including the [HTA Policy and Methods Review](https://www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review). As such, the proposed recommendations in this report are relevant to strengthening consumer engagement across the entire health technology pathway. Furthermore, the proposed recommendations for PBAC processes may be relevant and transferrable to other HTA committees such as the Medical Services Advisory Committee (MSAC) and the Medical Device and Human Tissue Advisory Committee (MDHTAC).

As the CWG continue to develop the recommendations, input is sought about this consultation report from consumers and other stakeholders. Please see the information at the beginning of this report about [how to provide input](#_How_to_provide) via a survey.

More information about the CWG and the project overall is available in the [Introduction](#_Introduction_1) section of this report and on the [project webpage](https://www.health.gov.au/our-work/co-design-of-an-enhanced-consumer-engagement-process).

# Section 1:

# Summary of Proposed Recommendations for Enhanced Consumer Engagement

## 

## Proposed Recommendations

The CWG developed the recommendations proposed in this report during iterative co-design meetings, workshops, and discussions held from October 2023 to February 2024.

The proposed recommendations were informed by the following design principles established by the CWG:

1. Consumer evidence and experience is prioritised and integral in health technology assessment processes.
2. Recommendations to enhance consumer engagement must not delay access to medicines.
3. Enhancements for consumer engagement may be prioritised to achieve maximum impact through implementation.

These principles were created from discussions examining the key themes from prior consultations and policy documents, such as the [Conversations for Change](https://www.health.gov.au/resources/publications/conversations-for-change-report-2023?language=en) report and the [2022 National Medicines Policy](https://www.health.gov.au/resources/publications/national-medicines-policy?language=en). The CWG looked to these principles as they developed the recommendations and will return to them again alongside the consultation results to further refine their work.

As noted in the [Project Background](#_Project_Background_2), the proposed recommendations described in this report refer to enhancing consumer engagement in relation to HTA processes undertaken by PBAC (as per the Strategic Agreement). At the same time, the recommendations account for the interrelated flow-on effects for strengthening consumer engagement across the entire health technology pathway and may also be transferrable to other HTA committees.

The CWG, therefore, identified the need to recommend system-wide enhancements, as well as enhancements that sit within key areas of the health technology pathway, from clinical research through to the processes undertaken by the [Therapeutic Goods Administration](https://www.tga.gov.au/) (TGA), PBAC (and other HTA committees), and onwards to subsidised listing and post-market reviews. This broad view resulted in proposed recommendations organised into four categories:

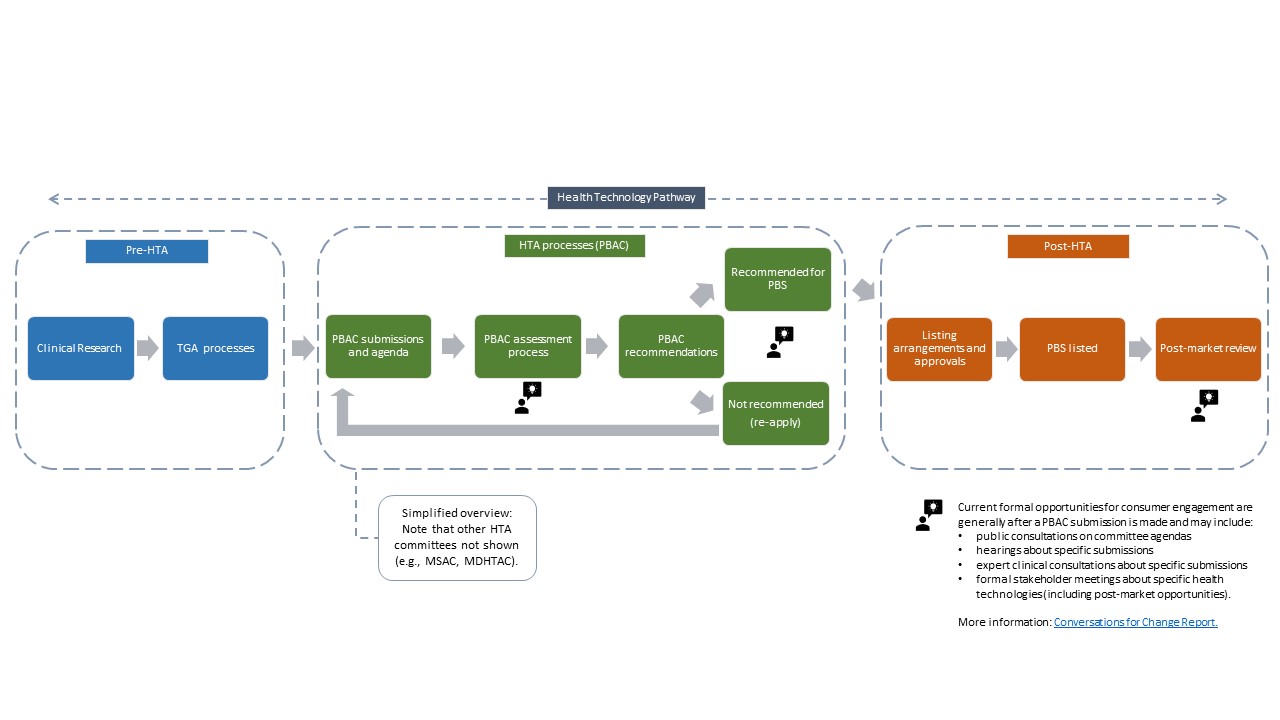
* **System-wide enhancements** that provide foundational support for embedding consumer evidence and experience across the end-to-end health technology pathway.
* **Pre-HTA enhancements** that enhance consumer engagement before submissions are made to PBAC (or other HTA committees), specifically with regard to clinical research and the TGA.
* **HTA process enhancements** that enable consumer engagement when a submission is under assessment by PBAC (or other HTA committees).
* **Post-HTA enhancements** that enable consumer engagement after HTA decision-making and recommendations for subsidised listing.

**Figure 1** below provides a visual map of the health technology pathway noting *current opportunities* for consumer engagement.

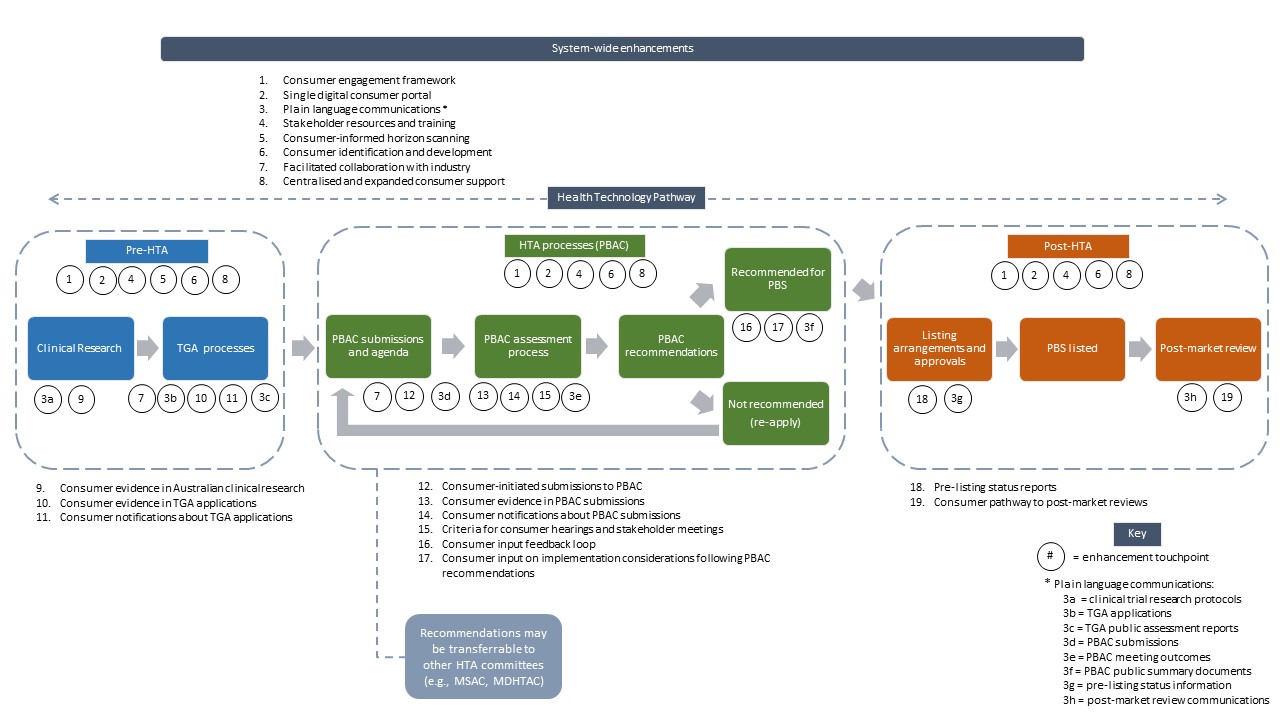
**Figure 2** shows the visual map with the *proposed recommendations* to enhance consumer engagement.

**Table 1** provides a summary of the proposed recommendations with further details provided in [Section 2](#Section_2) of this report.

**Figure 1: Map of current opportunities for consumer engagement in the health technology pathway**



**Figure 2: Map of proposed recommendations to enhance consumer engagement in the health technology pathway**



**Table 1: Summary of Proposed Recommendations for Enhanced Consumer Engagement**

**SYSTEM-WIDE ENHANCEMENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Status** |  | **Proposed Recommendation** | **Purpose of Recommendation** |
| Various policy frameworks provide guidance for engaging consumers in different parts of the health technology pathway, from clinical research through to HTA processes. |  | **1.Consumer engagement framework**  Develop and implement an overarching framework outlining and embedding consumer engagement across the health technology pathway. | * Embed the role of consumers across key touchpoints in the end-to-end health technology pathway, including clinical research, the TGA, HTA committees, and post-market review processes. * Support and make visible equity and inclusion of First Nations communities and socially and culturally diverse and underrepresented groups. |
| Information and resources to support consumer engagement in the health technology pathway is challenging to navigate across different Departmental websites. |  | **2.Single digital consumer portal**  Create an online ‘one-stop-shop’ portal providing consumer engagement resources and regularly updated notifications about activities occurring in the health technology pathway. | * Consolidates information about consumer engagement resources, tools, training, and HTA committee notifications in one online location. * Establishes an online location to communicate and house other resources relevant to recommendations in this document. |
| Communications about health technologies and assessment processes are either not available in some parts of the health technology pathway or not written with consumers in mind as a target audience. |  | **3.Plain language communications**  Co-design a series of plain language and consumer-focused communications provided at key touchpoints across the health technology pathway. | * Increase consumer engagement and understanding of the status and outcomes relevant to health technologies. * Enable flow-on-effects of communications aimed at consumers across the health technology pathway. |
| Government, industry, and consumers do not yet have centralised and standard resources and training to guide robust consumer engagement for HTA processes. |  | **4.Stakeholder resources and training**  Establish a central unit offering training and resources to government, industry, and consumers. | * Increase knowledge and capacity of all stakeholders in consumer engagement methods, and the value of consumer evidence and experience. * Increase consumers’ capacity as independent, informed, and equal partners in HTA processes. * Embed equity and inclusion principles in training to support engagement with First Nations representatives and people from culturally and socially diverse and underrepresented groups. |
| The Strategic Agreement between the Commonwealth and Medicines Australia initiated the first annual horizon scanning forum in 2022; however, a more formally coordinated horizon scanning system with an embedded role for consumers is not yet established. |  | **5.Consumer-informed horizon scanning**  Formally recognise consumers as active contributors to the evolving horizon scanning system and embed inclusion of consumer feedback sessions in annual horizon scanning forums. | * Include consumers’ expertise in horizon scanning to identify potential health technologies relevant to specific disease areas and unmet clinical needs. * Enable informed consumers and other stakeholders to prepare for the impact and implementation needs of emerging health technologies. |
| Consumer engagement is currently overly reliant on consumers themselves pro-actively participating in HTA processes. |  | **6.Consumer identification and development**  Establish a process whereby the Department proactively identifies consumers and develops their capabilities as experts in their relevant disease areas. | * Provide visibility to government about consumer interest in specific health technologies relevant to disease areas. * Enhance consumers capacity to provide expert advice in relation to consumer evidence and experience into HTA processes. |
| There are no formal embedded pathways for industry sponsors and consumers to collaborate when applications and submissions are prepared for the TGA and HTA committees. |  | **7.Facilitated collaboration with industry**  Develop Departmental processes to facilitate collaborations between industry and consumers to prepare applications and submissions. | * Enhance the quality of applications/submissions with consumer evidence and experience. * Support the medicines industry to work with consumers to prepare industry sponsored applications/submissions while also respecting ethical and legal limitations. |
| The CEEU supports consumers to engage with HTA processes, however, this support requires ongoing commitments to enable enhanced consumer engagement. |  | **8. Centralised and expanded consumer support**  Expand dedicated Departmental support to facilitate consumer engagement across the health technology pathway and implement the recommendations of this report. | * Support collaboration and partnerships between government, industry, and consumers. * Lead implementation of interdependent recommendations to enable the flow-on effects of enhanced consumer engagement processes. |

**PRE-HTA ENHANCEMENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Process** |  | **Proposed Recommendation** | **Purpose of Recommendation** |
| Guidance from funding schemes such as the NHMRC and MRFF outline the important benefits of consumer involvement in clinical research, however, consumers are not consistently engaged to provide their expertise in the research lifecycle. |  | **9.Consumer evidence in Australian clinical research**  Strengthen existing guidance to establish a designated and mandatory role for consumers in the design and execution of Australian clinical research. | * Formalise consumers as early and active contributors in the research lifecycle to ensure that their priorities, evidence, and unmet needs are consistently considered in study designs and outcomes. * Enable a broader array of methodologies to collect evidence about consumers’ clinical needs and experiences (e.g., PREMS, PROMS, qualitative studies). |
| Consumers are not generally informed about how consumer evidence and experience is used in TGA applications and decision-making. |  | **10.Consumer evidence in TGA applications**  Implement checks to ensure TGA applications demonstrate inclusion of consumer evidence and experience. | * Enable alignment of TGA decision-making about health technology approvals with consumer clinical needs, evidence, and experience. * Provide transparency to consumers about how their evidence and experience is considered by the TGA. |
| TGA processes are currently experienced as a ‘closed system’ to consumers. |  | **11.Consumer notifications about TGA applications**  Notify consumers about TGA applications and agendas and provide opportunities for consumers to have input into health technologies under assessment. | * Embed consumer evidence and experience in TGA hearings and decision-making processes. * Enable greater alignment between consumer engagement in the TGA and downstream HTA processes in PBAC and other committees. * Increase consumer involvement and understanding of TGA processes. |

**HTA PROCESS ENHANCEMENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Process** |  | **Proposed Recommendation** | * **Purpose of Recommendation** |
| Consumers do not currently have a facilitated and formal pathway to initiate submissions to PBAC. |  | **12. Consumer-initiated submissions to PBAC**  Establish a pathway to enable consumer-initiated submissions to PBAC via Departmental facilitated collaboration with industry. | * Empower consumers to initiate PBAC submissions. * Value consumers as equal partners and leaders in driving HTA processes. * Create opportunities to assess health technologies for subsidisation that may address unmet clinical needs. |
| Consumers are not generally informed about how consumer evidence and experience is used in PBAC submissions and decision-making. |  | **13.Consumer evidence in PBAC submissions**  Implement checks to ensure PBAC submissions demonstrate the inclusion of consumer evidence and experience. | * Enable alignment of PBAC decision-making about subsidisation with consumer clinical needs, evidence, and experience. * Provide transparency to consumers about how their evidence and experience is considered by PBAC. |
| Consumers must navigate PBAC agendas to locate items relevant to their disease areas and health technology interests. |  | **14.Consumer notifications about PBAC submissions**  Implement automated and early notification of PBAC agenda items and submissions, including targeted notifications for specific disease areas. | * Consumers receive targeted notifications assisted by other recommendations including the single digital portal, consumer identification, and facilitated collaborations with industry. * Consumers have visibility of the content within submissions including details of the comparator and restrictions to enable input on implementation considerations. * Consumers have adequate time to prepare input for relevant submissions and initiate consumer hearings. |
| Procedural guidance advises PBAC to call consumer hearings and stakeholder meetings, however, the criteria for such meetings are unclear. |  | **15.Criteria for consumer hearings and stakeholder meetings**  Develop transparent criteria for consumer hearings and stakeholder meetings within HTA processes. | * Increase transparency about the purpose for hearings and meetings and support consumer to provide input in an inclusive and accessible way. * Empower consumers to initiate hearings when criteria are met. * Increase opportunities for PBAC decision-making to be informed by consumer evidence and experience. |
| PBAC Public Summary Documents provide information about HTA outcomes, however, these communications lack information about how consumer input informed decision-making. |  | **16.Consumer input feedback loop**  PBAC to provide information and feedback about the use of consumer input in decision-making. | * Demonstrate the impact of consumer input on PBAC decision-making. * Enable consumers to develop the quality of their input and evidence relevant to health technologies considered by PBAC. |
| PBAC recommendations are made after careful consideration, however, there is no established process for consumers to provide input about potential implementation issues prior to listing. |  | **17. Consumer input on implementation considerations following PBAC recommendations**  Establish efficient process for input by expert identified consumers on implementation issues for positive PBAC recommendations. | * Engage consumer expertise about the medical, practical, and equitable implementation issues for recommended health technologies. * Ensure there is an efficient pre-listing opportunity, which does not delay timelines, for consumers to have input on implementation issues ideally identified through earlier engagement in HTA processes. |

**POST-HTA ENHANCEMENTS**

|  |  |  |  |
| --- | --- | --- | --- |
| **Current Process** |  | **Proposed Recommendation** | **Purpose of Recommendation** |
| The Medicines Status Website provides minimal information about the status of a health technology after it is approved, but not yet listed, while pricing negotiations are underway. |  | **18.Pre-listing status reports**  Implement a plain language status report providing essential information about the timeline for pricing negotiations and reasons for delay. | * Consumers are kept informed about the status of approved health technologies prior to listing. * Support opportunities for consumers to offer expertise that may help to alleviate delays and improve timely access to medicines. |
| Post-market reviews are initiated by PBAC based on stakeholder recommendations however, consumers do not yet have a clear pathway in this process. |  | **19.Consumer pathway to post-market reviews**  Establish a pathway for consumers to initiate a post-market review of a listed health technology. | * Consumers provide valuable post-market evidence regarding the real-world impacts and experiences of using a health technology after it is subsidised and available to the public. |

## Implementation Considerations

The CWG accounted for various implementation considerations for the proposed recommendations as shown below in **Table 2**.

**Table 2: Implementation Considerations for the Proposed Recommendations**

|  |  |
| --- | --- |
| **Implementation considerations** | **Key points** |
| **Leverage existing and emerging strengths for consumer engagement** | * The recommendations leverage and build upon the existing and emerging strengths in the health technology pathway to enhance consumer engagement and prioritise the inclusion of consumer evidence and experience. * Examples of such strengths include Consumer engagement guidelines for research funding (e.g., NHMRC, MRFF); PBAC procedural guidelines; the Summary of Information Pilot; the DCAR process in MSAC; the Department’s CEEU and the Consumer Consultative Committee (CCC); horizon scanning forums; and the HTA Policy and Methods Review. |
| **Commit to timely consumer-focused reform** | * Harnessing the focus and momentum emerging from this co-design project in a timely way will result in significantly strengthening consumer engagement and demonstrate the Government’s commitment to enhanced processes that are co-designed with consumers and for consumers. |
| **Partnership work for positive flow-on effects** | * The recommendations create an opportunity to strengthen partnership work across government bodies, consumer groups, and industry partners to enable positive flow-on-effects to support consumer engagement across the health technology pathway. * While a commitment to timely reform ought to be a priority, it is also acknowledged that some flow-on-effects may take time to bear results - enhancements in earlier stages (e.g., clinical research and TGA), may not be feasibly implemented before downstream enhancements (e.g., in PBAC and post-market reviews). |
| **Address health equity and access needs** | * The implementation and evaluation of the recommended enhancements must prioritise principles of equity, access, and inclusion to ensure that changes meet the needs of First Nations communities and diverse and underrepresented groups across Australia. |
| **Invest in systemic change** | * Many of the recommended enhancements represent discreet projects and new processes that will require funding to bodies within, and outside of, the Department to enable consumer engagement. * Such investment is needed to support the participation of individual consumers and consumer groups, as they do not typically have the resources or time to provide extensive input into HTA processes while managing health concerns and caring responsibilities. * Legislating a consumer voice in HTA processes may be a mechanism to ensure a lasting investment in systemic change. |
| **Strengthen the use of consumer evidence and experience** | * Implementing the recommended enhancements requires a new vision to strengthen and embed consumer evidence and experience into the health technology pathway from clinical research through to the examination of evidence during TGA approvals and HTA processes overseen by PBAC and other committees. * This vision entails the acceptance of consumers’ input into PICO scoping and methodologies that account for consumer evidence, such as PREMS, PROMS, RWE, qualitative studies, and health equity studies. |
| **Facilitate beneficial communication between the medicines industry and consumers** | * Legislative restrictions prohibit information sharing between industry and consumers to mitigate the risk of direct-to-consumer advertising and exposing confidential information. While these prohibitions intend to protect the Australian public, they also create barriers to consumer engagement in early stages. * Some of the recommended enhancements intend to maintain these important protections while also carefully facilitating opportunities to harness the value of consumer input and evidence early in the health technology pathway. * Implementation will require careful consideration to ensure that the benefits of consumer engagement in the proposed recommendations do not exacerbate risks to confidentiality and conflicts of interest. |

# Section 2:

# Detailed Descriptions of Proposed Recommendations for Enhanced Consumer Engagement

# Introduction

## Background

The [2022–2027 Strategic Agreement between the Commonwealth Government and Medicines Australia](https://www.pbs.gov.au/info/general/medicines-industry-strategic-agreement) includes a project to “co-design and agree upon an Enhanced Consumer Engagement Process, for consideration by the Minister for Health and Aged Care, to capture consumer voices in respect to applications to list new medicines on the Pharmaceutical Benefits Scheme (PBS)”.

This co-design project was commissioned by the Department of Health and Aged Care (the Department) and is managed by the Consumer Evidence and Engagement Unit (CEEU), in the Office of Health Technology Assessment (OHTA). A ‘consumer-led proposal’ developed by a reference group of consumer advocates provided initial guidance to the CEEU to secure independent co-design facilitators from The University of Melbourne and establish a Co-design Working Group (CWG) of consumer, government, and medicines industry representatives.

## Purpose and Scope

The purpose of the project is to:

*Develop a report with recommendations, for the consideration of the Minister for Health and Aged Care, on the design and implementation of the Enhanced Consumer Engagement Process for Health Technology Assessments relevant to Pharmaceutical Benefits Advisory Committee, as per the 2022-2027 Strategic agreement between the Commonwealth and Medicines Australia.*

The scope includes:

* applications to list new health technologies (single or class) on the PBS (i.e., medicines, vaccines, nutritional products, codependent technologies)
* changes to early stages of the HTA pathway
* clarifying the relationship with horizon scanning information
* understanding where conflicts of interest may need to be managed.

Importantly, while the purpose and scope focus on enhancing consumer engagement in relation to the Pharmaceutical Benefits Advisory Committee (PBAC), as per the Strategic Agreement, the CWG identified the importance of strengthening consumer engagement across the entire health technology pathway, including in pre and post PBAC processes such as those involved in clinical research, the Therapeutic Goods Administration (TGA), and post-market reviews. Additionally, the proposed recommendations for PBAC processes may be transferable to other HTA committees including the Medical Services Advisory Committee (MSAC) and the Medical Device and Human Tissue Advisory Committee (MDHTAC). Further, the proposed recommendations provide an opportunity to contribute to the broader reforms of the [HTA Policy and Methods Review](https://www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review).

## Co-design process

The CWG developed the proposed recommendations in this document through iterative co-design meetings, workshops and discussions held from October 2023 to February 2024.

CWG members first agreed on the project’s workplan, purpose and scope through planning discussions with the independent facilitators. The workplan is built on a co-design methodology that enables members to iteratively share their ideas, experience, and evidence to design solutions and develop recommendations over time. This methodology is underpinned by values of democratic participation, shared decision-making, critical reflection, and centralising consumers’ lived experience and expertise. Gathering feedback from stakeholders through the survey that accompanies this consultation document is a critical part of this iterative, co-design approach.

Early co-design activities were informed by a design brief prepared by the independent facilitators. The brief documented relevant issues from a range of prior consultation reports and policy documents, such as (but not limited to) [Conversations for Change](https://www.health.gov.au/resources/publications/conversations-for-change-report-2023?language=en), the [National Medicines Policy (2022)](https://www.health.gov.au/resources/publications/national-medicines-policy?language=en) and the [New Frontier Report – Delivering better health for all Australians (2021)](https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Newdrugs/Report).

Using this brief, the CWG members worked together to establish the following design principles to guide the development of the proposed recommendations:

1. Consumer evidence and experience is prioritised and integral in health technology assessment processes.
2. Recommendations to enhance consumer engagement must not delay access to medicines.
3. Enhancements for consumer engagement may be prioritised to achieve maximum impact through implementation.

The CWG continuously audit their approach and recommendations against these principles and will return to them again in future workshops to produce the final report for the Minister for Health and Aged Care.

More information about the co-design activities and processes undertaken by the CWG is available in the workshop communiques on the [project webpage](https://www.health.gov.au/our-work/co-design-of-an-enhanced-consumer-engagement-process).

# Proposed Recommendations

As per the project purpose and scope (see [Introduction](#_Introduction_1)), the proposed recommendations described below pertain to enhancing consumer engagement across the entire health technology pathway from clinical research through to the TGA, PBAC, and post-market considerations. These recommendations may also be relevant and transferrable to other HTA committees.

Given this context, the proposed recommendations are organised into four categories:

* **System-wide enhancements** that provide foundational support for embedding consumer evidence and experience across the end-to-end health technology pathway.
* **Pre-HTA enhancements** that enhance consumer engagement before submissions are made to PBAC (or other HTA committees), specifically with regard to clinical research and the TGA.
* **HTA process enhancements** that enable consumer engagement when a submission is under assessment by PBAC (or other HTA committees).
* **Post-HTA enhancements** that enable consumer engagement after HTA decision-making and recommendations for subsidised listing.

There are currently 19 recommended enhancements proposed in this report. They are numbered consecutively to match with **Figure 2** and **Table 1** shown in [Section 1](#_Section_1:).

## System-wide Enhancements

Recommendations for system-wide enhancements provide foundational support for embedding consumer evidence and experience across the end-to-end health technology pathway and support other recommendations found in the subsequent sections (pre-HTA, HTA processes, and post-HTA).

### Consumer engagement framework

The CWG recommend an overarching framework to align and embed the recommendations of this co-design project and other reform initiatives (e.g., the HTA Policy and Methods Review), into government strategies, implementation planning and evaluation activities.

The framework should address the principle of early and continuous consumer engagement across the end-to-end health technology pathway providing a roadmap and authorising environment to involve consumers formally in clinical research, the TGA, HTA committees (e.g., PBAC, MSAC, MDHTAC), subsidisation funding schemes (e.g., PBS, MBS, PL, NDSS, etc.), and post-market activities.

The framework could also enable the prioritisation of consumer engagement in new strategic agreements between government and industry, national policy documents (e.g., the National Medicines Policy), and provide the outcomes measures needed to evaluate the success and impact of system-wide enhanced consumer engagement. These inclusions would demonstrate the value the Government places on consumer experience and evidence within HTA processes and the broader Australian healthcare system. As such, stakeholders for the framework may include consumers, researchers, clinicians, health professionals, government, and the medicines industry.

Importantly, developing this framework presents an opportunity to embed equity and inclusion in the health technology pathway to pro-actively formalise consumer representation with First Nations Peoples and people from socially and culturally diverse communities and underrepresented groups such as consumers from rural and remote areas and consumers that have other unmet needs, including patients with rare diseases.

### Single digital consumer portal

The CWG advise that it is challenging to locate and navigate information and resources to support consumer engagement across different Departmental websites. This fragmentation of information makes it difficult for consumers to receive timely notifications about TGA and PBAC (or other HTA committees) agenda items, applications, submissions, and other relevant processes. Furthermore, this creates a barrier for consumers to effectively offer their expertise and input into health technologies relevant to their disease areas and health conditions.

The CWG recommend a single digital portal on a website to provide a ‘one stop shop’ where consumers can access resources that enable their engagement across the health technology pathway. The portal could house information and resources relevant to many of the recommended enhancements described in this report, such as:

* The consumer engagement framework
* Stakeholder resources and training
* Tools and templates that support consumers to document their evidence and experience
* Notifications about TGA and PBAC (and other HTA committees) agendas and applications/submissions
* Criteria for consumer hearings and stakeholder meetings
* Consolidation of information currently (and disparately) provided on other key websites, such as HTA committee websites, the Medicines Status Website, and the OHTA consultation hub.

These enhancements and other resources developed for the portal must also be accessible to diverse audiences, including the public, consumer groups, First Nations communities, and diverse and underrepresented populations.

### Plain language communications

Clear, plain language communication is an essential part of enhancing consumer engagement. The CWG identified touchpoints (see Figure 2 in [Section 1](#Section_1)) across the health technology pathway where plain language communication would benefit enhanced consumer engagement. These touchpoints are:

3a. clinical trial research protocols

3b. TGA applications

3c. TGA public assessment reports

3d. PBAC submissions

3e. PBAC meeting outcomes

3f. PBAC public summary documents

3g. pre-listing status information

3h. post-market review communications

To start, the CWG recommend that the Summary of Information Pilot be fully operationalised. The Pilot trialled plain language summaries of submissions to PBAC using a template to communicate more effectively with consumers. Building on this approach, the CWG recommend a co-design project to develop additional templates for the other touchpoints to remedy any remaining plain language communication gaps.

Notably, implementing these communications may help enhance the flow-on effects of early consumer engagement. For example, plain language summaries of TGA applications may function as a ‘living document’ with further information added to other communications relevant to PBAC, other HTA committees, and further along the health technology pathway.

### Stakeholder resources and training

The CWG recommend that the Department establish stakeholder training and resources for government, industry, and consumers. Indeed, the CWG noted that consumers are well-positioned to increase the capability of government and industry stakeholders in consumer engagement methods and understanding the value of consumer evidence and experience. At the same time, enhancing consumer engagement also necessitates dedicated training and access to resources for consumers to enable their independent, informed, and equal partnership in HTA processes.

This training approach should be co-designed with consumers, government, and industry stakeholders. As a start, the CWG recommend bringing together current resources in Departmental websites to provide training about:

* opportunities for consumers to provide their own input and evidence across the health technology pathway, before, during and after HTA processes and decision-making.
* the processes used by clinical researchers, the TGA and HTA committees to consider consumer input and evidence in their decision-making.
* the standard of evidence required for consumer input and hearings to the TGA, PBAC and other HTA committees with guidance in the form of tools and templates to support the collection and presentation of robust patient data.

Training must be inclusive and provide equitable access to support a broad spectrum of consumers from First Nations communities and socially and culturally diverse populations and underrepresented groups. Training should include different levels of standardised training, plain language resources, and mixed media resources such as webinars, videos, and infographics.

### Consumer-informed horizon scanning

Horizon scanning is a process that systematically identifies, assesses, and plans for the potential impact of new and emerging technologies. The Strategic Agreement sets a foundation for an annual horizon scanning forum with the first forum held by Medicines Australia in December 2022. The forum brought together stakeholders from across the Commonwealth Government, State and Territory Governments, the medicines industry, life sciences companies, researchers, clinicians, and consumer organisations.

The CWG recognised that horizon scanning is new and evolving in Australia. They considered recent reports from [Medicines Australia](https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/06/MA-Horizon-Scanning-Forum-v5-June-2023.pdf) and industry stakeholders such as [Bristol Myers Squibb](https://www.bms.com/assets/bms/australia/documents/Horizon%20Scanning%20report%202022_Final.pdf), which both recommend the inclusion of consumer evidence and experience in horizon scanning processes. Such processes include the annual forum, however, the CWG noted that a coordinated and centralised horizon scanning system is also recommended by these reports.

The CWG recommend that consumers have an active role in the evolving horizon scanning system and annual forums via a dedicated consumer feedback opportunities and forum sessions. Consumer-informed horizon scanning recognises that consumers have a unique and significant role in providing insights into unmet patient needs and emerging health technologies for specific diseases and conditions. Consumer engagement in horizon scanning must also involve an equity lens to ensure that diverse and underserved populations are included, and a distinct recognition and engagement process dedicated to First Nations communities.

### Consumer identification and development

Consumer engagement in the heath technology pathway currently relies substantially on consumers themselves navigating complex online information about health technologies undergoing approvals and subsidisation assessments. The aforementioned [single digital portal](#_Single_Digital_Consumer) will help to consolidate some of this information; however, the CWG recommend that the Department also establish a process to identify individual consumers and consumer groups so that they may receive targeted information about TGA and HTA committee processes, agenda items, and decision-making outcomes relevant to their disease areas and health conditions of interest. Notably, this formal identification process would also enable the recommendation for earlier [facilitated collaboration](#_Facilitated_collaboration_with) between consumers and industry to improve the quality of TGA applications and HTA submissions that identify consumer evidence and experience.

This recommendation may also support capacity development for identified consumers so that they are equipped to provide expert advice earlier and throughout the health technology pathway (for example, through the provision of recommended [stakeholder resources and training](#_Stakeholder_resources_and)). As such, identifying and targeting consumers with information, and further developing their capacity, will provide assurances that consumers are equipped and supported to provide input relevant to specific health technologies and disease areas.

### Facilitated collaboration with industry

The CWG advised that early collaborations between consumers and the medicines industry will enhance the quality of applications and submissions to the TGA and HTA committees by ensuring the early inclusion of consumer priorities, evidence, and experience for relevant health technologies.

The CWG noted significant impediments to collaboration due to prohibitions on direct-to-consumer advertising and commercial-in-confidence issues prescribed under the *Therapeutic Goods Act 1989* and the *Competition and Consumer Act 2010*. These laws have important protections for the Australian public, yet also make it difficult for consumers and the medicines industry to collaborate under the principle of enhanced consumer engagement.

The CWG therefore recommend that the Department establish and facilitate ethical and lawful collaborations between consumers and the medicines industry when industry-sponsored applications and submissions for the TGA and HTA committees are in development.

### Centralised and expanded consumer support

The CWG recommend that the Department expand the support mechanisms available to consumers (such as those currently provided by the CEEU), to facilitate their engagement with the health technology pathway and HTA processes.

Expanding dedicated support to consumers represents both an enhancement for consumer engagement as well as an implementation enabler for the recommendations of this co-design project (see [Implementation Considerations](#_Implementation_Considerations)).

This expansion is critically important given the interdependent nature of many of the recommended enhancements and their potential flow-on-effects, which requires high-level oversight, coordination and continuous communication and engagement with consumers and key stakeholders in clinical research, the medicines industry, the TGA, PBAC, and other HTA committees.

## Pre-HTA Enhancements

The following are proposed recommendations to enhance consumer engagement before submissions are made to PBAC (or other HTA committees), specifically with regard to clinical research and the TGA.

### Consumer evidence in Australian clinical research

The [National Health and Medical Research Council](https://www.nhmrc.gov.au/about-us/publications/statement-consumer-and-community-involvement-health-and-medical-research) (NHMRC) and other funding schemes, such as the [Medical Research Futures Fund](https://www.health.gov.au/committees-and-groups/medical-research-future-fund-consumer-reference-panel) (MRFF), emphasise the importance of consumer engagement in clinical research to elevate the quality of research and develop health technologies that robustly account for consumer evidence and experience. This guidance, however, does not always translate into consistent opportunities for consumers to engage across the research lifecycle nor does it guarantee that consumer-informed findings are inputted into TGA and HTA decision-making processes.

The CWG recommend a designated and mandatory role for consumers in the design and execution of clinical research trials undertaken by the medicines industry and research sector in Australia. This role will ideally enable the inclusion of consumer evidence and experience in research using methodologies such as Patient Reported Experience Measures (PREMS), Patient Reported Outcomes Measures (PROMS), qualitative studies, health equity studies, and Real-World Evidence (RWE).

Further down the health technology pathway, it is essential that assessment processes in the TGA and PBAC check that clinical research conducted in Australia demonstrated consumer engagement and included information about consumer evidence and experience.

### Consumer evidence in TGA applications

Related to the [above recommendation for clinical research](#_Consumer_Evidence_in), the CWG recommend that the TGA check that applications for health technologies demonstrate consumer engagement in research design and delivery as well as the inclusion of consumer evidence and experience in study results. Furthermore, the TGA ought to assess this information and describe how it has informed decision-making for health technology approvals. This approach may involve undertaking a review of the values and methodological assumptions used to assess health technologies (see [Implementation Considerations](#_Implementation_Considerations)).

The CWG also recognise that TGA applications may involve health technologies that underwent clinical research outside of Australia, which may have inconsistencies in the level of consumer engagement and evidence compared to this proposed recommendation for Australian-based research. Nevertheless, in these circumstances, the CWG recommend that Australian consumers are consulted to define the Population, Intervention, Comparator, Outcome (PICO) prior to the TGA application. This engagement may be enabled by partnership work between the Department, industry and consumer groups and [facilitated opportunities for collaboration](#_Facilitated_collaboration_with) amongst these stakeholders as described in the system-wide enhancements.

### Consumer notifications about TGA applications

The CWG discussed how the TGA assessment and approval processes are experienced as a closed system that could be improved by establishing dedicated consumer engagement practices mirroring the enhancements suggested for the PBAC processes described below.

Central to this is the CWG’s recommendation that consumers are notified when applications are made to the TGA and provided opportunities to provide input and attend hearings during the TGA assessment process. This recommendation is relevant for new applications, parallel applications (jointly made to TGA and PBAC), applications for repurposing health technologies, or applications for new indications.

## HTA Process Enhancements

The following are proposed recommendations to enhance consumer engagement during the HTA processes undertaken by PBAC and may also be relevant to other HTA committees (e.g., MSAC, MDHTAC).

### Consumer-initiated submissions to PBAC

There is currently no formal pathway for consumers to initiate a submission to PBAC or other HTA committees. Indeed, a pharmaceutical company is typically the primary sponsor for such submissions as they hold the necessary scientific data and other clinical information needed to inform decisions for subsidised listing. Sponsors also pay a fee to cover the costs of the assessment processes as per the [Australian Government Cost Recovery Policy](https://www.finance.gov.au/government/managing-commonwealth-resources/implementing-charging-framework-rmg-302/australian-government-cost-recovery-policy) and associated guidelines. Furthermore, because a pharmaceutical company is a private entity, it makes its own decisions about the availability of its medicines in the Australian market, and the Department is unable to compel companies to apply for TGA registration or HTA assessments for subsidised listing.

The CWG advised that relying primarily on the medicines industry to initiate HTA submissions is a significant concern as health technologies that may be potentially helpful, and lifesaving, may never be assessed for subsidisation due to a lack of commercial incentive for pharmaceutical companies. Furthermore, individual consumers and consumer groups generally do not have the resources or funds to develop submissions and pay the relevant fees.

As such, the CWG advised that there is a need to establish a formal pathway to empower consumers to initiate and drive the development of submissions themselves. Similar to the recommendation for [facilitated collaborations](#_Facilitated_collaboration_with) for industry-initiated submissions, this recommendation would require Departmental support to enable collaborations between consumers and industry that attend to legislative barriers for direct-to-consumer advertising and commercial-in-confidence prescribed under the *Therapeutic Goods Act 1989* and the *Competition and Consumer Act 2010*.

As a start, a potential consideration for this recommendation is the example of the [Department Contracted Assessment Report (DCAR)](http://www.msac.gov.au/internet/msac/publishing.nsf/Content/Documents-for-Applicants-and-Assessment-Groups) used by MSAC. In this process, the Department contracts an HTA Evaluation Group to develop the assessment report on a topic nominated by a stakeholder, such as a health professional or consumer representative group, in consultation with the product sponsor. HTA evaluation groups are independent external providers with demonstrated subject matter and technical expertise selected from a panel maintained by the Department.

### Consumer evidence in PBAC submissions

Like the [recommendation for TGA applications](#_Consumer_evidence_in_2) above, the CWG recommend checks that submissions made to PBAC (and other HTA committees) demonstrate consumer engagement and the inclusion of consumer evidence and experience.

Similarly, where the submission involves a health technology that underwent clinical research outside of Australia, the CWG recommend that consumers are still consulted for PICO scoping to inform PBAC submissions. Consumer evidence should therefore be included as a standard in submissions and reviewed by committees with a [feedback loop](#_Consumer_input_feedback) to inform consumers about how their input was factored into PBAC decision-making for subsidisation.

### Consumer notifications about PBAC submissions

The CWG advised that current processes for notifying consumers about PBAC submissions and input opportunities need to occur as early as possible. Similar to recommended [TGA notifications](#_Consumer_notifications_about) above, the CWG recommend systematic, automated notifications of new submissions, parallel applications (jointly made to TGA and PBAC) and potentially submissions made through alternate pathways, such as the recommended [consumer-initiated submissions](#_Consumer-initiated_submissions_to). This process would help alleviate the time intensive work that consumers undertake to constantly check PBAC agendas for relevant items. Automated notification enables consumers to review the PBAC agenda and the content of submissions, prepare their own input (including evidence gathering), and initiate [consumer hearings](#_Criteria_for_consumer) if needed.

This recommendation has a relationship with the recommendations for the [single digital consumer portal](#_Single_Digital_Consumer) and [consumer identification and development](#_Consumer_identification_and) as consumers could be targeted with timely information about items on the PBAC agenda that are relevant to their nominated disease areas. [Facilitated collaborations](#_Facilitated_collaboration_with) with industry would go even further by supporting earlier engagement with consumers as submissions are prepared.

### Criteria for consumer hearings and stakeholder meetings

The [PBAC Procedure Guidance](https://www.pbs.gov.au/info/industry/listing/listing-steps) advises that when an HTA process is underway, the PBAC may call consumer hearings (for consumers only) or stakeholder meetings (including consumers and other stakeholders such as the medicines industry) to gather more information for assessment and decision-making.

The CWG recommend further development of clear and transparent guidance about the criteria used to call a consumer hearing or stakeholder meeting. This guidance will support consumers to understand the purpose of hearings and initiate such hearings themselves when the criteria are met.

Consumer hearings and stakeholder meetings must also be managed in an inclusive way, providing guidance to consumers in how they can contribute to these processes in-person, via video or in written formats.

### Consumer input feedback loop

Consumers put significant effort and resources into developing comprehensive input during HTA processes, yet they do not often receive feedback about whether their input had any bearing on PBAC decision-making. This is related to the enhancement above, in which the CWG recommend checks to ensure that consumer experience and evidence is used in decision-making during TGA and PBAC (or other HTA committee) processes.

The CWG advised that consumers want to know if their input could be improved for future input about relevant health technologies. The CWG, therefore, recommend a feedback loop to provide advice to consumers on these matters. This feedback loop has a relationship with [plain language communications](#_Plain_language_communications_1), whereby the outcomes of PBAC meetings (even prior to producing public summary documents), are communicated to consumer groups directly involved in specific submissions. This feedback loop also pertains to outcomes when PBAC does not recommend a health technology for subsidisation.

### Consumer input on implementation considerations following PBAC recommendations

The CWG advise that consumers often have insights into the potential impacts of PBAC’s recommendations to list a medicine on the PBS. Specifically, consumers can help identify potential issues and unintended consequences related to the medical, practical, and equitable implementation of a recommended health technology in ‘real world’ settings. The CWG therefore recommend that the Department establish a process that enables consultation with consumers with disease area expertise, such as those who are formally [identified and developed](#_Consumer_identification_and) to provide advice on such matters.

This process will require attention to efficiency as the CWG are alert to the need to avoid any delays in access to medicines. Ideally, the enhancements recommended in the [earlier stages of the pathway](#_Pre-HTA_Enhancements) will enable consumers to provide input about potential implementation considerations prior to PBAC decision-making. This recommendation, however, provides a check to ensure that consumer advice on these matters is not missed as a health technology transitions to subsidised lists and availability in the market.

## Post-HTA Enhancements

The following are proposed recommendations to enhance consumer engagement after PBAC (or other HTA committees) have made decisions to recommend a health technology for subsidised listing.

### Pre-listing status reports

While HTA processes for PBAC run on an established and transparent schedule, consumers find they are unable to receive sufficient or timely information about the status of a health technology once it is approved for listing but is still awaiting a pricing outcome from negotiations between the industry sponsor and the Government. Currently, the [Medicines Status Website](https://www.pbs.gov.au/medicinestatus/home.html) only informs the public that a health technology is recommended and undergoing ‘agreement to listing arrangements’ and ‘government processes’ (both which pertain to pricing arrangements) and the dates these steps commenced. In some circumstances, these steps can continue for some time delaying access to approved medicines.

The CWG understand that pricing negotiations are highly sensitive and confidential matters and do not expect that consumers or the public are privy to commercial-in-confidence negotiations. The CWG do recommend, however, that the Department publish pre-listing status reports (potentially on the Medicines Status Website or via the single digital portal) using plain language communications to describe the timeline for negotiations and high-level reasons for the delay. The CWG also advised that if consumers were aware of a non-pricing aspect of the delay (e.g., issues related to population or the disease area), they may be able to offer expertise to assist with the process and mitigate further delays.

### Consumer pathway to post-market reviews

Post-market reviews provide an opportunity to identify how well health technologies perform in real world conditions and the impacts on consumers accessing PBS listed medicines. Post-market reviews are initiated by PBAC based on stakeholder recommendations however, consumers do not yet have a clear pathway in this process.

The CWG advised that consumers offer an important perspective on how health technologies are used and experienced after they are subsidised and available to the Australian public. The CWG therefore recommend that a pathway is established for consumers to initiate a post-market review and submit evidence, with appropriate guidance, to post-market reviews, about consumers’ experiences and usage of the health technology during this process.

# Implementation Considerations

As the CWG developed the proposed recommendations, they also accounted for various implementation considerations to inform future implementation planning.

Notably, the interrelated flow-on-effects of the recommendations enables their implementation as they work in tandem to scaffold consumer engagement and the input of consumer evidence and experience across the health technology pathway from clinical research through to post-market reviews. System-wide enhancements, in particular, provide a foundation for implementing and enabling many of the other recommended enhancements described in this report.

Each of the implementation considerations are described further below.

Leverage existing and emerging strengths for consumer engagement

The recommendations leverage and build upon the existing and emerging strengths in the health technology pathway to enhance consumer engagement and prioritise the inclusion of consumer evidence and experience. Examples of such strengths include consumer engagement guidelines for clinical research (e.g., NHMRC, MRFF); the PBAC procedural guidelines; the Summary of Information Pilot; the DCAR process in MSAC; the Department’s CEEU and the Consumer Consultative Committee (CCC); horizon scanning forums; and the HTA Policy and Methods Review.

Commit to timely consumer-focused reform

Harnessing the focus and momentum emerging from this co-design project in a timely way will result in significantly strengthening consumer engagement and demonstrate the Government’s commitment to robust and responsive enhanced processes that are co-designed with consumers and for consumers.

Partnership work for positive flow-on effects

The recommendations create an opportunity to strengthen partnership work across government bodies, consumer groups, and industry partners. Strengthening partnerships will enable positive flow-on-effects to support consumer engagement across the health technology pathway as medicines transition from clinical research through to TGA approval phases, submissions for subsidisation (via PBAC and other HTA committees) and so forth into listing and post-market considerations.

While a commitment to timely reform ought to be a priority, it is also acknowledged that some flow-on-effects may take time to bear results as enhancements in earlier stages (e.g., clinical research and TGA), may not be feasibly implemented before enhancements specifically relevant to downstream HTA processes and post-market activities.

Address health equity and access needs

The implementation and evaluation of the recommended enhancements must prioritise principles of equity, access, and inclusion to ensure that changes meet the needs of First Nations communities and diverse and underrepresented groups across Australia.

As such, consumer representatives from First Nations communities and socially and culturally diverse populations must be strategically engaged to further develop, implement, and evaluate the recommendations in this document.

Invest in systemic change

Many of the recommended enhancements represent discreet projects and new processes that will require funding to bodies within, and outside of, the Department. Such investment is needed to support individual consumers and groups to participate in the HTA processes, as they often do not have the resources to provide extensive input while managing health concerns and caring duties.

Dedicated investment strategies are also required to enable equitable access to consumer engagement for First Nations communities and diverse populations.

Further, legislating a ‘consumer voice’ may be a mechanism to ensure lasting investment in systemic change for enhancing consumer evidence and experience in the HTA pathway.

Strengthen the use of consumer evidence and experience

Implementing the recommended enhancements requires a new vision to strengthen and embed consumer evidence and experience into the health technology pathway from clinical research through to the examination of evidence during TGA approvals and HTA processes. This vision entails the acceptance of consumers’ input into PICO scoping and methodologies that account for consumer evidence, such as PREMS, PROMS, RWE, qualitative studies, and health equity studies.

Facilitate beneficial communication between medicines industry and consumers

Legislative restrictions via the *Therapeutic Goods Act 1989* and the *Competition and Consumer Act 2010* prohibits information sharing amongst industry and consumers to mitigate the risk of direct-to-consumer advertising and exposing confidential information. While these prohibitions intend to protect the Australian public, they also create barriers to consumer engagement, especially in early stages when TGA applications and HTA committee submissions are in development.

Some of the recommended enhancements intend to maintain these important protections while also carefully facilitating opportunities to harness the value of consumer input and evidence early in the health technology pathway and in collaboration with industry sponsors; however, implementation will require careful consideration to ensure that the benefits of consumer engagement in the proposed recommendations do not exacerbate risks to confidentiality and conflicts of interest.

# Conclusion

This consultation document presented the proposed recommendations of the CWG for the Enhanced Consumer Engagement Process.

These recommendations intend to enhance consumer engagement not only in PBAC processes, as per the Strategic Agreement between the Commonwealth and Medicines Australia, but also across the health technology pathway with key inclusions that may also be relevant for other HTA committees.

As noted, the recommendations provided are a work in progress, which the CWG will further refine after reviewing consultation feedback from consumers and other stakeholders.

Please return to the start of this document for information about [how to provide input](#_How_to_provide) via a consultation survey.

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| **The University of Melbourne**  Grattan Street, Parkville, Victoria 3010 Australia  13 MELB (13 6352)  +61 3 9035 5511 (International)  **unimelb.edu.au** |

