

Response

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3
What is your name?
 Brandon Jones

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
 Johnson and Johnson Innovative Medicines

9
Are you making feedback on behalf of 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 incentive 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
 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
 Neutral

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)

28
If you would like to expand on your answer above you can do so below:
 Both options are positive changes to the system. However, for maximum stakeholder engagement the system needs to be proactive in its outreach to stakeholders rather than reactive, and requiring only those literate with the system to engage

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

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:
 Positive changes to First Nations representation and improving equity of access to therapies

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
 Neutral

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)

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
 Negative

43.3
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)
 Negative

44
If you would like to expand on your answer above you can do so below -Increase opportunities for consultation and work sharing
 As HTA should be done at the federal level with a single federal payer for therapies, including cell and gene therapies funded by the NHRA, Janssen do not consider this to be a worthwhile option

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)
 Janssen support the Medicines Australia position and as outlined in Janssen consultation 1 submission that cell and gene therapies funded via the NHRA should be fully federally funded (a single payer) and HTA also only done at the federal level.

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
 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
 Don't know

50
Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))
 see attachment provided with online survey

60
If you would like to expand on your answer above you can do so below -Vaccine pathway
 see attachment provided with online survey

61
If you would like to expand on your answer above you can do so below -Expanding role of PBAC
 see attachment provided with online survey

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
 see attachment provided with online survey

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)

64

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

see attachment provided with online survey

65.1

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

Don't know

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

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)

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

Negative

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

Negative

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

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

Don't know

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

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

Neutral

67

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

see attachment provided with online survey

68

If you would like to expand on your answer above you can do so below -Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)

see attachment provided with online survey. Note the positive comment is for the streamlining of the pathway only, and Janssen does not support the linking of this path to a lower price

69

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

see attachment provided with online survey

70

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

see attachment provided with online survey

71

If you would like to expand on your answer above you can do so below -Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN

Alternative option 3: Early Price negotiation

see attachment provided with online survey

72

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

see attachment provided with online survey

73

If you would like to expand on your answer above you can do so below -Expanding resolution step to all relevant cost effectiveness submissions

see attachment provided with online survey

74

If you would like to expand on your answer above you can do so below -Development of a disease specific common model (reference case) for disease areas with high active product development

see attachment provided with online survey

75

If you would like to expand on your answer above you can do so below -Decouple the requirement for the TGA Delegate's overview to support PBAC advice

see attachment provided with online survey

76

If you would like to expand on your answer above you can do so below -Case manager

see attachment provided with online survey

77

Taking all Options within this section: 3.1. Determination of the Population, Intervention, Comparator, Outcome into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Mostly address the issue(s)

79.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased early stakeholder input

Positive

79.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increased transparency for stakeholders

Positive

79.3

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

Positive

81

If you would like to expand on your answer above you can do so below -Increased early stakeholder input

see attachment provided with online survey

82

If you would like to expand on your answer above you can do so below -Increased transparency for stakeholders

see attachment provided with online survey

83

If you would like to expand on your answer above you can do so below -Updated guidance

see attachment provided with online survey

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?

Address little or none 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

Neutral

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

Neutral

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

Neutral

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.

Neutral

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)

Neutral

86.7

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

Positive

89 If you would like to expand on your answer above you can do so below -Overarching principles for adopting methods in Australian HTA

see attachment provided with online survey

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

see attachment provided with online survey

92 If you would like to expand on your answer above you can do so below -Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors

see attachment provided with online survey

93 If you would like to expand on your answer above you can do so below -Develop an explicit qualitative value framework

see attachment provided with online survey

94 Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)

see attachment provided with online survey

95 If you would like to expand on your answer above you can do so below -Pharmacogenomic technologies

see attachment provided with online survey. Selected positive as opposed to neutral for others because there is little to no guidance at the moment for these therapies (unlike those other situations noted above)

96 Taking all Options within this section: 3.3. Economic evaluation 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)

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

see attachment provided with online survey

98.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Selection of the comparator

Very negative

98.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Valuing of long-term benefits

Very negative

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

Very negative

100 If you would like to expand on your answer above you can do so below -Selection of the comparator

see attachment provided with online survey

101 If you would like to expand on your answer above you can do so below -Valuing of long-term benefits

see attachment provided with online survey

102 If you would like to expand on your answer above you can do so below -Valuing overall

see attachment provided with online survey

103 Taking all Options within this section: 4.1. Approaches to funding or purchasing new health technologies 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)

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

whilst there are some positives, there are some don't knows and a clear negative with CMA price reductions - hence address little or none of the issue

refer to attached submission with the online survey

105.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Very negative

105.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit

Very negative

105.3 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Investigate further options to address budget impact implications of high-cost/high impact health technologies

Don't know

105.4 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pricing offer (PO) and negotiation guidance framework

Don't know

105.5 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Post-listing re-assessment of health technologies

Don't know

105.6 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN

Positive

105.7 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Approaches for managing uncertainty - revised guidance on the uses of different managed entry tools

Positive

107 If you would like to expand on your answer above you can do so below -Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

refer to attached submission with the online survey for details

108 If you would like to expand on your answer above you can do so below -Recognising competition between new health technologies that deliver similar outcomes:

Alternative option 2: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit

refer to attached submission with the online survey for details

109 If you would like to expand on your answer above you can do so below -Investigate further options to address budget impact implications of high-cost/high impact health technologies

refer to attached submission with the online survey for details

110 If you would like to expand on your answer above you can do so below -Pricing offer (PO) and negotiation guidance framework

refer to attached submission with the online survey for details

111 If you would like to expand on your answer above you can do so below -Post-listing re-assessment of health technologies

refer to attached submission with the online survey for details

112 If you would like to expand on your answer above you can do so below -Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN

refer to attached submission with the online survey for details

113 If you would like to expand on your answer above you can do so below -Approaches for managing uncertainty - revised guidance on the uses of different managed entry tools

refer to attached submission with the online survey for details

114 Taking all Options within this section: 4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR) into account.

Overall, to what extent could the options (if implemented) address the issues that relate to them?

Don't know

116.1 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - HTA Fee exemptions for products that address AMR

Don't know

116.2 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - HTA Policy and Guidance changes for products that address AMR

Don't know

116.3 If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Funding and reimbursement-related changes to support availability of antimicrobials

Don't know

121 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?

Mostly address the issue(s)

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

refer to attached submission with the online survey for details

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

Very 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

Neutral

125
If you would like to expand on your answer above you can do so below -Oversight " reforms to optimise access to and use of RWD in HTA

refer to attached submission with the online survey for details

126
If you would like to expand on your answer above you can do so below -Develop a strategic approach to increase confidence, awareness, and acceptance of cross-jurisdictional and cross-sectoral RWD access and use in HTA

refer to attached submission with the online survey for details

127
If you would like to expand on your answer above you can do so below -Data infrastructure

refer to attached submission with the online survey for details

128
If you would like to expand on your answer above you can do so below -Methods development

refer to attached submission with the online survey for details

129
If you would like to expand on your answer above you can do so below -Develop Guidance framework

refer to attached submission with the online survey for details

130
If you would like to expand on your answer above you can do so below -Collection of utilisation and outcome data for provisionally listed health technologies

refer to attached submission with the online survey for details

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?

Don't know

132
If you would like to expand on your answer above you can do so below:

refer to attached submission with the online survey for details. Don't know has been selected as its unclear if this will speed up access, however in principle Janssen are supportive of the option to address gaps in the PBS and areas of HUCN

133.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of a priority list

Don't know

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)

Don't know

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

Don't know

133.4
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Proactive submission invitation and incentivisation

Don't know

133.5
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early PICO scoping

Don't know

135
If you would like to expand on your answer above you can do so below -Development of a priority list

refer to attached submission with the online survey for details

136
If you would like to expand on your answer above you can do so below -Identifying therapies to meet priority list (horizon scanning)

refer to attached submission with the online survey for details

137
If you would like to expand on your answer above you can do so below -Early assessment and prioritisation of potentially promising therapies

refer to attached submission with the online survey for details

138
If you would like to expand on your answer above you can do so below -Proactive submission invitation and incentivisation

refer to attached submission with the online survey for details

139
If you would like to expand on your answer above you can do so below -Early PICO scoping

refer to attached submission with the online survey for details

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?

Address some but not most of the issue(s)

141
If you would like to expand on your answer above you can do so below:

refer to attached submission with the online survey for details

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)

Don't know

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

Neutral

144
If you would like to expand on your answer above you can do so below -Horizon scanning for advanced therapies (including high cost, HSTs funded through the NHRA) and other potentially disruptive technologies

Positive provided the horizon scanning triggers meaningful actions and progression to submission and listings. refer to attached submission with the online survey for details

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)

refer to attached submission with the online survey for details

146
If you would like to expand on your answer above you can do so below -Horizon Scanning to help operational and capacity planning for HTA and health systems

refer to attached submission with the online survey for details

147
Taking all Options within this section: 5.3. Consideration of environmental impacts in the 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)

148
If you would like to expand on your answer above you can do so below:

refer to attached submission with the online survey for details

149.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Environmental impact reporting

Don't know

151
Environmental impact reporting

refer to attached submission with the online survey for details

152
Taking all Options within this section: 5.4. Mechanisms for continuous review and improvement 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)

153
If you would like to expand on your answer above you can do so below:

refer to attached submission with the online survey for details

154.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - A program of continuous review and improvement for current HTA policies and methods

Don't know

156
If you would like to expand on your answer above you can do so below -A program of continuous review and improvement for current HTA policies and methods

refer to attached submission with the online survey for details

157

Taking all Options within this section: 5.5. Capacity and capability of the HTA system 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)

159.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improve HTA capacity and workforce in Australia

Don't know

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?

Address little or none of the issue(s)

163

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

refer to attached submission with the online survey for details

164.1

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

Negative

164.2

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

Negative

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

Negative

166

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

refer to attached submission with the online survey for details

167

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?

Not at all confident

168

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

refer to attached submission with the online survey for details. However, in summary, whilst some process changes are positive, there is little change from the current system in terms of value recognition of therapies. Barriers in value recognition were highlighted as the key barrier to earliest possible access.

Thus, unless there is positive changes in appropriate value recognition and invest in innovative therapies then we will not see the goals of the HTA review regarding fast and equitable access being achieved.

221

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.

see attachment provided with online survey

222

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.

see attachment provided with online survey

229

If you would like to expand on your answer above you can do so below -Work sharing for individual submissions

refer to attached submission with the online survey for details

230

If you would like to expand on your answer above you can do so below -Collaboration with international jurisdictions to deliver sustainable access to health technologies

refer to attached submission with the online survey for details

231

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.

see attachment provided with online survey

232

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.

see attachment provided with online survey

233

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.

see attachment provided with online survey

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 limited 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 limited 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

Don't know

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

235

What comments do you have about the relative strengths and weaknesses of these alternative potential reform options?

Option 4 is the strongest as it occurs post HTA Committee assessment and involves the decision makers in the process unlike other options

236

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

Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised

237

Why did you select that response above?

see attachment provided with online survey

238.1

Under the subject 'Recognising competition between new health technologies that deliver similar outcomes', there are two 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: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Not at all

238.2

Under the subject 'Recognising competition between new health technologies that deliver similar outcomes', there are two 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: In conjunction with options for proportionate assessment of cost-minimisation submissions, incentivise offers of a lower price for health technologies that provide no added benefit.

Not at all

239

What comments do you have about the relative strengths and weaknesses of these alternative potential reform options?

refer to attached submission with the online survey for details

240

Which of the proposed reform options do you think offers greatest scope to address the issues identified in consultation to date?

Neither of these

241

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.
refer to attached submission with the online survey for details

242

Why did you select that response above?

refer to attached submission with the online survey for details

243

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.
refer to attached submission with the online survey for details

251

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252

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253

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254

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256

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.
refer to attached submission with the online survey for details