Co-design of an Enhanced Consumer Engagement Process for health technology assessment

Asthma Australia Survey Response, April 2024

ABOUT ASTHMA AUSTRALIA

Asthma is a respiratory condition that affects 2.8 million Australians, with children being the most impacted. Asthma is responsible for at least one Australian death every day, making it a serious health concern. More than 30,000 people are hospitalised each year due to asthma, yet at least 80% of these hospitalisations are considered potentially avoidable.

Despite the prevalence of asthma, it is often misunderstood, causing fear and anxiety for those living with the condition. Asthma Australia has been the leading charity for people with asthma and their communities for over 60 years.

The challenges of climate change, unhealthy air, and health inequity make it more important than ever for people with asthma to have a voice. We search for new and progressive approaches to challenge the status quo. Our work is grounded in evidence and centred on the experiences of people affected by asthma. We believe by listening to those living with asthma, designing solutions with them, and influencing change, people with asthma can live freely, unrestricted by their asthma.

OUR ONLINE SURVEY RESPONSE

This is Asthma Australia's response to the online survey of the consultation on 'Co-design of an Enhanced Consumer Engagement Process for health technology assessment'. We have not included survey questions 1-9 below as they were questions relating to demographics and survey consent.

We have responded to survey sections and questions that are relevant to consumers and the work we undertake on their behalf. The consultation document can be found here.

Q10. The consultation document proposes 'System-wide' recommendations that intend to embed consumer evidence and experience across the end-to-end health technology pathway as a whole. See Section 1 (table 1) for an overview of 'system-wide' recommendations or refer to Section 2 for a more detailed description.

We are interested in the System-wide recommendations that are most important to you.

To respond, please rank the recommendations listed below in order of importance.

1. Plain language communications
2. Single digital consumer portal
3. Consumer identification and development
4. Consumer-informed horizon scanning
5. Centralised and expanded consumer support
6. Stakeholder resources and training
7. Facilitated collaboration with industry
8. Consumer engagement framework

Q11. Thinking now about your top three 'System-wide' recommendations, what difference do you think they will make for enhancing consumer engagement in health technology assessments?

Please describe your response below.

A key outcome of an enhanced consumer engagement process for health technology assessment (HTA) should be that **it enables all consumers with an interest in HTA to engage with it**. We consider plain language communications to be central to this end. Currently, HTA communications available to the general public are not consumer-friendly and use technical and inaccessible language, which may confuse and exclude consumers. Plain language communications, if tailored to the needs of a range of consumer population groups, should help the general public to understand HTA information and processes and help consumers feel welcome and influential in HTA processes. For the same reasons, we value the Co-design Working Group's (CWG) recommendation of the development of a single digital consumer portal, which could help consumers navigate the system and find the resources and information they require.

We also note TGA and PBAC applications are not made available to the general public ahead of HTA meetings. While Public Summary Documents are released after HTA committees make decisions, the lack of publicly available information limits the ability of consumers to provide input to inform decisions. We strongly support the proposal described in Figure 2 to provide plain language summaries of TGA and PBAC applications before TGA and PBAC assessment processes, to ensure consumers are appropriately informed and can provide meaningful input.

Finally, we chose consumer identification and development as a priority as it has the potential to optimise the contribution of consumers and their representatives and ensure that their lived experienced and knowledge is appropriately valued and utilised in HTA processes in a timely manner. Consumers and consumer organisations, such as Asthma Australia, can provide insight and value in every HTA process, including the adaptation and dissemination of information in language and formats that are appropriate to a range of consumers with whom they work.

Q12. The consultation document proposes recommendations described as 'Pre-HTA enhancements', 'HTA Process Enhancements', and 'Post HTA Enhancements'. See Section 1 (table 1) for an overview of these recommendations or refer to Section 2 for a more detailed description.

We are interested in which of these recommendations are most important to you.

To respond, please rank the recommendations listed below in order of importance.

1. Consumer-initiated submissions to PBAC
2. Consumer evidence in Australian clinical research
3. Consumer evidence in TGA applications
4. Consumer evidence in PBAC submissions
5. Consumer notifications about TGA applications
6. Consumer pathway to post-market reviews
7. Consumer input feedback loop
8. Consumer input on implementation considerations following PBAC recommendations
9. Consumer notifications about PBAC submissions
10. Pre-listing status reports
11. Criteria for consumer hearings and stakeholder meetings

Q13. Thinking now about your ranking for the top three recommendations above, what difference do you think they will make for enhancing consumer engagement in health technology assessments?

Please describe your response below.

We identified consumer-initiated submissions to PBAC as the highest priority as, currently, there is no opportunity for consumers to propose the inclusion of a product to the PBS. This leaves the entire responsibility and cost to the sponsor of the product. Taking into account the cost of preparing the submission, the cost-benefit of a PBAC application may not be favorable and the sponsor may decide not to pursue PBS listing. This may be the case for medicines that are expected to be used in a very small population, leaving considerable cost to consumers. It is imperative that consumers be given a voice to designate medicines that may be highly beneficial to their health yet are not a business priority for their sponsor. Similarly, consumers should be given the opportunity to initiate post-market reviews.

We identified consumer evidence as high priorities as embedding consumer engagement into clinical research design/delivery and TGA submissions/applications ensures that consumer needs, experiences and population outcomes are integral to new discoveries and HTA processes. While Randomised Clinical Trials provide the highest level of evidence, they often include restrictive population criteria and may have poor generalisability in the community. Consumer evidence may

help better assess effectiveness, improvements in quality of life, risks and safety in real-world settings. Consumer evidence should provide the basis for key HTA decisions.

We strongly support the other CWG recommendations. Each of them would play an important role in ensuring that consumers are included and can provide input at every step of the HTA so that decisions better reflect their concerns, needs and experiences.

Consumer notifications and criteria for consumer hearings and stakeholder meetings are important elements of a reformed system but we have ranked them towards the end as we perceive them to be normal administrative activities required to effectively implement other suggested reforms.

Q14. How can we improve any of the proposed recommendations?

Please describe your response below.

Further consideration about how HTA consumer engagement processes can support the development, listing and subsidisation of paediatric medicines is needed. Among all medicines available for children with asthma in similar economies around the world, comparably few are registered for use in Australia, and around 7% of applications to the PBAC for PBS subsidy are for new paediatric indications.[1] It may not be cost-effective for sponsors of some medicines to generate the evidence and prepare submissions to the TGA and PBAC for the paediatric population, which can lead to limited access to medicines despite a high therapeutic need. Indeed, children with asthma in Australia bear a disproportionate burden from this disease and the relative availability of effective treatments should reflect this fact. This has been a long-standing issue, which restricts both the access children have to medicines as well as their choice in using alternative medicines that may be more appropriate to their condition or personal circumstance (e.g. cost/side effects). For example, for children under 6 years old with asthma, there is only one asthma preventer inhaler available in Australia.[2] The lack of medicines for children may also lead to off-label prescribing. For these reasons, we would like to understand whether the CWG has considered how its recommendations would address the availability of paediatric medicines in Australia and would welcome further information to this end.

1. https://onlinelibrary.wiley.com/doi/10.1111/jpc.12629
2. National Asthma Council Australia 2022. Australian Asthma Handbook, Version 2.2. Melbourne: National Asthma Council Australia. Available online: https://www.asthmahandbook.org.au/

Q15. Are there any recommendations that you think we should add?

If so, please describe your proposed recommendation and its purpose.

We welcome the recommendations giving consumers an opportunity to provide input into the assessment of an application for TGA approval, including the publication of a plain language summary of the TGA application before its assessment and potential participation to TGA stakeholder hearings. We would also welcome the opportunity to provide written comments, mirroring the process for PBAC submissions. Consumers may have additional perspectives that may not be fully represented in TGA applications even when consumer evidence is included as part of clinical trial designs.

In addition, we note that the timeframe between the release of a PBAC meeting agenda and the closing date to provide comments is short and inappropriate for consumers to review the information available and submit comments. We therefore recommend extending the timeframe between notifications of TGA or PBAC submissions, and closing date for submitting comments. This would remove a significant barrier in providing input into HTA processes.

Q16. Are there any recommendations that you do not support or require further explanation?

Please describe your response below.

N/A

Q17. The consultation document describes implementation considerations for the proposed recommendations. See Section 1 (table 2) for an overview of these considerations or refer to Section 2 for a more detailed description.

We are interested in the implementation considerations that are most important to you.

To respond, please rank the implementation considerations listed below in order of importance.

1. Invest in systemic change
2. Commit to timely consumer-focused reform
3. Strengthen the use of consumer evidence and experience
4. Address health equity and access needs
5. Leverage existing and emerging strengths for consumer engagement
6. Facilitate beneficial communication between the medicines industry and consumers
7. Partnership work for positive flow-on-effects

Q18. Please describe why you selected your #1 most important implementation consideration.

As with the other ranking questions, it is difficult to rank the options provided as they each would add value to the implementation process of the proposed recommendations and assist HTA accommodate the objectives of the National Medicines Policy in terms of accessibility and equity. We have highlighted the need to appropriately invest in systemic change as a top priority as without appropriate funding, the ambitions of CWG recommendations for consumer engagement cannot be fully realised. As the consultation document outlines, there is a need for investment to support consumers and consumer groups to participate in HTA processes, as well as First Nations communities and diverse population groups. We also would support the legislation of a consumer voice to ensure consumer evidence and experience is embedded into the HTA system.

In addition, it is important that such reforms build on the momentum of the current HTA Review and be implemented in a timely manner to ensure the progress made to date is not lost by governments' changing priorities in the future. Finally, we have ranked strengthening consumer evidence and experience as a high priority as too much weight is currently placed on clinical trials that are often not representative of real-word evidence. Consumer evidence needs to be given a stronger role in HTA.

Q19 Are there any implementation considerations that you would like to change or add?

Please describe your response below.

N/A.

Q20. Do you have any further comments you would like to make about the consultation document?

Asthma Australia welcomes the recommendations that CWG has outlined in the consultation document. Some of the questions in this survey have asked us to rank options that are co-dependent or that we value similarly, and hence, we would like to make it clear that we support the appropriate funding, development and implementation of all the recommendations presented. The appropriate focus on, and value and influence of, consumers in HTA processes would be met if the suggested reforms are effectively implemented. Such reforms are likely to significantly elevate HTA outcomes in terms of accessibility and equity by ensuring that consumers can play a central part in processes that support decision-making.