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

2

What is your name?

Peter Germanos

CCCI

Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice

Pharmaceutical / Medical technology company

0 1

What is the name of your organisation? - My organisation is called: - Text

Boehringer Ingelheim

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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

10

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)

iviostiy a

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 Very positive

very |

. 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

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

To support consumer advocacy groups, clear guidance is required on the types of evidence that the PBAC would consider appropriate.

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

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

Very 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)

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

Without agreement from all states and territories, this option could increase the level of detail required for an HTA submission, especially if there are unique state requirements.

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

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)

Patient access could be enhanced and efficiencies could be gained if a body like the PBAC determines a therapy as cost effective, allowing the states to implement it without additional evaluations.

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

Very positive

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 Very positive

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

Boehringer Ingelheim generally supports the proposed option. However, further consultation with Medicines Australia is deemed necessary to understand and determine the practical details of its implementation.

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

Boehringer Ingelheim generally supports the proposed option. However, further consultation with Medicines Australia is deemed necessary to understand and determine the practical details of its

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)

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

Positive

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

Neutral

65.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)

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

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

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

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

Neutral

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

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

Boehringer Ingelheim supports the option to triage submissions. However, further consultation with Medicines Australia is deemed necessary to understand and determine the practical details of its implementation.

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)

The streamlined pathway for cost-minimisation submissions must be decoupled from the proposal to incentivise or require companies to offer a lower price. Boehringer Ingelheim does not support the proposal to incentivise or require companies to offer a lower price via a cost minimisation pathway.

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

Boehringer Ingelheim does not support an option that limits the number of resubmissions permitted.

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

The proposal aims to extend the early resolution step to all relevant cost-effective submissions following a pilot. However, it is crucial that the pilot occurs as promptly as possible, ideally within one or two PBAC cycles, to expedite access for patients without unnecessary delays.

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

Boehringer Ingelheim does not support the option for disease specific common models.

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

In principle, Boehringer Ingelheim supports the proposal to assign a case manager for each cost-effectiveness submission. However, further detail regarding the scope of the case managers responsibilities and their interactions with the sponsor is required to be able to assess the usefulness and any unintended consequences.

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

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)

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

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,

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

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

26.7

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

Positive

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)

98.1

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

Negative

98.2

96.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Valuing of long-term benefits

Negative

98.3

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

Neutral

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

The topic of the lowest cost comparator has been a longstanding concern within the industry. The current legislation was not intended to select the lowest cost comparator. However, due to certain undefined terms (such as '"cost'), over time, the interpretation of section 1013b has tended to favour the lower cost comparator. Boehringer Ingelheim suggests that the HTA review should include an examination of the historical guidelines and recommend greater flexibility in the interpretation of section 1013b to the PBAC.

101

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

The proposed option to further consider a reduction of the discount rate and conduct more modelling does not move beyond the status quo.

Discount rates have already undergone independent assessment, and the PBAC has issued recommendations on this matter. As outlined in the Strategic Agreement (Clause 5.2), Medicines Australia submitted a proposal to the PBAC in January 2022, advocating for a reduction of the base case discount rate from 5% to 1.5%. This adjustment would align Australia with other countries that have lowered their discount rates, recognising the growing importance of long-term health outcomes for their populations.

Boehringer Ingelheim recommends maintaining alignment with Medicines Australia, given the substantial effort already invested in examining discount rates.

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)

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 henefit

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

Positive

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

Positive

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

Negative

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

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

Boehringer Ingelheim does not support the option to require or incentivise lower price offers. The potential impact of this option on stakeholders and any unintended consequences are significant.

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

Boehringer Ingelheim does not support the option to require or incentivise lower price offers. The potential impact of this option on stakeholders and any unintended consequences are significant.

111

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

The post-market review framework was recently updated in February 2024, following an extensive consultation process. It is not clear what this option adds to the existing process.

It is also unnecessary to review every product that has a PBS listing given the substantial resources required for such evaluations. Notably, the PBAC has also already deemed the product cost effective, provided they are used appropriately. As such, there is a need for clear criteria to determine which products require undergoing the post-market review.

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?

Mostly address the issue(s)

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

Positive

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 Positive

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

Positive 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)

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

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

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**

Taking all Options within this section: 5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS into account.

123.5

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

Positive

technologies

Positive 131

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)

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 Positive

133.4

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

Positive

133.5

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

Positive 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)

141

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

Boehringer Ingelheim supports the option for horizon scanning programs. However, it is essential that these programs are guided by well-defined and publicly available disease priorities established by the Department. Any implementation of horizon scanning programs should be accompanied by augmented investment in the PBS.

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

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?

Mostly address the issue(s)

149.1

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

Neutral

151

Environmental impact reporting

Boehringer Ingelheim supports the underlying premise of the need to embed sustainability across all industries. However, further detail is required to understand the proposed environmental impact reporting obligations. Furthermore, any proposed changes should not make the submission process more onerous and detract from the fundamental issue of faster patient access.

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?

Mostly address the issue(s)

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

Positive

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

Boehringer Ingelheim supports the concept of continuous improvement. However, there must be a consultation period with Medicines Australia whenever changes are made to the PBAC guidelines, as this has been the established process thus far.

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?

Mostly address the issue(s)

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

Positive 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 some but not most of 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

Neutral

164.2

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

Neutral 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

Very negative

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 very confident

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

In addition to the concerns raised throughout this survey, there are some notable gaps that have not been addressed in the options presented in Consultation 2. The submission from Medicines Australia raised several options which appear to have been overlooked (please refer to their submission) and no options have been put forth that addresses some of the inefficiencies within the post-PBAC process. It is crucial to explore options that enhance efficiencies of this process, ensuring more timely access to new and innovative medicines.

The HTA Review also provides an opportunity for the Department to seek additional funding for the PBS. This funding boost would enhance patient access, value and choice. Regrettably, it seems this opportunity has not been given due consideration.

212

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.

The broad societal, health, and economic benefits of medicines and vaccines for patients, carers, and the Australian community should be considered in HTA evaluations. While HTA assessments typically focus on direct benefits and costs, it is crucial to also account for indirect impacts, such as reduced carer burden, workforce productivity, and overall economic effects. Countries like the UK, the Netherlands, and Canada already incorporated broader social and economic impacts in their HTA processes, but Australia has yet to adopt this approach or provide guidance on appropriate methodology and usage in PBAC decision making.

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.

Boehringer Ingelheim supports the proposal for an early resolution mechanism, which aims to promptly resolve issues and expedite access for patients. However, Consultation 2 lacks sufficient detail to thoroughly evaluate each option and anticipate any unintended consequences.

Further detail on the available options to identify any potential unintended effects is required. Boehringer Ingelheim also recommends conducting a pilot of the preferred option to ensure it has the intended effects.

229

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

Adequate consultation with Medicines Australia is required to determine which aspects of the submission should be subject to collaboration with other HTA bodies. It is Boehringer Ingelheim's view, that Section 3 and 4 of the PBAC submission are not appropriate to share.

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 Boehringer Ingelheim does not support international purchasing.

222 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

To a limited 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

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

238.1

Under the subject 'æRecognising 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

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