

# Conversations for Change report: improving consumer engagement in Health Technology Assessment



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### **Contents**

Introduction	1
Current involvement of consumers in the Australian HTA process	2
Consultation activities	4
Report Framework	7
What you told us	9
Consumers are informed and engaged	11
Consumers are supported and knowledgeable	13
Consumers are included in HTA processes and methods	15
Consumers are actively participating	17
Consumers are equal partners	19
Additional input from participants	

### Introduction

Every day, millions of Australians use health technologies within the health system. These might be used to screen for, diagnose, treat, cure or prevent illness. The Australian Government wants to ensure that the medicines, medical products and services (health technologies) that really benefit patients are available, accessible and affordable for everyone that needs them.

Health technology assessment (HTA) processes have been established by the Australian Government to enable expert advice to be provided on what might be subsidised by government for public health care. Ensuring HTA processes continue to evolve with medical technology innovations and consumer expectations is fundamental to delivering best practice health care to Australians. The involvement of consumers (patients, their families/carers, consumer organisations) in HTA processes ensures that the advice provided is informed by the needs of the people living with health conditions. This involvement and input bring context to the real benefits of health technologies such as why they might be useful (or not), how they impact everyday life and how they might best be accessed.

In the recent past, there have been several reviews and reforms that are relevant to Australia's health technology assessment, approval and access processes and pathways. These include the Expert Panel Review of Medicines and Medical Devices Regulation (2015)<sup>i</sup>, The House of Representatives Standing Committee on Health, Aged Care and Sport Inquiry into approval processes for new drugs and novel medical technologies in Australia (2021)<sup>ii</sup> and the National Medicines Policy Review (2022)<sup>iii</sup>. These reviews have looked at ways to improve health technology regulatory and subsidisation assessment and access processes to facilitate the delivery of medicines, medical products and services in a timely manner. They have all sought public consultation to inform the findings.

The current Strategic Agreement<sup>iv</sup> between the Commonwealth of Australia and Medicines Australia contains various reform initiatives aimed at gaining earlier access to new medicines. This includes co-designing an Enhanced Consumer Engagement Process.

It is within this setting that the Office of Health Technology Assessment's (Office of HTA) Consumer Evidence and Engagement Unit (CEEU) conducted the *Conversations for Change* consultation.

This report details the consultation activities and 'what you told us' in the consultation responses, presented as key themes, suggestions and considerations.

- i Australian Government Response to the Review of Medicines and Medical Devices Regulation. www.tga.gov.au/news/news/australian-government-response-review-medicines-and-medical-devices-regulation 15 September 2016.
- ii The New Frontier Delivering better health for all Australians. www.aph.gov.au/Parliamentary\_Business/Committees/House/Health\_Aged\_Care\_and\_Sport/Newdrugs/Report November 2021.
- iii National Medicines Policy 2022 (plain language). www.health.gov.au/sites/default/files/2022-12/national\_medicines\_policy\_2022\_-\_plain\_language.pdf.
- iv Strategic Agreement in relation to reimbursement, health technology assessment and other matters (2022-2027). Commonwealth of Australia and Medicines Australia Limited. www.pbs.gov.au/general/medicines-industry-strategic-agreement-files/MA-Strategic-Agreement-Signed.pdf.

# **Current involvement of consumers in the Australian HTA process**



Most consumers and consumer organisations engage with HTA processes out of a desire for earlier, affordable access to a health technology. This includes engaging with the assessment processes for subsidisation of new health technologies on Government programs such as the Pharmaceutical Benefits Scheme (PBS) for medicines and the Medicare Benefits Schedule (MBS) for medical services and technologies.

In recent years the visibility of patient involvement and consumer representation has increased. In 2017, the HTA Consumer Consultative Committee (CCC) was established. This was followed by the formation of the Department of Health and Aged Care's CEEU in 2019.

Both these initiatives have worked to support and improve the ways consumers and patients engage with HTA processes. For the Pharmaceutical Benefits Advisory Committee (PBAC) and Medical Services Advisory Committee (MSAC) processes, consumers and patients currently have opportunities to provide input to these processes either directly or via representation through:

- public consultations on committee agendas,
- hearings about specific medicine submissions,
- expert clinical consultations about specific medicine submissions, and/or
- formal stakeholder meetings on specific health technologies (including post market opportunities).

Much of this involvement is centred at the later stages of the HTA process, after the development and submission of a sponsor application for subsidisation assessment, as highlighted in **Figure 1**.

Therapeutic Goods Phamaceutical Benefits Advisory Committee (PBAC) Administration Medical Services Advisory Commitee (MSAC) (TGA) Recommended items for SUBSIDY - e.g PBS or Committee Research data Assessment for advice Committee on new or medicine or medical Government published. consideration funding of Government vices to be medicine or medicine or medical service sold in Australia medical service advice. Items NOT (22) Consumer PBS: Pharmaceutical Benefits Scheme Consultation

Figure 1: Opportunities for consumer consultation in current HTA processes.

Simplified overview of HTA processes

Recent reviews and reports about Australia's HTA approval and access pathways and processes have provided suggestions on improving consumer and patient engagement. These have included:

- more plain language information on HTA processes and deliberations (for example workshops and webinars on HTA process),
- more support for individuals and organisations to contribute to HTA processes (for example people and information to guide consumers on how best to use their lived experience in HTA),
- more inclusive and active opportunities to participate in HTA processes (for example meetings with consumers and others involved in the process when an application is submitted), and
- more documented evidence of consumer input incorporated into applications (for example all HTA applications to state how patient relevant outcomes have been considered).

The *Conversations for Change* consultation was developed by the CEEU to inform its future work, with the intent of improving its support of consumers and consumer organisations engaging with HTA processes.

The consultation asked participants **what**, **when** and **how** consumer views and experiences can best be provided during HTA processes.

### **Consultation activities**

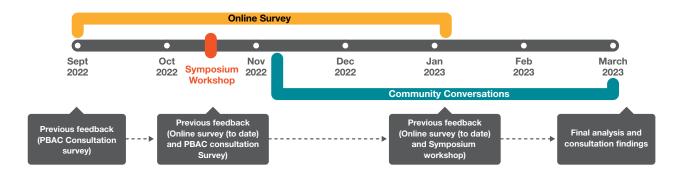
To reach a wide range of consumers, carers, consumer organisations, health professionals and other interested stakeholders, a series of activities were held between September 2022 and March 2023. This included:

- An online survey,
- A workshop at the 2022 HTA Consumer Symposium, and
- Virtual and face-to-to face community conversations.

### Methodology

All consultation activities required qualitative responses from participants. The activities were planned so that responses from prior activities could be analysed and presented in subsequent activities, enabling increasingly deeper considerations of the emerging needs and suggestions (**Figure 2**).

Figure 2: Consultation series methodology – sequential response analysis for each activity.



#### **Online Survey**

The online survey, open to anyone who was interested, was accessible via the Office of HTA Consultation Hub from September 2022 to January 2023. The survey initially asked participants what they liked about the current opportunities for consumer input into the HTA process. Further questions asked where consumer input could be increased in the process, why this would improve the current system and how the consumer voice should be included and supported. The final question asked participants what, in their opinion, was the most important suggestion. There was also opportunity to provide any further comments.

Resources were provided to assist individuals accessing the online survey which included:

- narrated presentations of an introduction to HTA and further information on the Conversations for Change consultation series,
- a simplified diagram highlighting current consumer consultation opportunities in HTA processes (**Figure 1**), and
- past suggestions on improvements to communication and inclusions of consumer views and experiences in HTA processes (**Table 1**).

Table 1: Some past suggestions on improvements to consumer engagement in HTA processes, as provided within the Conversations for Change online survey.

### a) More active participation in process

- Meetings with consumers and others involved in the process when an application is submitted
- Attend and participate in advisory/ decision making committee meetings
- More consumer advisory committees

### b) More documentation on consumer input

- Collect or coordinate the collection of lived experience
- All applications to state how consumers have been involved in the development of the health technology
- Show evidence that patient relevant outcomes have been considered

### c) More information on HTA processes

- Get notified when a health technology is being assessed by a HTA committee
- Workshops and webinars on HTA processes
- Seeing other consumer input received for an application

### d) More support preparing consultation input

- Have easy-to-understand summary versions of the applications
- People and information to guide consumers on how best to use their lived experience in HTA
- Sharing of what input was valuable and suggestions for future input

### **Symposium Workshop**

As part of the 2022 HTA Conversations for Change Consumer Symposium (18 and 19 October), past feedback and survey responses collected to date were presented as part of a consultation workshop. Participants in the Symposium were then invited to use an online poll to rank four areas (as also noted in the online survey; **Table 1**) for further discussions. The two highest ranked areas ('a' and 'd', **Table 1**) were considered separately, and participants provided suggestions and/or comments for improvements.

### **Community Conversations**

Qualitative responses from the Symposium Workshop and survey (to date) were analysed, summarised and presented as key themes for consideration in the community conversations (**Figure 2**). These conversations were held from November 2022 to March 2023. The majority were held as stakeholder group conversations with some additional individual interviews conducted due to participant availability. Conversation participants included consumers, representatives of consumer organisations, members of the HTA CCC, industry representative members of Medicines Australia, health professionals and academics working in the area.

Each conversation had a similar agenda which included an overview presentation of the consultation activities, review of responses to date and key themes, followed by questions for discussion. The consultation questions were tailored to suit participant groups but in general participants were asked the following:

- Are there important areas/issues that are missing?
- Of the feedback, are there any you think may be challenging from a consumer or consumer organisation perspective?
- What do you think we should focus on for consumer input?
- What does 'consumer engagement' mean to you in the HTA context?
- Do you have any suggestions on better support for consumer engagement in HTA?

### **Participants**

Across all the consultation activities, responses were received from 133 participants. **Table 2** details the various stakeholder groups that provided input into the consultation.

Table 2: Consultation activities' schedule, participant types and participant numbers.

Activity	Participant type	Participant number	Dates
Online Survey	Consumers, consumer organisation representatives	39	September 2022 – January 2023
Symposium Workshop	Consumers, consumer organisation representatives, consumer representatives (HTA committees)	34	19 October 2022
Community Conversations	Consumers, consumer organisation representatives, consumer representatives (HTA committees)	30	November - December 2022 February 2023
	Industry representative members	9	November 2022
	Health professionals	12	February 2023
	Academics working in HTA field	9	March 2023
Total:		133	

### **Report Framework**

### **Reviewing the findings**

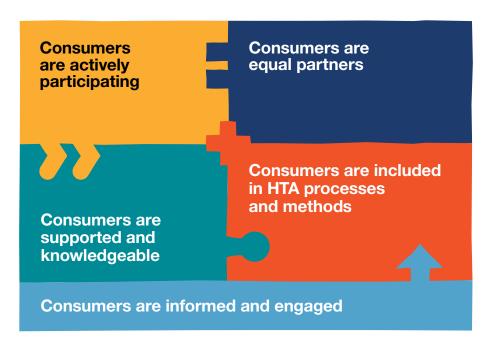
Input was reviewed by the CEEU and an independent consumer facilitator. The independent consumer facilitator was involved in all the consultation activities.

On completion of all community conversations, findings were grouped into themes and the key points and highlighted challenges were summarised. Additional comments provided by participants which fall outside of 'how consumer views and experiences can best be provided during HTA processes' are noted on page 21-22.

### **Consultation findings - themes**

Five themes, focused on outcomes, emerged from the input received. There was some overlap of key points between the themes, which indicates their interdependence. To illustrate the connection between these themes, a conceptual diagram is presented (**Figure 3**).

Figure 3: Conversations for Change findings – key themes illustrate the interdependence of factors which support improved consumer involvement in HTA processes.



Being 'equal partners' with other stakeholders in HTA processes is the main aspirational 'end goal' for consumers. Reaching this goal depends on the support of the four other related outcomes. This is described as follows.

#### Consumers are:



**Informed and engaged:** a baseline awareness of HTA processes, what these are for and a desire to engage with these, achieved through open communication and transparency.



**Supported and knowledgeable:** consumers have a developed understanding of how HTA works and how they can be involved in it, with guidance and support from the CEEU and other stakeholders.



**Included in HTA processes and methods:** consumers' input and participation are acknowledged and embedded into HTA processes i.e. via documentation of what/when/how consumers are included.



**Actively participating:** with the above three elements, consumers are better equipped to actively participate in the processes, being informed and engaged, supported and knowledgeable.



**Equal partners:** over time, the embedding of consumers in HTA processes and their active participation evolves into equal partners with other stakeholders. It is more than consultation or engagement, consumers are as much a part of the process as, for example, industry.

Further consideration of the five themes is presented on pages 11-20.

### What you told us

The survey results indicated that people appreciated the various current opportunities to contribute and noted that peoples' lived experiences were informing decision making in HTA processes.

Many respondents highlighted the positive work and support from the CEEU in improving opportunities and guidance for consumer input. The commitment of HTA committees' Chairs and Deputy Chairs to seek out and allow time for consumer input in meetings was also noted as a positive feature, particularly within the current system around medicine listing.

There was a consistent message that for consumer input to be effective in informing HTA, and enabling faster access, involvement must start at the beginning of the process as part of clinical research and regulatory assessment. This must include engagement between government, sponsors, and consumers to build trust and facilitate transparency. **Figure 4** presents how the elements of the themes identified in the consultation findings may inform and enable consumer input throughout the extended HTA process.

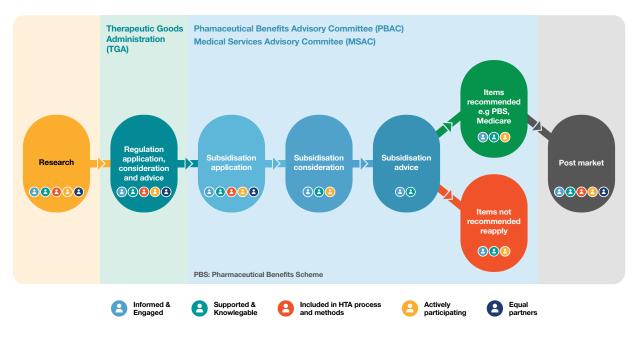


Figure 4: Consumer involvement in HTA processes – suggested future opportunities.

Simplified overview of HTA processes

Further engagement is needed with an emphasis on greater diversity of consumers and the wider community. Increased international collaborations are also needed particularly for conditions with small patient populations.

Participants across all stakeholder groups also spoke of challenges in the current system. This included the challenges in changing established processes to ensure that participation and partnerships between consumers, consumer organisations and other stakeholders achieve HTA processes that are truly co-designed, and implementable. The compliance framework for industry and how to address potential conflicts of interest in building stronger, earlier partnership with consumer organisations was also noted.

When considering such changes, caution is needed to ensure these do not overburden consumers and consumer organisations, require unattainable additional resources, or extend the time to access new health technologies. Processes to increase consumer participation will need to be implemented with outcome measures that are important to consumers. Therefore, consumers must be involved in the design of outcome measures and evaluation process.

# Consumers are informed and engaged



Communication is highlighted in this theme, with consumers and consumer organisations needing more openness and transparency from other stakeholders. This applies from early in the process (prior to submission) to post-committee meetings (feedback loop) as well as once a technology has been implemented.

Raising awareness of the HTA process is needed across diverse patient populations and the broader community. Plain language resources will provide more accessible information for consumer engagement.

It was thought that an optimal outcome for this was that consumers and consumer organisations have access to the same information as all stakeholders and committees.

### **Suggestions**

The following points summarised from responses, provide insight into areas for improving communication.

- Raise and expand awareness of HTA consumer input opportunities; advertise the consultations.
- **Broaden engagement** to facilitate further inclusion of rural and remote consumers, First Nations people, culturally and linguistically diverse (CALD) communities, people with disability, LGBTQI+ community, and the general public.
- **Consultation schedules and templates** for consumer organisations to prepare and inform their networks when a relevant application is submitted and open for consultation.
- **Direct and earlier communication/automatic notification** to consumers/organisations on potential applications and on publication of HTA committee recommendations to allow for more considered input and identification of gaps in evidence from a 'real-world' perspective.
- **Feedback loop:** communication to show how and where consumers have been consulted and HTA committee consideration of this input, to build trust that the consumer 'voice' is heard.
- A plain language summary of the application so consumers can comment before the assessment process.
- **Improved transparency** of HTA processes and how the evidence is considered by committees.
- **Plain language**, consistent terminology, use of infographics/videos when talking about HTA.

"Consumers don't understand the jargon and medical speak".

### **Challenges**

Awareness raising and engaging the wider public, through inclusive plain language information, needs consideration of the diverse needs across population groups and the shared responsibility of government, industry and consumer organisations.

Capturing consumer diversity from clinical trials through to HTA committee and into post market considerations requires commitment and support from all stakeholder groups.

Supporting early communication from industry to consumer organisations on planned applications for HTA will require changing culture and established practices to enable consumers to access and contribute to application development. This may include considerations such as pre-registration restrictions and Medicines Australia Code of Conduct documents.

"Feedback loop so consumers understand the impact their comments may have had."

# Consumers are supported and knowledgeable



This theme highlights the needs and requirements for consumers and consumer organisations to build their confidence and capacity to contribute effectively. Consumer organisations spoke of needing guidance and support to collect consumer data that are 'useful and used' in HTA decision making.

There is also a need to understand that many consumers providing input are unwell or are supporting someone who is unwell. Providing lived experience commentary can add to emotional and physical burden, as can the uncertainty of an outcome.

### **Suggestions**

The following summarised from responses provide insight into areas to improve support and knowledge.

- Education and training on HTA processes: consistent, broad training needs to be widely available to prepare people, and build capacity and confidence to participate in the process.
- **Guidance on preparing relevant input** including lived experience, real world data, quality of life, the value of knowing and patient reported outcomes (PROs).
- **Guidance on developing submissions** for consumers/consumer organisations, outlining the aspects of consumer experience that may add value to assessment processes.
- Resources and funding for consumer organisations to collect or coordinate data on lived experience and PROs, provided with support from other stakeholder groups.
- Broaden capacity to include diversity including rural and remote consumers,
   First Nations people, CALD communities, people with disability, LGBTQI+ community, and the general public.
- **Build resilience** to support consumers sharing their lived experience.
- Online portal as a resource to include support, process navigation, training, resources, templates, videos and case studies, supported by a 'HTA Navigator' role for further guidance and support.

"Consumer engagement is talked about, like co-design, but it's often a tick box".

### **Challenges**

Education and training for consumers, consumer organisations and the broader population will require stakeholders to work collaboratively to develop resources to build capacity and increase inclusivity of diverse population groups.

The implementation of education and training on HTA processes, preparing submissions and raising awareness with the broader population is within the remit of the CEEU.

Agreed processes, and funding will be required to facilitate greater two-way conversations between the CEEU, consumers, consumer organisations and members of the public on a regular basis. These will need to occur at points in the HTA process that will facilitate inclusion and collaboration.

Greater understanding is also needed of broader public health considerations such as how to determine consumer needs within diverse community groups. A strong foundation around communication and information is critical and will require extension of the resources already in place.

"Consumers feel disempowered if in a room where people 'know everything' and (they) 'know nothing' – except the experience of the disease."

### Consumers are included in HTA processes and methods



Various participants recommended improvements that would require changes to existing HTA processes and guidelines to show how consumer input is valued. These suggestions ranged from including the acknowledgement of consumer evidence in HTA guidelines, establishing a dedicated consumer evidence base in the HTA process, to formalising evidence collection to assist with access or post market review.

Other participants imagined an HTA environment where consumers were fully embedded within the process.

### Suggestions

The following points summarise the suggestions for inclusion of consumers and consumer input within HTA processes, including pre-regulatory process.

- **Develop a consumer engagement framework** to show how consumers and consumer input is used across all processes.
- **Demonstration of consumer involvement through documentation** in all HTA submissions (from regulation to implementation, post market and disinvestment).
- **Include methodological guidance** on lived experience, real world evidence, the value of knowing and PROs for applicants.
- Broaden the methodological framework beyond quantitative data to integrate consumer qualitative input into HTA.
- **Dedicated consumer evidence base** to develop specific measurement tools and to collect relevant data.
- Establish disease specific consumer expert/advisory panels, to provide information on the specific needs of the patient populations.
- Condition/disease repositories established for baseline information in multiple submissions and to track changing patient expectations over time as treatment options impact outcomes.
- Further HTA documentation to acknowledge how consumer input has been considered and used in committee deliberations.

"Having the patient voice heard all the way through – what is meaningful and of greatest benefit to them"

### **Challenges**

Process and methodological change were considered essential to strengthen the role of consumers within HTA processes.

Assurance is needed for resources to support changes to process and methods, for example around the development of condition/disease repositories and data collection.

Some suggestions to improve consumer input into HTA processes will require careful consideration of the legislation, particularly within the current system around medicine listing.

Proposed changes to increase opportunities for consumer input will need to be fully explored to ensure there is not a negative impact on 'real time' availability of products. It may also require improved interaction between the Therapeutic Goods Administration (TGA) and other HTA processes for consideration of matters raised, such as data sharing.



# Consumers are actively participating



Participants made positive suggestions to support consumer and consumer organisation participation in HTA processes.

Including consumer 'experts' with lived experience in committee meetings would provide real world context during considerations. Consumer involvement should be a continuous pathway extending from clinical trials to regulatory process, throughout subsidisation considerations and into post-market reviews.

Collaboration with international networks may support evidence provision, particularly for rare diseases.

### Suggestions

A summary of suggestions for improved consumer participation in HTA processes includes the following points.

- Early, active, inclusive participation of consumers with lived experience in the process from pre-TGA application and throughout the HTA process.
- **Pre-submission inclusion** of consumer organisations and clinicians alongside applicants.
- **Extend post-implementation** opportunities for consumers to input into how a health technology is being used in the community (post-market reviews).
- **Consumer experts** with lived experience are empowered to have a 'voice' in the process and observe and/or directly contribute to an item of interest in committee meetings.
- Facilitation of international collaborations to share input for use in multiple submissions.
- **Meaningful, direct engagement** such as meetings with consumers/stakeholders when an application is being developed for a submission.
- Expand consumer input options beyond an online survey.
- **Increase diversity** by expanding opportunities for input from hard-to-reach groups and the general public.

"Consumers feel their input is undervalued. If committees truly understood that, then maybe together we can find a better way to 'engage.'"

### **Challenges:**

Responses called for early, active and inclusive participation in the HTA process. This would require greater transparency around information, and for consumers and consumer organisations to be supported and knowledgeable in HTA processes.

It was also noted that greater participation could present challenges for a process operating within firm timeframes and further consideration would need to be given as to when and how early engagement could occur.

The suggestion of having consumer experts or a consumer hearing during committee meetings to discuss specific items in 'real time' would require changes to the current processes. It will require allocation of funded resources to support and enable more active participation and collaboration.



### **Consumers are equal partners**



Responses included words such as 'respect', 'trust', 'genuine' and 'equitable' within suggestions of **what**, **when** and **how** consumer views and experiences can best be provided. In this theme, there is a desire for involvement beyond engagement. Consumers want an equal partnership with other stakeholders in the HTA process and to work closely with industry and clinicians in contributing towards evidence and applications that may lead to better health outcomes.

An optimal outcome was that consumer organisations have the same opportunities to identify health technologies for consideration within HTA process, to ensure affordable access.

### **Suggestions**

The following points highlight key suggestions within this theme.

- Equitable processes that share the power.
- Authentic dialogue rather than a 'tick box'.
- Clarity on how different stakeholders could be seen to work together.
- Consumers to have the same opportunities as industry in the HTA process, such as at meetings, access to data, to put forward applications.
- Consumers/organisations directly involved in decision making and governance of HTA processes.
- **Respect and trust** of the healthcare system and that consumer input is valued and considered, and this is reflected in documentation.
- Consumers are seen as partners in the design and collection of evidence for applications.
- **Early involvement** with consumers by Government and industry when a health technology is first developed.

"Share the power in the room... so there is equity in the room"

### **Challenges:**

All stakeholder groups aspired to cultivate stronger partnerships. Several barriers to achieving equal partnership were identified, including the need for clarity on compliance frameworks concerning industry and consumers/consumer organisations.

Guidance would be needed on how partnerships could operate, for example who has responsibility for the application or data ownership for evidence generation.

It was noted that effective partnerships would require greater transparency of information and data between stakeholders as well as substantial guidance to support these activities. It would also require greater acknowledgement and inclusion of consumers within HTA methods.



### Additional input from participants

Conversations for Change consultations were held with consumers, consumer organisation representatives, health professionals, academics (health economists and researchers), pharmaceutical industry representatives and consumer representative members in HTA committees (Table 2, page 6).

As previously mentioned, the focus of *Conversations for Change* was on **what**, **when** and **how** consumer views and experiences can best be provided during HTA processes.

All participants were supportive of increased opportunities for consumers to be involved; "as clinicians we can be a voice for consumers, but not their voice". There was also a strong sentiment for consumer evidence to be formally acknowledged in HTA guidelines as an additional form of evidence.

Some participant groups provided additional comments that spoke more broadly about current barriers in the HTA processes and suggestions for improvement. These are included below.

"We need a healthcare-driven HTA pathway".

#### Clinicians/Health Professionals

- Additional avenues/support are needed to facilitate clinician-led submissions for clinical need such as dose changes, combination therapies (particularly oncology), re-submissions (if sponsor not pursuing) and extending indications in off-label usage.
- Greater transparency and understanding is needed around equitable access considerations
  for specific patient groups, such as paediatric (where indication is for ≥ 18 years of age), rare
  diseases, rural/remote communities.
- Open calls for clinical experts to be directly involved in HTA committee meetings for highly specialised HTA items and major submissions, to provide deep knowledge of clinical perspectives and advise on delivery pathways for specialised therapies and devices, to facilitate equitable access.
- Expanded managed access programs for novel therapies and/or small patient populations to facilitate treatment access whilst continuing to build evidence.

"Tinkering round the edges of HTA will not produce the results we need".

#### **Academics**

- More clinical trials to be co-designed to generate evidence for HTA processes. This would require capacity building with researchers to understand the type of evidence needed to inform HTA processes.
- Public education on the wider perspective of population health, on which HTA is based, is needed to provide individuals with context when preparing consumer and other input for HTA considerations.

"There are 2 rationales (for consumer engagement):

- 1) substantive engagement will improve committee deliberations, and
- 2) democratic give people a say. Both these aims need to be met".



The Office of Health Technology Assessment's Consumer Evidence and Engagement Unit sincerely thanks all participants in this consultation.

We hope the report respectfully reflects the responses from the many people who participated in the *Conversations for Change* activities.

