



Health Technology Assessment Policy and Methods Review – Consultation 2

Asthma Australia Submission, February 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 submission to the online survey of Consultation 2. We have responded to the sections and questions, corresponding to the [Consultation 2 Options Paper](#), that are relevant to consumers and the work we undertake on their behalf.

1. TRANSPARENCY, COMMUNICATION, AND STAKEHOLDER INVOLVEMENT IN HTA

1.1. Transparency and communication of HTA pathways, processes and decisions

Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don’t know

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

Asthma Australia raised the issues identified in this section in our submission to Consultation 1 and we welcome the options to address them. Communication and consultation with consumers and their representatives is currently inadequate, inappropriate and inconsistently applied across different HTA processes. Further, the language used in HTA communication and consultation is inaccessible for many consumers, the website is difficult to navigate and information on the workings of the regulatory system as a whole is lacking or difficult to access.

Providing plain language summaries of sponsor submissions, HTA committee decisions and work and HTA processes, and plans to improve the website, including through adding a visual dashboard on submissions, would help to address these issues. We have responded that the proposed options would ‘mostly address’ these issues for the following reasons:

- The **health literacy of consumer populations varies widely** and information will need to be tailored to make it as accessible and informative as possible to enable engagement into HTA processes. This can be challenging and may require **several different versions of the same information**. To this end, consumer organisations, such as Asthma Australia, can help to adapt and disseminate information to a range of consumers as they have access to consumer groups with whom they can work to develop suitable information as well as



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knowledge of their needs. Asthma Australia would welcome being involved in this work particularly given people with asthma have been found to be the population group with the lowest health literacy and find it hardest to engage with healthcare.¹

- The **website needs wholesale redesign** to make them consumer friendly.
- These options will require **adequate resourcing** to be effective.
- As noted in the Options Paper, the accessibility of the information depends to some extent on the complexity of the system, which has been addressed in other options for reform.

1. <https://www.swinburne.edu.au/news/2019/05/its-tough-to-have-lung-disease--new-australian-data-shows/>

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Publish plain language summaries**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Plain language summaries would assist consumers and all stakeholders with an interest in HTA in accessing key information about health technologies. This is particularly important for consumers as decisions about them should not be made without them. In addition, providing plain language summaries of decisions affecting consumers may help consumers to understand reasons behind decisions and to see how their needs were considered. This may increase consumer acceptance of these decisions and engagement in their healthcare. All assessment summaries and decision-making communications should **clearly state how consumer needs have been considered**.

For Asthma Australia, plain language summaries would also help to reduce the time involved in the development of submissions **if sponsors are required to publish them at the same time at the same time as they submit their application**. Currently, we do not have access to sponsors' applications. Hence, in order to prepare a submission on a therapy we often have to access documentation hosted on the health technology assessment websites of other countries where the information is available, from the sponsor's Australian website or their website in another country, or we request information from the sponsor. Having access to a summary of the sponsor's application would help us to more quickly and easily understand the expected benefits, safety risks and targeted population of the health technology. Plain language summaries of the application would also be particularly helpful in the absence of key regulatory documents, such as the Consumer Medicine Information



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and the Product Information, when the health technology is being assessed in parallel by the TGA and PBAC and the TGA has yet to complete its assessment.

- **Improvements to the HTA webpage including development of a dashboard**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

A dashboard would help interested consumers and Asthma Australia's staff keep up to date with the progress and developments of relevant health technologies and HTA processes by reducing the need to search for relevant information on the website. Currently, this is a time-consuming and often circular exercise given how the website is structured. The proposed visual and colour-coded approach may be helpful in providing a visual understanding of how HTA works and of where stakeholders can provide their input, which may be of notable help to consumers.

We would strongly welcome **a dashboard that has the capability to alert stakeholders** about HTA processes and timings, and invite their input this way. Such a mechanism would help to ensure that all interested parties could monitor the progress of an assessment and have their say. It could also provide stakeholders with sufficient warning about upcoming consultation opportunities so they can plan ahead and ensure they can engage with the process.

The dashboard could also be a useful method to share HTA the key performance indicators (KPIs) that are to be developed in relation to HTA processes. For example, it could highlight KPIs for processing times for health technologies at differing stages, as well as the reasons for any delay. This would help bring further transparency to the system, and help consumers understand the reasons for any blockages in the system to accessing technologies, whether they be HTA-led or sponsor-led for example.

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

Appropriate resourcing of HTA and consumer groups is essential to ensure that these options are effective as the development of communications tailored to the needs of consumers requires their co-design with consumers. Asthma Australia is well positioned to help to develop resources targeting consumers and to disseminate them.



1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA

Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

N/A

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Develop an engagement framework**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

HTA decisions, processes and outcomes **should prioritise consideration of consumers** and their needs because HTA is a function to facilitate timely, equitable and affordable consumer access to treatment and healthcare. The creation of the Consumer Evidence and Engagement Unit and Consumer Consultation Committee were welcome first steps in acknowledging the importance of consumers in HTA. If implemented effectively, the options presented would more fully embed the needs, input and experiences of consumers in HTA.

Asthma Australia particularly **welcomes the inclusion of consumers earlier and more consistently** throughout the HTA processes. Crucially, we hope that the inclusion of consumers in horizon



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scanning, pipeline analysis, early assessment, Population, Intervention, Comparator, Outcome (PICO) scoping workshops and pre-submission meetings would **help to address notable gaps in health technologies**. For example, we hope that Asthma Australia and consumers would have an opportunity to be systematically involved in these measures so we might continue to raise the issue of the dearth of asthma medicines for children in Australia.

We welcome the addition of consumer participation in HTA committee meetings, which again reflects a recommendation in our first submission. It sends an important message to consumers about their value to HTA processes and may help to further their engagement more broadly. Consumers invited to participate must be drawn from **a wide range of backgrounds and reflect a wide range of health issues**. There must also be ways to represent consumers who cannot attend meetings, such as children.

Asthma Australia welcomes the additional measures to help consumers engage with and better understand HTA processes, such as through providing information, support, education and training to support more meaningful input. This again is an area in which organisations like Asthma Australia could add value in relation to resource development and dissemination.

- **Strengthen consumer evidence**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

The strengthening of consumer evidence, including in relation to additional PBAC guidelines on the use of real world data and evidence (RWD/RWE) and of consumer evidence such as patient reported measures (e.g. patient reported experience measures, PREMs and patient reported outcome measures, PROMs), are important aspects of HTA that are not visible in the current system. We support measures to support their appropriate use and consideration in HTA. The suggested inclusion of consumers in the determination of questions that can be addressed by RWD/RWE and in the codesign of communication materials is not only welcome but **critical to ensuring consumer evidence reflects their concerns, needs and priorities**.

We would like to see more detail on the establishment of the mechanism/methods to collate patient perspectives formally and routinely as we have established consumer engagement approaches within Asthma Australia that may be of use to HTA and this end.



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The feedback loop for consumer inputs to show how and where consumers have been consulted and how HTA committees have considered this input is also very welcome. It will provide much needed transparency and enable organisations like Asthma Australia to hold HTA to account.

Finally, we would strongly advocate that the establishment of a dedicated consumer evidence base and condition/disease repository **includes an asthma repository** to track adverse events, medicine use and outcomes. This would help to identify where in the system consumers and healthcare professionals require more support or education. Significant health gains and savings could be made with such a resource on asthma given it is largely a manageable condition when guidelines are effectively implemented and followed.

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

Asthma Australia is concerned by the approach taken to Consultation 2 as it has not been a consumer or a stakeholder friendly process for the following reasons:

- A key area of the HTA Review’s work and the Options Paper is to improve consumer engagement and make HTA more accessible to consumers, yet:
 - The Options Paper is 174 pages and the survey is 65 pages.
 - The Options Paper, as itself notes, covers highly complex and technical issues and options using complex and technical language.
 - The Online Consultation Forums hosted participants from a range of organisations, which meant discussions did not flow.
 - The Online Consultation Forums were facilitated by facilitators who had no knowledge of the subject area and so were not able to probe participants meaningfully about their responses.
 - The consultation timeframe was only 4 weeks, with no clear reason as to why it was so short. In relation to organisational feedback, the duration of the consultation has not factored in competing staff workload, staff holidays, sickness and review and approval processes.

While we understand that timeframes may be pressing for the Reference Committee, getting the HTA system right requires appropriate time and consultation. To have been most effective, each section of the Options Paper should have been consulted on in a timely manner, to enable all interested parties to process and reflect on the issues and options it covers. **We hope that the approach taken to this consultation will not be mirrored in future** and strongly advise that consumers and their representatives are given sufficient time to consider complex issues with the support of reader friendly resources to ensure their input is meaningful.

Nevertheless, the measures included in these options reflect the long-overlooked importance of consumers to HTA and we therefore strongly welcome their addition. In addition to resourcing, methods used for their development will be critical to their effectiveness, and we recommend that all measures are developed using meaningful co-design approaches with consumers. We look forward to being involved in their development and implementation.



1.3. First Nations people involvement and consideration in HTA

Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account.

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

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

Asthma Australia strongly welcomes a focus on ways to improve HTA processes and outcomes for First Nation peoples, not least as the prevalence of asthma is significantly higher among Aboriginal and Torres Strait Islander people (18%) than other Australians (11%), and asthma mortality rates for Aboriginal and Torres Strait Islander people are 2.5 times higher than for other Australians.¹ Moreover, the wider, ongoing health inequities that exist between First Nations peoples and other Australians and the structural and systemic issues compounding these disparities have again been recently highlighted by the Productivity Commission's first review of the National Agreement on Closing the Gap. HTA has a role to play in helping to address these inequities, particularly in view of the significant disparity in PBS spending for First Nations peoples (\$167 per person) and non-Indigenous people (\$427), noted in the Options Paper.

The suggested measures could be valuable in helping to strengthen the voice, engagement and outcomes of Aboriginal and Torres Strait Islander people in HTA. A First Nations Advisory Committee and a First Nations representative on the PBAC are likely to raise the profile of First Nations' issues but similar policy and governance approaches in relation to Aboriginal and Torres Strait Islander health issues have repeatedly failed to meet their objectives in the past. To this end, the Options Paper does fall short in acknowledging the scale of the issue, which as noted by the Productivity Commission's Closing the Gap Review about governments more broadly, are likely to be compounded by institutional racism and unconscious bias. We selected that the measures are likely to 'address some but not most of the issues' as the HTA Review does not seem to have given sufficient attention or resource to this issue and options.

Key to the development of this area of HTA will be **meaningful co-design with First Nations peoples, groups and their consumer organisations**. The Review should recognise the need for a strengths-based approach to co-design with Aboriginal and Torres Strait Islander groups and ensure they remain critical, ongoing partners throughout the development and implementation of the HTA reform so that the new system appropriately learns from and adapts to their needs, views, knowledge and experiences.

1. AIHW. 2023. Chronic Respiratory Conditions: Asthma. Web article. Available online: <https://www.aihw.gov.au/reports/chronic-respiratory-conditions/asthma-1>



If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **First Nations peoples partnership in decision making**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Asthma Australia would benefit significantly from opportunities to learn from Aboriginal and Torres Strait Islander peoples in the HTA processes. Raising the profile of First Nations peoples in this way would also help us to raise the importance of HTA amongst Asthma Australia's Aboriginal and Torres Strait Islander consumer groups to thereby better identify and feedback issues affecting them in relation to asthma health technologies.

Further, we particularly welcome the requirement that sponsors would have to consider and assess the impact on health outcomes for Aboriginal and Torres Strait Islander peoples as this would be an important first step in the required system-wide transformation of HTA to incorporate and consider First Nations voices, needs and outcomes.

- **Dedicated resource for HTA submissions and education**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Dedicated resources and education to assist organisations representing First Nations peoples' health outcomes in making HTA submissions would be valuable if they are **developed by Aboriginal and Torres Strait Islander peoples**. Such resources are likely to help organisations that represent



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Aboriginal and Torres Strait Islander people more broadly, such as Asthma Australia, to engage with First Nations consumers and to support their engagement and feedback in HTA processes.

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

This area of HTA reform will require appropriate resourcing to be effective, particularly to enable meaningful co-design work with Aboriginal and Torres Strait Islander people, as well as a wholesale review of HTA processes and systems in place currently that may unwittingly reflect or support institutional racism or unconscious bias to thereby result in health inequities.

2. HEALTH TECHNOLOGY FUNDING AND ASSESSMENT PATHWAYS

2.1. Streamlining and aligning HTA pathways and advisory committees

Taking all Options within this section: 2.1. Streamlining and aligning HTA pathways and advisory committees into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

The development of a unified, national HTA pathway for all health technology evaluation is likely to be helpful in providing a single-entry gateway to all stakeholders seeking to engage with HTA. However, care must be taken not to inadvertently recreate the same system at great expense, noting point 2 that the committee structure may need to be augmented over time. Notwithstanding, creating a committee structure that is fit for managing contemporary issues and the reformed HTA system makes sense and, if effectively implemented, will hopefully **help to reduce unnecessary time delays in consumers accessing subsidised health technologies.**

We would recommend that consumers are provided with periodic opportunities to have their say about the development of the single-entry gateway as it develops to ensure it is accessible to those whose needs the system is designed to support.



If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

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

N/A

- **Vaccine pathway**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Expanding role of PBAC**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Unified HTA pathway for all health technologies with Commonwealth funding**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

N/A

2.2. Proportionate appraisal pathways

Taking all Options within this section: 2.2. Proportionate appraisal pathways into account

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

Some of the options presented are very technical and hence we deemed it only possible to suggest that they might 'mostly address the issue/s' given that they seem to be sound options and based on the Review's investigative research over past months.

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Triaging submissions**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

The triaging of submissions in terms of an effective risk management approach and allocation of resourcing could be very positive if triaging decisions were effectively communicated to stakeholders, perhaps using the visual dashboard in some way.



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- **Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Streamlining the pathway to enable generics to come to market earlier would be very positive for people with asthma who, as noted in our first submission to the Review, spend significant proportions of their income on medicines every year to control their asthma (e.g. on preventer and reliever inhalers), as well as to treat other comorbidities.

Further, the development of generics for biologics, which have started to come to market in other countries, is particularly important for people with severe asthma. This is because current eligibility criteria to access biologics under the PBS is restrictive in view of their high cost, meaning many people cannot access them. In addition, eligibility criteria include having to demonstrate substantial use of oral corticosteroids, which have significant, harmful side effects associated with short and long-term use. Hence, much cheaper generics in this area may help pave a way to removing these criteria and increasing access to biologics.

- **Expanding resolution step to all relevant cost effectiveness submissions**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



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- **Development of a disease specific common model (reference case) for disease areas with high active product development**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

The proposal to increase transparency and provide plain language summaries of a sponsor's application is critical if HTA decouples the requirement for TGA Delegates overview to support PBAC advice. This is because the plain language summary of the application will enable consumers and other stakeholders to provide comments on the submission, without which there would be little to comment on (as is sometimes the case with the parallel process currently). In addition, this option may speed up the assessment process in cases where the TGA is very slow, and we welcome timely access to medicines as long as the safety and risk evaluation is still thorough.

- **Case manager**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



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

This could be a positive step for consumers and their representatives also if the role of the case manager had scope to liaise with consumers about the application as well (e.g. so that consumers could contact the case manager when they are struggling to access information about the application).

3. METHODS FOR HTA FOR AUSTRALIAN GOVERNMENT SUBSIDY (TECHNICAL METHODS)

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

Taking all Options within this section: 3.1. Determination of the Population, Intervention, Comparator, Outcome into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

Asthma Australia welcomes the option of increased early input on the PICO from consumer and clinical communities to ensure that all relevant patient populations who could potentially benefit from the new therapy are considered in the HTA. The plain language summaries of the PICO would bring a particularly welcome element of transparency to the process and would be a valuable resource that Asthma Australia would use in the consideration and development of submissions to PBAC.

Finally, we welcome the new and explicit requirement to consider equity and priority populations for new technologies but would like more detail about how this would influence decision-making on a health technology in practice. We would also like to understand **if this measure would directly help to address the longstanding issue relating to the lack of paediatric medicines in Australia.**



If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Increased early stakeholder input**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Increased transparency for stakeholders**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Updated guidance**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

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 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 this reason, we would like to understand whether the options discussed in this section are intended to 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. Australian Burden of Disease Study 2015: Interactive data on disease burden. Cat. no. BOD 24. Canberra: AIHW.

4. HEALTH TECHNOLOGY FUNDING AND PURCHASING APPROACHES AND MANAGING UNCERTAINTY

4.3. Understanding the performance of health technologies in practice

Taking all Options within this section: 4.3. Understanding the performance of health technologies in practice into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

We support the suggested options to enhancing the use of RWD in HTA, particularly the establishment of a multi-stakeholder advisory group to co-design and oversee the development and implementation of guidelines, enabling systems, research and evaluation to optimise access and use of RWD in HTA. It will be important that this advisory group has consumer representation who have **a range of backgrounds and health issues**, and who represent groups who cannot represent themselves (e.g. children). We also welcome the placing of consumer and community engagement and co-design at the centre of a strategic approach designed to improve the use and confidence in cross-jurisdictional and cross-sectoral RWD access and use in HTA. This appropriately reflects the importance of consumer input into HTA and takes seriously the need for RWD to reflect their priorities, experiences and concerns.



If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Oversight – reforms to optimise access to and use of RWD in HTA**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Develop a strategic approach to increase confidence, awareness, and acceptance of cross jurisdictional and cross-sectoral RWD access and use in HTA**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Data infrastructure**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



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- **Methods development**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Develop Guidance framework**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Collection of utilisation and outcome data for provisionally listed health technologies**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



5. FUTUREPROOFING AUSTRALIA’S SYSTEMS AND PROCESSES

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

Taking all Options within this section: 5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

N/A

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Development of a priority list**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



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- **Identifying therapies to meet priority list (horizon scanning)**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Early assessment and prioritisation of potentially promising therapies**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Proactive submission invitation and incentivisation**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Early PICO scoping**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



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

We would like to see children be listed as a priority group. There are a lack of medicines for children in Australia, including asthma medicines, when compared with countries with similar economies. Children with asthma have the highest burden of the disease, with asthma being the leading condition contributing to total burden of disease in children aged 5-14 years old in Australia, yet this age group have limited access to treatment options.¹ Significant steps must be taken to address this inequity. Adding children to the priority list would help if the subsequent options were followed so that suitable medicines could be found through horizon-scanning and sponsors were then invited or incentivised to make a listing application.

1. Australian Institute of Health and Welfare. Australian Burden of Disease Study 2023. Canberra: AIHW, 2023 [cited 2024 Jan. 5]. Available from: <https://www.aihw.gov.au/reports/burden-of-disease/australian-burden-of-disease-study-2023>

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

N/A

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

Taking all Options within this section: 5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

The options presented are very technical and hence we deemed it only possible to suggest that they might 'mostly address the issue/s' given that they seem to be sound options and based on the Review's investigative research over past months.



If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

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

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Horizon Scanning to help operational and capacity planning for HTA and health systems**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

We support the establishment of horizon scanning programs to ensure Australia's HTA system is aware of and responsive to emerging technologies or patterns of use.



Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

In the horizon scanning process, we would advocate that HTA considers the use of patents by companies in relation to inhaler devices and similar technologies. The patents that sponsors have on inhaler devices raises the costs of critical medicines (e.g. preventer and combination inhalers) that consumers often have to use on a daily basis. We would welcome further discussion on this issue.

5.3. Consideration of environmental impacts in the HTA

Taking all Options within this section: 5.3. Consideration of environmental impacts in the HTA into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

Asthma is heavily influenced by environmental conditions and many of the repercussions of climate change can cause or exacerbate asthma symptoms, such as increased pollen, extreme weather events and the effects that extreme weather events have on housing (e.g. mould, damp and poor air quality). In addition, there is a feedback loop as health technologies designed to treat asthma (and other conditions) contribute to emissions driving climate change through their manufacture, distribution and use. We would therefore welcome the development of environmental impact reporting as part of HTA and its use in the assessment of cost-effectiveness by Australian HTA bodies and approval and reimbursement decisions as part of a drive to reduce healthcare emissions.

To support this measure, more guidance for healthcare professionals is needed to ensure that they can appropriately utilise environmental impact reporting to inform their clinical decision-making and their approach to discussions with consumers about their medicine options. It is important, for example, that consumers are not made to feel pressured to change from a pressurised metered dose inhaler with a high carbon footprint that can be controlling their asthma well or guilty for deciding not to change their inhaler. The health of consumers must come first and clear guidance on how to have appropriate conversations with consumers is critical to support this change. **Asthma Australia is currently leading national work on asthma inhalers and carbon emissions** and would welcome discussions with the Reference Committee about this work.

In addition, ensuring that medicines are appropriately used (with asthma, for example, this includes correct inhaler device technique, use of preventer inhaler as guided by a healthcare professional and appropriate use of oral corticosteroids) and not wasted is an important aspect of the work of HTA



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and of reducing the impact of health technologies on the environment. To this end, we would support the development of QUM guidance on optimising the appropriate use of medicines and minimising medicine waste with an environmental perspective.

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Environmental impact reporting**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

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

Given the particularly harmful impact that the effects of climate change have on the health of people with asthma and the significant contribution of health technologies to climate change, appropriately resourced, planned and co-designed environmental impact reporting could be very positive on consumers and Asthma Australia.

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable

Climate change mitigation is an advocacy priority of Asthma Australia and measures that reduce Australia's emissions are urgently needed. However, the holistic needs of consumers who access health technologies is paramount and hence they must be an integral part of the development and use of environmental impact reporting. Appropriate resources must be developed to support their needs throughout the process, including their engagement with healthcare professionals about possible changes to their treatment.

With these caveats, we strongly support the Reference Committee's suggestion that Australia be a leader in the development of the international regulatory environment in this area, that HTA require manufacturers to measure and report emissions on products and that this information informs HTA decision-making with the aim of reducing the carbon emissions of health technologies.



5.4. Mechanisms for continuous review and improvement

Taking all Options within this section: 5.4. Mechanisms for continuous review and improvement into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

As noted in the Options Paper, the Australian Government has committed to working with Medicines Australia to develop and make publicly available a range of KPIs on the time it takes for new medicines to be listed on the PBS. These indicators will include measures controlled by the medicines industry (e.g. the time involved in applications in Australia and in other countries) and measures controlled by the Australian Government (e.g. the time taken to assess applications/resubmission churn). They should also include sponsor-led delays such as decisions not to list medicines that have been approved to be listed under the PBS.

KPIs would help to track progress in improving HTA processes in terms of streamlining and reducing timeframes, assist future reviews in identifying areas for improvement and would help consumers and all stakeholders understand the blockages in delays to listing. As noted previously, these KPIs could be shared on the, or using a, visual dashboard on the website. We would like to have more information about the development of these KPIs, including whether consumers will be involved and timeframes.

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **A program of continuous review and improvement for current HTA policies and methods**

Very negative

Negative

Neutral

Positive

Very positive

Don't know



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

We support measures to ensure that the HTA is continuously improving and responsive to the needs of consumers and emerging system-wide developments and issues.

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

Appropriate resourcing and consultation with consumers in the development and implementation of continuous improvement measures will be required to ensure their effectiveness.

5.5. Capacity and capability of the HTA system

Taking all Options within this section: 5.5. Capacity and capability of the HTA system into account

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

The scale of the capacity and capability issues outlined by the Options Paper do not seem to have been adequately addressed by the options presented.

While we support the measure, the development of a sponsored internship program should not be seen as a cheap way to resource the HTA and interns should be appropriately compensated for their work.

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- Improve HTA capacity and workforce in Australia

Very positive



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

An HTA that has optimal capacity and workforce will be of benefit to consumers by helping to ensure that they have access to health technologies in the shortest timeframe possible, and by helping to ensure that risk, safety, equity and other values such as the environment have all been appropriately considered and accommodated in this process. However, this will require appropriate resourcing.

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

Further consideration of options to improve this area is required, including how to increase HTA financial resources.

5.6. Strengthen international partnerships and work-sharing

Taking all Options within this section: 5.6. Strengthen international partnerships and work-sharing into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Completely address the issue(s)

Mostly address the issue(s)

Address some but not most of the issue(s)

Address little or none of the issue(s)

Don't know

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

Some of the options presented are very technical and hence we deemed it only possible to suggest that they might 'mostly address the issue/s' given that they seem to be sound options and based on the Review's investigative research over past months.



If implemented, overall would these Options have a positive or negative impact on you (/your organisation)?

- **Harmonisation of HTA evaluations**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Work sharing for individual submissions**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

- **Collaboration with international jurisdictions to deliver sustainable access to health technologies**

Very negative

Negative

Neutral

Positive

Very positive

Don't know

Do you have further comments or concerns to add specific to this topic that should be considered? For example, here you can detail any unintended consequences or overlooked considerations if applicable.

Asthma Australia supports efforts for HTA to collaborate internationally and the options suggested could be valuable ways to optimise the use of limited resources and increase Australia's market power.



SUMMARY: ALL OPTIONS OVERALL

In summary, considering all the draft reform options together:

How confident are you that the reform options (if implemented) will make health technology assessments better overall?

Very confident

Somewhat confident

Not very confident

Not at all confident

Don't know

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

The Options Paper presents a range of well-considered options for HTA reform that could provide significant improvement to the existing system if they are appropriately resourced, co-designed with consumers and delivered as a whole.

While disappointed by the consultation approach for the Options Paper, which seemed counter to its ambition of improving HTA accessibility for consumers, the options that are intended to improve consumer engagement, system transparency and the speed at which health technologies are listed under the PBS, among others, are welcome.

We note the absence of specific pathways or approaches to improve accessibility and availability of paediatric medicines in Australia. There are aspects of the reform that could incorporate this oversight in the system and we ask that the Reference Committee clarify whether these reforms are intended to do so.

Consumer organisations, such as Asthma Australia, have significant value to offer HTA in the development and implementation of these reforms and we look forward to working with HTA representatives and wider stakeholders to this end.

