

<b>Response</b>
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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
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<b>What is your name?</b>
Penny Lello
<b>7</b>
<b>Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice</b>
Patient or consumer (or representative organisation)
<b>13</b>
<b>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.</b>
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
<b>14</b>
<b>Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA</b>
1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA
<b>15</b>
<b>Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways</b>
2.2. Proportionate appraisal pathways
<b>16</b>
<b>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)</b>
3.2. Clinical Evaluation Methods
<b>17</b>
<b>Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions</b>
4.3. Understanding the performance of health technologies in practice
<b>18</b>
<b>Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes</b>
5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS
<b>27</b>
<b>Taking all Options within this section: 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA into account.</b>
<b>Overall, to what extent could the options (if implemented) address the issues that relate to them?</b>
Address some but not most of the issue(s)
<b>29.1</b>
<b>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework</b>
Very positive
<b>29.2</b>
<b>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence</b>
Very positive
<b>63</b>
<b>Taking all Options within this section: 2.2. Proportionate appraisal pathways into account</b>
<b>Overall, to what extent could the options (if implemented) address the issues that relate to them?</b>
Address some but not most of the issue(s)
<b>65.1</b>
<b>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager</b>
Positive
<b>If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Triaging submissions</b>
Positive
<b>65.2</b>
<b>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)</b>
Positive
<b>65.3</b>
<b>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:</b>
<b>Alternative option 1: Introducing an optional resolution step before HTA committee consideration</b>
Positive
<b>65.4</b>
<b>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:</b>
<b>Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution</b>
Positive
<b>65.5</b>
<b>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:</b>
<b>Alternative option 3: Early Price negotiation</b>
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

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

Positive

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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?

Address some but not most of 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

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

Positive

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.

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

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

Positive

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Taking all Options within this section: 4.3. Understanding the performance of health technologies in practice 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)

123.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Oversight " reforms to optimise access to and use of RWD in HTA

Positive

123.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop a strategic approach to increase confidence, awareness, and acceptance of cross-jurisdictional and cross-sectoral RWD access and use in HTA

Positive

123.3

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

Positive

123.4

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

Positive

123.5

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

Positive

123.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Collection of utilisation and outcome data for provisionally listed health technologies

Positive

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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?

Address some but not most of 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

Neutral

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)

Neutral

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

Neutral

133.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Proactive submission invitation and incentivisation

Neutral

133.5

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

Positive

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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

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 moderate 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 moderate 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 moderate 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 moderate extent

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

