Response
2
The Department may, at its discretion, publish part or all of the information provided in your submission on the Department's website or in related documents. If information from your submission is published, the Department may identify you and/or your organisation as the author of the submission. All personal contact details will be removed prior to publishing.
Yes, I consent to my identified submission being published
3
What is your name?
Tracy Merlin
7
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice
University or research sector
8.1
What is the name of your organisation? - My organisation is called: - Text
Adelaide Health Technology Assessment (AHTA), University of Adelaide
9
Are you making feedback on behalf or your organisation?
Yourself
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
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)
3.2. Clinical Evaluation Methods
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,4.3. 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,5.5. 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)
22
If you would like to expand on your answer above you can do so below:
(Note COI: some of the presented options were raised in our research papers) The ability to address the transparency and communication issues will critically depend on how well the plain language summaries, improvements to the HTA webpage and development of a dashboard are executed. It will be very difficult to translate the technical information in the PBAC Guidelines, for instance, into non-technical language. These activities could potentially become the responsibility of the HTA Consumer Evidence and Engagement Unit. I also think that part of the transparency in communications about the delays in approving medicines should acknowledge that there are two agents involved in the negotiation, and that the delays can be the responsibility of either or both agents. Sometimes there are different understandings by industry and HTA decision-makers of the value of the clinical benefits to patients, and to the health system, of a medicine. There are also different understandings of the wider consequences of a positive funding decision for a medicine (in terms of what other medicines can't then be funded and the flow on effect of other health benefits prevented) .
23.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries
Neutral
23.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard
Positive
25
If you would like to expand on your answer above you can do so below -Publish plain language summaries
I have assumed the plain language summaries would not be written by the evaluation groups. Hence, the response of neutral.
26
If you would like to expand on your answer above you can do so below -Improvements to the HTA webpage including development of a dashboard
It would be helpful for the evaluation groups to see where medicines and near market comparators are in the HTA system.
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:

(Note COI: some of the presented options were raised in our research papers)

Greater consumer engagement in trial development, horizon scanning, PICO scoping and in technology appraisal/decision-making should be encouraged.

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

47

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

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))

Neutral

48.2

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

Don't know

48.3

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

Very positive

48.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Unified HTA pathway for all health technologies with Commonwealth funding

Very positive

50

Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))

Supported.

60

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

b."The PBAC evaluators and vaccine evaluation experts evaluate the sponsors submission and produce a single comprehensive assessment report" - this will be feasible if the PBAC evaluators are also vaccine evaluation experts but could prove challenging - within existing timeframes -for evaluations that involve two different groups. The timeframes might need to be amended for vaccine evaluations as a consequence.

3. "Develop a mechanism and criteria to have the assessment of vaccines be proportionate to the level of risk of the product." The risk may be higher for vaccines than for other technologies because the people being vaccinated are healthy and so the individual risk/benefit trade-off is different than for people who are unwell and are needing a treatment. Is the intention then to make the evaluation more fulsome than currently?

61

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

(Note COI: some of the presented options were raised in our research papers)

Supported, although PBAC will have to be differently constituted to have the expertise to address a broader range of technologies.

The expanded remit of PBAC will hopefully expedite decision-making on co-dependent technologies without the need to defer until the sister committee has provided advice. When we developed the codependent technology evaluation framework and process 10 years ago we initially advised that a single committee should take responsibility for the decision-making but there were concerns about legislative barriers at that time. It is great to see this approach has now been recommended.

It will mean that the codependent technology evaluation reports/commentaries will be streamlined, without the need to provide two executive summaries (as currently) that are the basis for the Public Summary Documents.

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

Supported. The unified pathway should streamline processes.

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:

(Note COI: some of the presented options were raised in our research papers)

Support most of the options but not all - see below.

65.1

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

Very positive

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

Very positive

65.2

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

Very 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

Don't know

65.4

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution

Very 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

Neutral

65.6

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN:

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

Very 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

Very 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

Very 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

67

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

(Note COI: this option was raised in our research papers)

Supported.

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)

Supported.

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

(Note COI: this option was raised in our research papers)

ESC is not currently a decision-making committee. Currently most of the ESC advice is based on the Commentary's Executive Summary and main issues raised. To undergo a resolution step there needs to be clear direction regarding what submission elements are/are not acceptable to the committee and what points raised in the evaluation are valid and need addressing by the sponsor. Without a clear direction/signal from a decision-making committee it is unlikely that the resolution process will proceed satisfactorily. We canvassed a post-ESC/pre-PBAC resolution step in Paper 1 but this was not preferred over a post-PBAC resolution step, partly because PBAC makes a decision while ESC does not. If, however, the nature of ESC changes and it becomes more definitive about the deficiencies in the submission that need amending, then this approach might work.

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

(Note COI: this option was raised in our research papers)

ESC is not currently a decision-making committee. Currently most of the ESC advice is based on the Commentary's Executive Summary and main issues raised. To undergo a resolution step there needs to be clear direction regarding what submission elements are/are not acceptable to the committee and what points raised in the evaluation are valid and need addressing by the sponsor. Without a clear direction/signal from a decision-making committee it is unlikely that the resolution process will proceed satisfactorily. We canvassed a post-ESC/pre-PBAC resolution step in Paper 1 but this was not preferred over a post-PBAC resolution step, partly because PBAC makes a decision while ESC does not. If, however, the nature of ESC changes and it becomes more definitive about the deficiencies in the submission that need amending, then this approach might work.

However, I disagree with the additional post committee resolution because then the process of "resubmission churn" would just be similar to the current process - and the point of the Review was to reduce resubmission churn and speed up patient access to medicines. If there is no possibility of resubmission and the resolution timeframe is mandated, then both parties (Government/Government-related agents and industry) would have greater incentive to reach a solution.

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

(Note COI: this option was raised in our research papers)

As mentioned above, if the nature of ESC changes and it becomes more definitive about the deficiencies in the submission that need amending and signals the price that is likely to be acceptably cost-effective, then this early price negotiation approach might work.

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

(Note COI: this option was raised in our research papers)

Supported.

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

(Note COI: this option was raised in our research papers)

Supported.

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

Supported.

The reference models can also be used as a tool for "living HTA" for highly specialised technologies addressing conditions of HUMN, undergoing coverage with evidence development. See Merlin, T., Street, J., Carter, D., Haji Ali Afzali, H. Challenges in the Evaluation of Emerging Highly Specialised Technologies: Is There a Role for Living HTA?. Appl Health Econ Health Policy (2023). https://doi.org/10.1007/s40258-023-00835-3

76

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

(Note COI: this option was raised in our research papers)

Supported.

84

Taking all Options within this section: 3.2. Clinical Evaluation Methods into account.

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

Mostly address the issue(s)

85

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

Note COI: most of these options were raised in our research papers. Some comments are given below regarding related issues.

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

Very positive

86.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of nonrandomised and observational evidence

Very positive

86.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Methods for the assessment of surrogate endpoints

Very 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.

Very 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

Very 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

Neutral

89

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

Note COI: this option was raised in our research papers.

Supported

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

Note COI: this option was raised in our research papers.

Supported, although it is noted that use and validity of this type of evidence will very much depend on the case/circumstances at hand (e.g. whether better quality data can be sourced). The main point to determine is whether the incremental observed effect is of such a magnitude that the probability of it occurring as a consequence solely through confounding is low. Irrespective of the methodological approach and the proposed guidance on the type of nonrandomised/observational evidence to present, the actual magnitude of effect is unlikely to be determined with precision and certainty, and this will impact on decision-making regarding the cost-effectiveness of the medicine.

91

If you would like to expand on your answer above you can do so below -Methods for the assessment of surrogate endpoints

Note COI: this option was raised in our research papers.

Supported, although it is noted that there is a great deal of guidance on this issue in the PBAC Guidelines but it is rare that this guidance is followed by submissions.

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

Note COI: this option was raised in our research papers.

Supported.

93

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

Note COI: this option was raised in our research papers.

Supported, particularly this statement "The value framework would allow enough flexibility for the deliberation process itself to add value to the decisions i.e. not be pre-weighted and scored."

94

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

Note COI: this option was raised in our research papers.

Supported.

A proposed process for developing a Statement of Principles on gene therapies/highly specialised technologies was given in the first part of the following article - Merlin, T., Street, J., Carter, D., Haji Ali Afzali, H. Challenges in the Evaluation of Emerging Highly Specialised Technologies: Is There a Role for Living HTA?. Appl Health Econ Health Policy (2023). https://doi.org/10.1007/s40258-023-00835-3

One thing that also needs addressing is the quality of primary research evidence on the topic. Advice on this could be provided.

95

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

The current codependent evaluation framework is effective for 'simple' pharmacogenetic technologies. No submissions had concerns regarding the methods, only the process delays associated with evaluating these technologies.

For pharmacogenomic technologies and technologies like CAR-T, a proposed process for developing a Statement of Principles on gene therapies/highly specialised technologies was given in the first part of the following article - Merlin, T., Street, J., Carter, D., Haji Ali Afzali, H. Challenges in the Evaluation of Emerging Highly Specialised Technologies: Is There a Role for Living HTA?. Appl Health Econ Health Policy (2023). https://doi.org/10.1007/s40258-023-00835-3

One thing that also needs addressing is the quality of primary research evidence on the topic. Advice on this could be provided.

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?

Mostly address 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 benefit

Neutral

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

Neutral

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

Neutral

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

Very positive

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

Very 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

While I am supportive of some sort of price penalty for "me-too" drugs, it is important that this is not so harsh that it generates insecurity of supply. Also, some "me-too" drugs have different formulations or allow greater efficiencies in delivery and these are important for health system functioning. So, "New therapies that offer no advantage in terms of improved efficacy or safety (i.e. no improved health outcomes), would be required to offer a lower price to be funded." might need to be extended to account also for the concept of health system efficiency/quality use of medicines.

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

As above. While I am supportive of some sort of price penalty for "me-too" drugs, it is important that this is not so harsh that it generates insecurity of supply. Also, some "me-too" drugs have different formulations or allow greater efficiencies in delivery and these are important for health system functioning. So, "New therapies that offer no advantage in terms of improved efficacy or safety (i.e. no improved health outcomes), would be required to offer a lower price to be funded." might need to be extended to account also for the concept of health system efficiency/quality use of medicines.

111

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

This is particularly important for those technologies on "bridging" funding but could also be extended to fast-moving areas of medicine development i.e. where there are multiple treatment options for one indication. The time period for review might differ depending on the disease area and rate of technological development.

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

Note COI: this option was raised in our research papers.

Supported.

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

This recommendation is a little vague. I wasn't quite clear on what was being suggested.

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

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

Very positive

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

Just also to note that not all relevant data will necessarily come from registries. Coverage with evidence development could also rely on trials that are underway and not yet mature, or on administrative data (such as usage, co-administration of medicines etc). The type of data required to reduce the decision-making uncertainty would need to be specified at the inception of provisional listing and would need to involve the HTA evaluators and committee discussants with the closest understanding of the submission.

132

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

Note COI: these options were raised in our research papers.

Supported.

133.1

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

Very positive

133.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Identifying therapies to meet priority list (horizon scanning)

Very positive

133.3

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Early assessment and prioritisation of potentially promising therapies

Very positive

133.4

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

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:

Note COI: these options were raised in our research papers.

Supported.

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

Very positive

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)

158

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

Note COI: this option was one of our suggestions and so is therefore supported. Suggest also Commonwealth Supported Places are offered for Public Health coursework degrees and Health economics coursework degrees.

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

Very positive

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

Positive

166

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

While I can see the value in more harmonisation, I am acutely aware that HTA processes have been set up to reflect the health systems, values and cultures in different countries and that these differ between countries (as seen in Paper 1). Harmonisation in methods and processes may not result in harmonisation of funding decisions (as was demonstrated in Europe). Also some methods and processes have values underpinning them that might be contrary to values in another jurisdiction. I am therefore neutral on the subject - I think it will depend on how it is rolled out.

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?

Very confident

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 only concern I have is whether greater consumer engagement will slow down the overall HTA/appraisal process. While I support greater consumer consultation/training, I would not want this to be detrimental to the interests of consumers seeking swifter access to new medicines.

229

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

While I can see the value in work sharing from an evaluation perspective, I am also aware that HTA processes have been set up to reflect the health systems, values and cultures in different countries and that these differ between countries. Any work sharing will depend on like-minded approaches to assessment and would therefore likely be a slow process - at least early on - and might not result in any efficiencies of process. It will depend on how it is implemented.

Work-sharing in terms of concurrent lodgement of submissions to multiple agencies and then work-split among agencies, could result in some efficiencies and early access to medicines but as PICOs/clinical pathways per disease area often differ between countries, the topics would have to be carefully screened to ensure the submissions are suitable for all of the participating jurisdictions.

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

Such an approach has been demonstrated by Beneluxa and others and may have benefits for Australia.

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

Not at all

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 significant extent

235

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

See earlier comments.

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?

Because there is a definitive assessment by the HTA committee (which includes consumers) of the strengths and weaknesses of the case presented by the submission, which can then be used as a basis for further negotiation and improvements to the submission/model through the resolution step. Without this clear direction from the HTA committee, industry and the evaluation groups will find it difficult to make progress, as it is likely that they will each interpret the ESC advice differently.

(unless of course for Options 1 to 3 there is an intent to have ESC change how it operates and it becomes a decision-making committee)

238.1

Under the subject 'œRecognising 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

To a limited extent

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.

To a limited extent

240

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

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

242

Why did you select that response above?

Of the two options, I think Option 2 would be more difficult to implement. However, either option would need to be implemented cautiously.

253

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.

Assessing the impact of environmental considerations in HTA is already been actively pursued. We included mention of this in a recent MSAC report. The problem to date has been the lack of primary research evidence on the topic. This will need to be provided in submissions to enable an evaluation and appraisal of the impact.