

Response
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The Department may, at its discretion, publish part or all of the information provided in your submission on the Department's website or in related documents. If information from your submission is published, the Department may identify you and/or your organisation as the author of the submission. All personal contact details will be removed prior to publishing.
Yes, I consent to my identified submission being published
3
What is your name?
Deidre Mackechnie
7
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice
Patient or consumer (or representative organisation)
8.1
What is the name of your organisation? - My organisation is called: - Text
Australian Patient Advocacy Alliance
9
Are you making feedback on behalf of your organisation?
Your organisation
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,2. Health technology funding and assessment pathways,3. Methods for HTA for Australian government subsidy (technical methods),4. Health technology funding and purchasing approaches and managing uncertainty
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
15
Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways
2.1. Streamlining and aligning HTA pathways and advisory committees,2.2. Proportionate appraisal pathways
16
Please select the topics within the chapter(s) you would like to provide feedback on. 3. Methods for HTA for Australian government subsidy (technical methods)
3.1. Determination of the Population, Intervention, Comparator, Outcome,3.2. Clinical Evaluation Methods,3.3. Economic evaluation
17
Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions
4.1. Approaches to funding or purchasing new health technologies
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:
It is the view of our members that transparency, communication and stakeholder engagement are not end goals but are enablers that, if effectively implemented, will support the achievement of many other elements
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
Publishing plain language summaries enables transparency and equity of consumer access in the context of diversity in health literacy. Current PBAC Agenda listings do not provide sufficient information for consumers.
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
Improvements to the HTA website are crucial to this outcome as this is the fundamental communication mechanism around HTA processes and decisions. It is imperative that there is consumer input to the design of the website to increase usability and effective knowledge translation.
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:
APAA support the involvement of consumers, clinicians and other relevant stakeholders in the development of an engagement framework. Whilst we recognise the diversity of stakeholders relevant to the HTA process, the consumer must have true equity as a key stakeholder.
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
46
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?
Mostly address the issue(s)
47
If you would like to expand on your answer above you can do so below:

48.1

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))
Very positive

48.2

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

48.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding role of PBAC
Very positive

48.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Unified HTA pathway for all health technologies with Commonwealth funding
Very positive

61

If you would like to expand on your answer above you can do so below -Expanding role of PBAC

APAA supports expanding the role of PBAC across a broader range of health technologies including co-dependent health technologies. This streamlined approach will be critical for genomics and cell-based therapies. Currently these emerging therapies are not included and have no clear funding pathway.

62

If you would like to expand on your answer above you can do so below -Unified HTA pathway for all health technologies with Commonwealth funding

The APAA members are supportive of a unified, national, HTA pathway for all health technology evaluation. This will enable the process to draw on appropriate specialists for all advanced therapies and technologies seeking public funding and to recommend the appropriate funding pathway.

63

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?

Mostly address the issue(s)

65.1

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

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

65.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)

Very positive

65.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Alternative option 1: Introducing an optional resolution step before HTA committee consideration

Don't know

65.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution

Don't know

65.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Alternative option 3: Early Price negotiation

Don't know

65.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised

Don't know

65.7

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding resolution step to all relevant cost effectiveness submissions
Very positive

68

If you would like to expand on your answer above you can do so below -Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)

APAA support streamlining a pathway for cost-minimisation submissions to avoid delay in gaining access.

77

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?

Address some but not most of the issue(s)

79.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased early stakeholder input
Very positive

79.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased transparency for stakeholders
Very positive

79.3

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

83

If you would like to expand on your answer above you can do so below -Updated guidance

APAA support updated guidance to require the explicit consideration of health equity and priority populations for new treatments. These populations should specifically include patient populations that can no longer benefit from the comparator classes of drugs due to either contraindications or prior loss of response.

84

Taking all Options within this section: 3.2. Clinical Evaluation Methods into account.

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

Mostly address the issue(s)

86.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Overarching principles for adopting methods in Australian HTA

Very positive

86.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of nonrandomised and observational evidence

Very positive

86.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of surrogate endpoints

Don't know

86.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors.

Very positive

86.5

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

Very positive

86.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)

Very positive

86.7

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

Very positive

90

If you would like to expand on your answer above you can do so below -Methods for the assessment of nonrandomised and observational evidence

Taking a more holistic assessment of the impacts of medicines to inform its cost effectiveness, rather than just baseline clinical outcomes based on the lowest common denominator is positive. Real-World Evidence as well as consumer experience and outcome measures as well as disease-related experience, including post market evidence, must be considered in decision-making processes.

96

Taking all Options within this section: 3.3. Economic evaluation into account.

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

Mostly address the issue(s)

98.1

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

Very positive

98.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Valuing of long-term benefits

Very positive

98.3

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

Very positive

100

If you would like to expand on your answer above you can do so below -Selection of the comparator

The current lowest price comparator model and subsequent price reductions is resulting in newer therapies, that may be first in class, not being brought to Australia, even when given a positive recommendation by the PBAC.

103

Taking all Options within this section: 4.1. Approaches to funding or purchasing new health technologies into account.

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

Mostly address the issue(s)

105.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Don't know

105.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit

Don't know

105.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Investigate further options to address budget impact implications of high-cost/high impact health technologies

Very positive

105.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pricing offer (PO) and negotiation guidance framework

Very positive

105.5

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Post-listing re-assessment of health technologies

Don't know

105.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN

Very positive

105.7

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Approaches for managing uncertainty - revised guidance on the uses of different managed entry tools

Very positive

112

If you would like to expand on your answer above you can do so below -Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN
APAA support bridging funding coverage for earlier access to specific therapies such as those that seek to address High Unmet Clinical Need, in particular for paediatric access to medicines.

167

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?

Somewhat confident

170

Finally, do you have any further comments about the draft Options Paper or consultation you would like to make before submitting your feedback?

The outcome we seek from this review is a structured way forward to achieve optimal, faster HTA processes consistent with the National Medicines Policy, the consumer consultation and co-design projects and the goals of the HTA review.

212

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.

Sustainable and systemic support to establish and embed consumer input is essential. The burden should not be on consumer groups to engage in the process, they should be supported to do so. Consideration of the inclusion of an advocacy body or advocacy representative on the PBAC in addition to a consumer would be of benefit as it is often difficult for a single consumer or two to represent all consumers. Advocacy bodies have a broader understanding of the consumer experience and can add value to the experience.

236

Which of the proposed reform options do you think offers greatest scope to improve the HTA assessment process?

Alternative option 3: Early Price negotiation

237

Why did you select that response above?

We support price negotiation earlier in the process. The current situation where a positive PBAC recommendation does not result in access due to high, non-sustainable cost is disheartening for patients and clinicians and a huge waste of resources.

238.1

Under the subject 'Recognising competition between new health technologies that deliver similar outcomes', there are two options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Don't know

238.2

Under the subject 'Recognising competition between new health technologies that deliver similar outcomes', there are two options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit.

Don't know