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?
Michele Robbins
7
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice
Pharmaceutical / Medical technology company
8.1
What is the name of your organisation? - My organisation is called: - Text
Antengene (AUS) Pty Ltd
9
Are you making feedback on behalf or 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,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
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
5.3. Consideration of environmental impacts in the HTA,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?**
Address little or none of the issue(s)
22
If you would like to expand on your answer above you can do so below:
One of the biggest issues is that the pharmaceutical industry needs to be more integrated into the HTA pathway(s), process and decisions, particularly upfront in the process, which could facilitate faster access for patients. This seems to be missing from this section. What we need is a process where, yes, we want to have clearer and more transparent description(s) of the committee deliberations, including clear reasoning for recommendations/decisions made, however we want a system that allows for collaboration and discussion from industry, stakeholders and the PBAC committee in reaching these conclusions as well. Transparency is also required during the submission and not just the outcome. There is still the essential continuing need for sponsor company confidential information redacted in the PSDs and plain language summaries as this is not essential for transparency purposes, rather the decision itself, how it was made and how did stakeholders contribute is more pertinent. Knowing the content of the plain language summaries would be helpful in order to make an informed decision about their usefulness.
23.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries
Neutral
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
Neutral
25
If you would like to expand on your answer above you can do so below -Publish plain language summaries
Publish plain language summaries are very worthwhile and have been successfully implemented in other markets around the world. There does need to be a consistent template applied by all sponsors that remains accessible for consumers/stakeholders and is relevant and short in page numbers. Knowing the content of the plain language summaries would be helpful in order to make an informed decision about their usefulness. Confidential company information should not be included.
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
A visual dashboard is useful as it helps to measure outcomes, achieving KPIs and impact of the process timeline, however we are still very unclear about the timelines of each decision point. The industry wants access to medicines within 60 days of TGA registration - this overarching goal needs to be agreed to first and of which timelines can be established. If we don't have clear KPIs we cannot measure, and if we cannot measure, we cannot adjust to improve efficiencies or outcomes. This also helps with achieving transparency.
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 little or none of the issue(s)
28
If you would like to expand on your answer above you can do so below:
Under 1.2, point 1 - Development of an engagement framework, it mentions the inclusion of consumers, clinicians and other relevant stakeholders. What is does not mention is industry as a key stakeholder. In order to effectively engage in horizon scanning, pipeline analysis etc, industry is a critical partner in the development of the medicine, clinical trials, patient outcomes and patient populations, industry needs to be able to contribute and collaborate in this process. Under 1.2, point 2 - consumer input into trials. The industry as a whole wants consumer input into their clinical trials protocol development, including patient reported outcomes and quality of life measures, and we are all working towards this. We must be mindful that many company sponsor registrational trials are established under FDA and/or EMA guidance, and whilst Australia can certainly provide their input and perspectives about what should be included in the protocol, it may not always be accepted. We need to have this as an ambitious vision; however we cannot mandate requirements around this. Section 1.2, point 3 - A dedicated consumer evidence base - this is a great ambition; however, it is not clear on what data will be collected, how it will be used for decision-making and at what time point. We fully support stakeholder engagement (from consumers, patients and clinicians), it is still unclear how this input will be used and also in what capacity for decision making.
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
Section 1.2, point 2 - Engagement with all stakeholders. Industry needs to be one of the key stakeholders of any co-designed new process so it would be good to ensure that this is mentioned explicitly.
32
If you would like to expand on your answer above you can do so below -Strengthen consumer evidence
As above
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:
Section 1.4 - Deveopment of central standardised data sharing. In principle this is very welcomed to have a centralised database to facilitate sharing and standardised data collection. Some concerns are still evident, how would this be facilitated, how long would it take to implement, how would the data be used in decision making and what weighting in decision making would it be? Another concern is determining what variables are being collected and is this proactive or retrospective. Proactive data collection may in fact delay access to medicines even longer and retrospective review of outcomes - does this mean all drugs listed would be subject to a review and in that context what does that actually mean? Also we need the ability to change variables over time in order to continue to be fit for purpose.
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)
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 little or none of the issue(s)
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

Don't know

48.3

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

Negative

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

Negative

50

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

The LSDP is a tool for faster access for patients. Appreciate the PBAC become the sole HTA committee to make the advisement, however what is missing is the timelines of when those decisions will be made. The recommendation is positive if it reduces time to access for patients, but only if that is achieved which is not clear.

61

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

Expanding the role of PBAC to be a 'single point of entry' could mean slower access to medicines/therapeutics are achieved. If subsequent funding decisions are not all made through the PBS, with more committees involved, it is certainly a risk to delay recommendations and approvals. This will only slow down access for patients. Therefore clear timelines and KPIs need to be developed and all stakeholders need to be able to access (transparency).

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

Point 1 - Drawing on appropriate specialists as needed. It will be imperative to have specialist input including clinical trial investigators, disease specialists as well as both regional/rural and metro perspectives. They need to be specific to the therapy being reviewed i.e. if the medicine being evaluated is for haematology, then a haematologist who specialises in that area is required, not an oncologist. Although equally knowledgeable and experts in their own right, specialists need to be specific and relevant to the area. This also is relevant to our consumer and patient organisations as well.

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 little or none of the issue(s)

65.1

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

Positive

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)

Neutral

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

Neutral

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

Neutral

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

Neutral

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

Negative

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

Negative

65.8