

Response

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3

What is your name?

[REDACTED]

7

Please select the type of individual(s) or organization(s) you represent. Please select all that apply. - Selected Choice

[REDACTED]

8.1

What is the name of your organisation? - My organisation is called: - Text

[REDACTED]

9

Are you making feedback on behalf of your organisation?

[REDACTED]

13

Please select which chapter/s you would like to provide feedback on. You may provide feedback on as many or few chapters as you wish.

1. Transparency, communication, and stakeholder involvement in HTA, 5. Futureproofing Australia's systems and processes

14

Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA

1.1. Transparency and communication of HTA pathways, processes and decisions, 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA, 1.4. State and territory government collaboration in HTA

18

Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes

5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS, 5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system, 5.6. Strengthen international partnerships and work-sharing

21

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?

Mostly address the issue(s)

22

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

The consumer voice must be informed by the consumer experience. It is clear that enhanced consumer engagement will lead to better clinical outcomes. There need to be clear timelines outlining the processes and ensure there is transparency and accountability throughout. This must include KPIs that mandate consumer involvement.

There is merit to the options proposed. The public summary documents must be relevant to the stakeholders and made available in plain language. Further, the HTA website is not user friendly.

23.1

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

Very positive

23.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard

Very positive

25

If you would like to expand on your answer above you can do so below -Publish plain language summaries

This is a great suggestion which we endorse.

26

If you would like to expand on your answer above you can do so below -Improvements to the HTA webpage including development of a dashboard

This would make the navigation much more user friendly and increase engagement.

27

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?

Mostly address the issue(s)

28

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

The development of the engagement framework we endorse. However, it must have consumer input mandated as a KPI. There would be significant benefits to this suggestion and support improved outcomes. This is especially important in the rare diseases space where there are smaller population groups. Their input is as important as the larger groups. More detail is required on these suggestions and how they would work but conceptually this is helpful progress.

29.1

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

Very positive

29.2

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

Very positive

31

If you would like to expand on your answer above you can do so below -Develop an engagement framework

More details is required and KPIs are necessary to measure the impact.

32

If you would like to expand on your answer above you can do so below -Strengthen consumer evidence

More details is required and KPIs are necessary to measure the impact.

39

Taking all Options within this section: 1.4. State and territory government collaboration in HTA into account.

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

Address some but not most of the issue(s)

40

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

It would be very helpful to have jointly funded health technologies by the Commonwealth and state and territory governments, especially for HSTs. This would enable cohesion in the implementation and equitable access to all consumers. However, more detail is required to outline how this model will be effective.

41.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of central standardised data sharing system for utilisation and outcome data

Positive

41.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increase opportunities for consultation and work sharing

Positive

41.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Health technologies that are jointly funded by the Commonwealth and state and territory governments (such as high cost, Highly Specialised Therapies (HSTs) delivered to public hospital inpatients)

Very positive

43

If you would like to expand on your answer above you can do so below -Development of central standardised data sharing system for utilisation and outcome data

More detail is required.

44

If you would like to expand on your answer above you can do so below -Increase opportunities for consultation and work sharing

More detail is required here.

45

If you would like to expand on your answer above you can do so below -Health technologies that are jointly funded by the Commonwealth and state and territory governments (such as high cost, Highly Specialised Therapies (HSTs) delivered to public hospital inpatients)

This is a critical piece of work to ensure that consumers health is not disadvantaged due to geography. It is unclear how this solution will be administered with equity but the concept we are supportive of. How will this be mandated at a local level? What are the key performance measures in place to ensure adherence? How will this be resourced?

131

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?

Address some but not most of the issue(s)

132

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

It is critical to prioritize the future of healthcare. In many areas, Australia lags behind other first-world nations. However, the reliance on a sponsor is too heavy. There is significant clinical research taking place independently which could lead to better health outcomes for Australians. A cross section of data must be considered and not simply be sponsor led/dependent. Further, international collaboration should be considered to further these objectives.

133.1

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

Very positive

133.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Identifying therapies to meet priority list (horizon scanning)

Very positive

133.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early assessment and prioritisation of potentially promising therapies

Very positive

133.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Proactive submission invitation and incentivisation

Very positive

133.5

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

Very positive

135

If you would like to expand on your answer above you can do so below -Development of a priority list

More detail is required here.

136

If you would like to expand on your answer above you can do so below -Identifying therapies to meet priority list (horizon scanning)

More detail is required here and international collaboration is essential.

140

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?

Address some but not most of the issue(s)

142.1

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 positive

142.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Horizon Scanning to meet priority areas (including addressing equity and HUCN)

Very positive

142.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Horizon Scanning to help operational and capacity planning for HTA and health systems

Very positive

162

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?

Address some but not most of the issue(s)

164.1

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

Very positive

164.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Work sharing for individual submissions

Very positive



[Redacted]
[Redacted]
[Redacted]
[Redacted]

23rd February 2024

To whom it may concern,

[Redacted]

While there is a high level of merit in many of the proposed options, they are currently difficult to assess because significantly more detail is required regarding how they will be implemented, resourced, and managed. Also, the measurement of these options is lacking the necessary key performance indicators to adequately assess their impact.

Below are specific comments relating to the options in the options paper.

1.1 Transparency, communication, and stakeholder engagement in HTA

This is a high priority and could be implemented quickly with relative ease. However, there must be resource allocation and details regarding how consumers will be consulted. Indeed, consumers need to be part of the HTA process from commencement. Adopting the use of plain language and public summary documents will aid a more transparent process with greater engagement. The engagement of consumers needs to be regulated to ensure compliance.

1.2 Consumer / Clinician/ Stakeholder Involvement in HTA

There needs to be clarity on the weighting given to consumer evidence and transparency of how it is taken into consideration. More detail is required to assess the appropriate options but there is merit in each and they should be prioritized as part of this review, especially given the timeframes required for implementation. Consumers must be involved in all areas of the HTA processes, and the resourcing must be provided to ensure this is effective. This will help support better decision-making and ultimately, better outcomes.

1.3 First Nations Involvement in HTA

This option is critically important, however, there must be clarity on how this will be actioned to ensure it is effective for our First Nations communities.

It is promising that points 1.1-1.3 have recognised the importance of the consumer voice in the HTA review. These options should be progressed.

1.4 State and Territory Collaborations in HTA

This option must immediately include consumers, clinicians, and patient organisations to address the inequitable funding and access barriers that are in place. There is a disjoint among health care in the states and territories across Australia. These options are a helpful step in overcoming this issue, but more work is required to focus on the patients and their outcomes and not simply the budgetary impact. However, there needs to be appropriate regulation to ensure that this takes place. Clarity is required on how joint Federal and State/Territory funding of HSTs will impact the overall local health system budgets and anticipated patient outcomes. The consumer perspective must be incorporated, with data to better understand the different state and territory responses if they provide a specific therapy based on budgets. This is particularly an issue around genetic therapies. How will emerging

technologies be funded? How will inequities in state and territory budgets ensure equitable health care for all citizens? It appears that this option, currently, could maintain the current lack of access as certain barriers will remain in place. Indeed, higher-cost therapies will continue to present challenges in this area and not comply with the National Medicines Policy. How will this be addressed? The increased visibility of PBAC decision-making and the local impact is mandatory and greater cohesion with federate and local budgets is required.

A centralized data-sharing system is theoretically favourable, but the ownership and access of the data need to be outlined. Further, the increasing data security threats need to be effectively addressed. Also, there needs to be clarity on how consumers provide input. Data sharing needs to be greater than HTA, especially in light of the increasing adoption of new health technologies so governments must unite to be most effective. This will have an immense impact on the lives of all Australians.

Overall, Section 1 could have a high impact on improving transparency, communication, and stakeholder engagement in HTA.

2. Health technology funding and assessment pathways

The options presented must move away from being submission-driven by sponsors, as is currently the case. There remain critical gaps that must be addressed including the necessary data and evaluation required for implementation of new pathways for drugs, especially for people with rare [REDACTED] [REDACTED] and the Life-Saving Drugs Program. There needs to be wider consideration for evaluation including eligibility, and value for money and the decision should not be dependent solely on the PBAC. Indeed, the option to expand the role of the PBAC is an area where more information is needed but could assist in the holistic review of appropriate decision-making. There are patient groups that are under-represented populations [REDACTED] that can easily get overlooked, especially those with rare gene mutations that require pathways to access. Further, this must be equitable and not dependent on a sponsor.

Section 2 requires more details on how these solutions will be administered and how the consumer voice will inform HTA.

Further matters to note include the vital nature of horizon-scanning and international collaboration to ensure Australia is at the forefront of optimum healthcare. This must be a formal, ongoing process with stakeholder engagement. This is vital for those with rare genetic diseases because for some people there are no therapies currently available here. Sadly, some Australians are not receiving treatments that are available in other jurisdictions.

A review of the TGA process is recommended and the timelines of TGA and PBAC should be revised and mandated to expedite access to new therapies. Further, there needs to be transparency in how products are registered, and the process needs to include more stakeholders including consumers.

Details are required on paediatric access to medicines. This is an area that is critical for the health care of future generations yet there is insufficient data in the options on how this will be addressed, especially given the challenges in securing the appropriate data.

The HTA has significant gaps in relation to rare diseases, [REDACTED]. This means that there are groups of stakeholders either not represented, or underrepresented in this process, deeming it ineffective. HTA needs to be equitable across the whole of the healthcare system. Given the nature of rare diseases, there are small patient populations and limited clinical trial data which makes it challenging to capture the full spectrum of the disease burden in HTA evaluations. Further, there is limited consideration for the unique ethical, social, and economic aspects of rare diseases in HTA

decision-making. This presents an opportunity for improvement as part of this review.

HTA must implement practices that consider the needs of underserved populations throughout all of the proposed options. Indeed, HTA processes need to be enhanced to better accommodate the needs of individuals with rare diseases [REDACTED]. This should include utilising innovative study designs, such as adaptive trials and real-world evidence, to generate high-quality data on rare diseases. Patient-centered outcomes and preferences must be incorporated into HTA assessments to effectively capture the full impact of treatments on people living with [REDACTED] [REDACTED] rare and genetic conditions. Also, HTA needs to commit to evidence-based medicine and transparent decision-making for health technologies for rare diseases. This could be aided by increased collaboration with HTA agencies, patient groups and industry stakeholders to ensure quality data, research, and other evidence is incorporated. There must be ongoing collaboration and innovation in HTA to support the health and well-being of people with rare diseases, [REDACTED] and their families.

All Australians should have fair and equitable access to the therapies they require. Standardisation is critical, coupled with increased understanding and transparency of the pathways so that everyone can have equitable access for their needs. The priorities must be around the implementation of these recommendations and sufficient details and accountability measures, to ensure their success.

I hope that by identifying these gaps, exploring the suggested opportunities for improvement, and leveraging existing strengths within the Australian HTA framework, we can work towards ensuring equitable access to effective treatments and improving outcomes for all individuals, especially those currently under-represented in the existing processes.

[REDACTED]

[REDACTED]