Response
2
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?
Dominic Tilden
7
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice
Consulting
8.1
What is the name of your organisation? - My organisation is called: - Text
THEMA Consulting
9
Are you making feedback on behalf or your organisation?
Yourself
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,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
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,4.3. Understanding the performance of health technologies in practice
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,5.3. Consideration of environmental impacts in the HTA,5.4. Mechanisms for continuous review and improvement,5.5. Capacity and capability of the HTA system
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?**
Address some but not most of the issue(s)
22
If you would like to expand on your answer above you can do so below:
Without an understanding of what the "plain language summaries" would look like and how they are written I am not sure we can say they will address the issue of patients lack of access to the HTA system. A few paragraphs in a public summary document won't do, but there probably is a way of writing these summaries in a way which can build up transparency and accountability in sponsors, evaluators and decision makers alike.
23.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries
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
Negative
25
If you would like to expand on your answer above you can do so below -Publish plain language summaries
I would welcome plain language summaries in order to make our entire process (from sponsors to evaluators to decision makers) more accountable. I would like these plain language summaries to follow a set structure (obviously in consultation with the relevant stakeholders) so that the plain language is useful, repeatable and reliable. That is, I wouldn't want it to be a summary of the HTA process with the jargon taken out. Rather, themes such as "What was claimed", "What was proven", "What was valued" are consistent across most of our submissions and can be answered with relatively plain speaking without the need to describe the heterogeneity in some obscure indirect treatment comparison. I wouldn't want the plain language summaries to in any way substitute for the technical information that is often important for understanding PBAC decision making when preparing submissions. Also, a common theme which will come through a lot of my responses will be, that this is an additional layer of work that needs to be added to the process and completed by someone and will need resources committed to it. I dont think a few paragraphs in each public summary document will be sufficient. The summaries of the PBAC submissions for publication with the agenda is also a layer of work that will require resources. Will the sponsor be able to provide input/feedback on what is being published before it is published?
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
To be honest, and this is probably a bit idealistic, but I think I would prefer a HTA process that was simple enough to not require the development of a dashboard. Maybe the dashboard could come after some of the proposed refinements to the process are implemented for example. Otherwise, are we at risk of having the HTA process determined by the IT department? (Sorry!)
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?**
Address some but not most of the issue(s)
29.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework
Neutral
29.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence
Neutral
31
If you would like to expand on your answer above you can do so below -Develop an engagement framework
I have answered neutral to this because I think I like the idea in principle. But I do baulk at things like frameworks/structures/processes that need to be followed because they add in a level of rigidity that has the potential to be counter-productive. I would prefer an engagement philosophy. And by this, I think I mean build requirements in to the system where sponsors, evaluators and decision makers are forced to engage with patients. EG: the PBAC guidelines could specifically ask sponsors to include information collected from patient groups. How they choose to engage with patients is not subject to some framework, but becomes an expectation.
32
If you would like to expand on your answer above you can do so below -Strengthen consumer evidence
I don't particularly like the idea of a curated list of methodologies. Methodologies can and should evolve over time. In fact, I think some of the methodologies we tend to use in PBAC submissions are because that is what we have always done instead of that is the best way of answering the question the PBAC want answered with the data available (eg: Bucher indirect comparisons have become a default curated methodology!). Rather, we could have a curated list of principles and philosophies with regards to what each section of the HTA submission is intended to achieve. Then, submisisons can be judged on how well a given methodology used in the submission meets these expectations/principles/philosophies. This would be better future proofed also. In a similar vein, I don't think we necessarily need more technical guidance on the use of RWD and RWE in to the guidelines. Rather, we need guidance on how it translates to the lived experience of being a patient. I acknowledge my preference for "principles/philosophies" as opposed to specific methodologies may decrease the reproducibility/reliability of the process. However, I think other options proposed (and which I will comment on later) can help use these principles/philosohies in an objective and reproducible manner. (e.g. Development of an explicit qualitative value framework in Section 3).
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
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?**
Address some but not most of the issue(s)
47
If you would like to expand on your answer above you can do so below:
Sorry, I think I am going to end up using this answer to most issues/options.
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))
Neutral
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
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
50
Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))

I answered neutral because I wonder if there could be an option to make the LSDP redundant. If the expanded PBAC has the flexiblity to provide value judgments on what is and isn't cost-effective, then rather than, "PBAC advises the Minister on key requirements to enable listing on the LSDP based on a comparative assessment of effectiveness and cost" (which is a form of cost effectiveness analysis by another name) could the PBAC just advise that listing on the PBS is sufficiently cost-effective in the circumstances. Thus making the LSDP funding mechanism redundant over time?

The statement of rationale referred to in the options paper could apply to these specific type of PBS listings.

60

If you would like to expand on your answer above you can do so below -Vaccine pathway

I really like this idea of having ATAGI advise ESC directly. I have found that writing the pre-ATAGI advice documents have been some of the most difficult documents to write in my line of work. Mainly because we are effectively writing a submission - but not properly.

61

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

I think this goes with the unified HTA pathway described below. I dont think you can have a unified HTA pathway without all roads leading to the same decision making body.

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

I feel positive about this because, associated with but not only due to, the emergence of hybrid technologies (THEMA) have worked on projects in the last few years where it feels like we spend more time thinking about which committee we should submit to than we do on the HTA assessment itself. And/or we get bounced around across and between the various secretariats.

An efficient one stop shop would take the guesswork out - for all parties involved.

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?

Address some but not most of the issue(s)

64

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

As I answered last time (sorry!). Addresses some issues, not all, adds in others.

65.1

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

Neutral

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

Neutral

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)

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

Positive

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

Positive

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

Positive

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

Positive

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

Positive

65.8

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of a disease specific common model (reference case) for disease areas with high active product development

Negative

65.9