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?
greg cook
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
bms australia
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,1.3. First Nations people involvement 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,4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR),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,5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system,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,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)
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
Positive
25
If you would like to expand on your answer above you can do so below -Publish plain language summaries
BMSA supports the implementation of plain language summaries for PBAC submissions. BMSA participated in the Summary of Information pilot and actively supports efforts to ensure patient organisations, and in turn patients, have information that facilitates their ability to provide input into HTA decision making and further, to support robust decision making. BMSA believes that criteria are needed to define which submissions are appropriate and would benefit from formal summaries and does not advoate that all submissions require a summary. In order for summaries and discourse with patient organisations at the time of PBAC submissions to be possible, BMSA encourages the Committee to have regard for the current legislative barriers including the direct to consumer guidance. Greater clarity around what is promotional or the legislative change required to facilitate early consumer engagement is critical. Plain language summaries of decisions would be welcomed by BMSA and other stakeholders and this has been relfected in our consultation with patient organisations and described in the following reports prepared by Biointelect: 'cBroadening the Evidence 'cBringing Patient Centricity to Life System Reform
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)
29.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework
Positive
29.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence
Positive
31
If you would like to expand on your answer above you can do so below -Develop an engagement framework
BMSA supports the development of an engagement framework that faciltates earlier and consistent engagement of consumers and clinicians throughout HTA processes. Again, BMSA encourages the Committee to consider any changes or updates to legislation that allow for greater discourse between industry and consumers earlier in HTA processes. BMSA supports the option for comparator and outcome (PICO) workshops to ensure that correct key indicators that reflect the Australian context are being considered. We note that legislation requiring the choice of comparator would need to be amended. With regards to items that are being removed from the PBS, we support a transparent, robust approach that ensures Australian patients are not adversely affected and are provided with as much information to prepare for any changes as possible.
32
If you would like to expand on your answer above you can do so below -Strengthen consumer evidence
BMSA supports the option to strengthen consumer evidence and the development of curated lists/tools that provide guidance on how to best collect data from patients and the community. BMSA supports the generation of data that aids robust PBAC decision making that priortises patient needs, values and preferences.
33
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?
Mostly address the issue(s)
34
If you would like to expand on your answer above you can do so below:
BMSA supports all closing the gap initiatives and recognises the tremendous issues facing Indigenous Australians' healthcare. BMSA would encourage the Committee to consider criteria for sponsor submissions requiring considerations and assessment of impact for First Nations people. Noting however, the ability to impact clinical trial protocols is limited for local affiliates of multi-national companies, and as such, applicable data may be limited.
35.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making
Positive
35.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education
Positive
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:
BMSA supports in principle the options presented to address issues relating to the HTA assessment and provision of highly specialised therapies (HSTs) that may be jointly funded by the commonwealth and the states and territories. We encourage all jurisdictions to complete the work identified in Schedule C of the Addendum to National Health Reform Agreement 2020-25 to implement 'œa financing system that is proactive, value-based and focused on individual and community needs' as soon as practicable. This should support a framework for the appropriate funding of HSTs and clarify the costs for all parties. A full, transparent and agreed understanding of the costs for jurisdictions will reduce delays in access by patients to HSTs. BMSA recognises the important role horizon scanning can play in helping jurisdictions prepare for the introduction of innovative medicines, particularly from a budget perspective. We support the options proposed in this section and in 5.2 of the options paper. Any new national approach to the assessment and funding of innovative medicines must maintain equity of access for patients. In particular, the options relating to consultation, data and work sharing must not delay unreasonably patient access to treatment.
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 some but not most 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))

Positive

48.2

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

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

Positive

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:

BMSA acknowledges the proposed options for '˜early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', however wishes to note that:
'cthese options look to formalize processes that currently occur , and as such, will not deliver significant improvement in the time to PBS listing for the ~<5% of submissions classified as delivering therapeutic advances in areas of HUCN, and
'cthe potential to expand the resolution step to all cost-effectiveness submissions (~65% of PBAC submissions) is only hinted at in the longer term '“ i.e. '˜after piloting with therapies in HATV in areas of HUCN the early resolution step could be expanded to other relevant cost-effectiveness submissions'.

65.1

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

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)

Negative

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

Neutral

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

Neutral

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

Neutral