

Response
<p>2</p> <p>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.</p> <p>Yes, I consent to my identified submission being published</p>
<p>3</p> <p>What is your name?</p> <p>Sam Mills</p>
<p>7</p> <p>Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice</p> <p>Patient or consumer (or representative organisation)</p>
<p>8.1</p> <p>What is the name of your organisation? - My organisation is called: - Text</p> <p>Breast Cancer Network Australia</p>
<p>9</p> <p>Are you making feedback on behalf of your organisation?</p> <p>Your organisation</p>
<p>13</p> <p>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.</p> <p>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),5. Futureproofing Australia's systems and processes</p>
<p>14</p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA</p> <p>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</p>
<p>15</p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways</p> <p>2.1. Streamlining and aligning HTA pathways and advisory committees,2.2. Proportionate appraisal pathways</p>
<p>16</p> <p>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)</p> <p>3.2. Clinical Evaluation Methods</p>
<p>18</p> <p>Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes</p> <p>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</p>
<p>21</p> <p>Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Mostly address the issue(s)</p>
<p>23.1</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries</p> <p>Very positive</p>
<p>23.2</p> <p>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</p> <p>Very positive</p>
<p>25</p> <p>If you would like to expand on your answer above you can do so below -Publish plain language summaries</p> <p>BCNA would welcome changes to how HTA processes and outcomes are communicated to improve accessibility and enhance the ways in which a diverse range of consumers can input into HTA and be informed.</p>
<p>26</p> <p>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</p> <p>BCNA would welcome improvements to how information is provided about complex HTA processes. Development of a dashboard would likely enhance the ability of smaller and less resourced patient groups to easily access information and input into HTA processes.</p>
<p>27</p> <p>Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Mostly address the issue(s)</p>
<p>29.1</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework</p> <p>Very positive</p>
<p>29.2</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence</p> <p>Very positive</p>
<p>31</p> <p>If you would like to expand on your answer above you can do so below -Develop an engagement framework</p> <p>Stakeholder engagement and evidence is currently undertaken in an ad hoc approach with consumers having no clarity in relation to how their input is being weighted or considered. A comprehensive framework detailing how consumer input can and should be gathered, and importantly how the feedback loop is closed, would go a significant way to address this issue.</p>
<p>32</p> <p>If you would like to expand on your answer above you can do so below -Strengthen consumer evidence</p> <p>BCNA is encouraged to see approaches in the Options Paper that seek to diversify the types of evidence valued by the HTA to consider and make decisions. BCNA supports the use of Real-World Data (RWD) (including patient-reported outcomes (PROMS)) where traditional data, such as that gathered through Randomized Control Trials (RCT), may not be relevant or sufficiently available such as for rare diseases or medicine repurposing where there is little or no commercial incentive to run RCTs.</p>
<p>33</p> <p>Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account.</p> <p>Overall, to what extent could the options (if implemented) address the issues that relate to them?</p> <p>Address some but not most of the issue(s)</p>
<p>35.1</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making</p> <p>Very positive</p>
<p>35.2</p> <p>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education</p> <p>Very positive</p>

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If you would like to expand on your answer above you can do so below -First Nations peoples partnership in decision making

BCNA fully supports greater participation of First Nations peoples in HTA decision making. We would like to see further details regarding implementation, including how partners with community controlled health organisations, could be leveraged to reach this goal.

38

If you would like to expand on your answer above you can do so below -Dedicated resource for HTA submissions and education

As above, BCNA would like to see community controlled health organisations engaged in the implementation stage of this recommendation.

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?

Mostly address the issue(s)

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

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

Very 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)

Neutral

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

BCNA full supports this recommendation and is acutely aware of specific data sharing issues in cancer control. We would want to see these recommendations work in awareness of and collaboration with other work in this area such as the development of cancer data frameworks as part of the Australian Cancer Plan, and work being undertaken by the Australian Digital Health Agency to full leverage all opportunities to increase data sharing. Most importantly, BCNA asserts that health data in Australia must be framed as an asset to be used as opposed to a risk to be managed.

44

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

BCNA full supports this recommendation.

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)

BCNA supports this recommendation in principle but would want to ensure that further disparities between states and territories are not created through partnerships only with specific jurisdictions and the Commonwealth.

We also note that many disparities exist within states/territories and between public and private health systems. Disparities in access between public and private appears to be excluded from any recommendations in the Options Paper. It is particularly important that treatments and tests subsidized through HTA processes are available on an equitable basis to all Australians according to their need and capacity to benefit, and not determined by where the patient lives or by which sector (public or private) they access for their healthcare.

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))

Don't know

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

Don't know

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

Neutral

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

BCNA supports this recommendation in principle, however has concerns about whether a unified HTA assessment pathway would ensure the correct expertise are applied to the diverse and varying range of health technologies. We are particularly interested in how codependent health technologies might be assessed by a unified HTA pathway (e.g. a new oncology drug with an associated genomic test). Where traditionally these two health technologies may be assessed separately yet co-dependently by the PBAC and the MSAC, a unified pathway might see these assessed together for their joint therapeutic value, hopefully resulting in faster access for consumers.

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

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)

Don't know

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

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

Positive

65.9

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Decouple the requirement for the TGA Delegate's overview to support PBAC advice

Don't know

67

If you would like to expand on your answer above you can do so below -Triaging submissions

BCNA supports the extensive reimagining of HTA processes contained in the Options Paper, particularly the proposed new step of 'triaging' that would see new applications appropriately risk-assessed with streamlined and expedited pathways for medicines that are low-risk and target diseases with HUCN. In oncology, this could include drugs to treat triple-negative breast cancer, metastatic breast cancer, and new and emerging breast cancer subtypes such as HER2-low. The Options Paper does not put forth a framework with which to determine HUCN need and low risk. Developing this further could strengthen the recommendations and ensure there are no perverse consequences (e.g. some medicines being considered faster than others despite the same level of need). One criterion that BCNA would support being included in a risk and HUCN framework is whether the drug or treatment is currently subsidized on the PBS for a different indication (e.g. pembrolizumab).

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

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.

Don't know

86.5

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

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)

Positive

86.7

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

Don't know

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

BCNA particularly supports the options presented to allow fast-tracked PBS subsidies for new therapies with high unmet clinical need (HUCN) that may not have adequate RCT evidence, for a fixed time period within which RWD can be gathered and reevaluated as to the cost-effectiveness of these therapies. BCNA notes there would need to be consideration given to navigating the event in which a therapy is removed from the PBS after this time period due to insufficient evidence.

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?

Mostly address the issue(s)

133.1

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

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

Don't know

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?

Mostly address 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

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)

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

Positive

145

If you would like to expand on your answer above you can do so below -Horizon Scanning to meet priority areas (including addressing equity and HUCN)

proactive and dedicated horizon scanning process was highlighted by BCNA as a key recommendation in our original Phase 1 HTA consultation response. Currently, the burden of horizon scanning is left to patients and patient groups in a majority of incidences, placing an unfair burden on smaller and less resourced disease types and meaning Australia's HTA is seldom prepared ahead of time for novel therapies and new types of treatment options. In oncology, these include precision medicines, genomics, antibody-drug conjugates, and drugs for new breast cancer subtypes such as HER2-low.

BCNA was pleased to see dedicated horizon scanning processes recommended in the Options Paper but notes that only tentative language is used to suggest the involvement of patients and patient groups who are currently central to this process and must be involved in horizon scanning processes moving forward. BCNA also notes that this is a resource-intensive process and questions whether specific capacity-building for rarer disease types could be included as a recommendation, and that processes concerned with horizon scanning are established in partnership with those already doing this work across the NFP and research sectors.

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?

Mostly address the issue(s)

164.1

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

Positive

164.2

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

Positive

164.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Collaboration with international jurisdictions to deliver sustainable access to health technologies

Positive

166

If you would like to expand on your answer above you can do so below -Harmonisation of HTA evaluations

Noting the interconnectedness of many of the recommendations in the Options Paper, BCNA encourages international harmonization to be part of horizon scanning activities to ensure consistency and equity with comparable jurisdictions overseas, as well as the potential to avoid overall duplication of work.

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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

211

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.

We would hope that these recommendations could be easily and quickly implemented regardless of the wider outcomes of the HTA review.

233.1

Section 2.2. of the Options Paper sets out four possible reform options relating to proportionate appraisal pathways to calibrate the level of appraisal required for HTA submissions to take the level of risk (levels of uncertainty and potential fiscal impact) and clinical need that the submission represents into account.

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some 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: Introducing an optional resolution step before HTA committee consideration

To a significant extent

233.2

Section 2.2. of the Options Paper sets out four possible reform options relating to proportionate appraisal pathways to calibrate the level of appraisal required for HTA submissions to take the level of risk (levels of uncertainty and potential fiscal impact) and clinical need that the submission represents into account.

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some 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: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution

To a significant extent

233.3

Section 2.2. of the Options Paper sets out four possible reform options relating to proportionate appraisal pathways to calibrate the level of appraisal required for HTA submissions to take the level of risk (levels of uncertainty and potential fiscal impact) and clinical need that the submission represents into account.

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some 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 3: Early Price negotiation

To a significant extent

233.4

Section 2.2. of the Options Paper sets out four possible reform options relating to proportionate appraisal pathways to calibrate the level of appraisal required for HTA submissions to take the level of risk (levels of uncertainty and potential fiscal impact) and clinical need that the submission represents into account.

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some 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 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised

To a limited extent

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

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