

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?
Monika Boogs
7
Please select the type of individual(s) or organisation(s) you represent. Please select all that apply. - Selected Choice
Patient or consumer (or representative organisation)
8.1
What is the name of your organisation? - My organisation is called: - Text
Painaustralia
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
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)
3.3. 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
4.3. 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,5.4. Mechanisms for continuous review and improvement
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:
Painaustralia welcomes the proposed reforms to improve transparency and communication of HTA pathways, processes and decisions (1.1) including the publication of plain language summaries and improvements to the HTA webpage comprising development of a dashboard. Further, the development of a consumer, clinician and other stakeholder engagement framework (1.2) to ensure these views are considered in HTA processes is supported. Measures to strengthen consumer evidence collection and utilisation; the involvement and consideration of First Nations peoples in HTA and decision-making (1.3); and supporting collaborative HTA working practices with state and territory governments through the development of a central and standardised data sharing system and increased opportunities for consultation and work sharing (1.4) are also supported. Painaustralia emphasises that the aforementioned proposed reforms must ensure engagement of all relevant or affected stakeholders and mitigate any potential for uneven influence or an overreliance on the views of some individuals, organisations or groups. Painaustralia considers that stakeholder engagement mechanisms must be designed to ensure that all relevant organisations, irrespective of size, have the capacity and opportunity to be involved in and participate in consultations. Any co-design engagement process must support the capture of voices at an early stage in the review process to support decision making that has a full " understanding of
23.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Publish plain language summaries
Very 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
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)
29.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Develop an engagement framework
Very positive
29.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Strengthen consumer evidence
Very positive
31
If you would like to expand on your answer above you can do so below -Develop an engagement framework
the development of a consumer, clinician and other stakeholder engagement framework (1.2) to ensure these views are considered in HTA processes is supported. Measures to strengthen consumer evidence collection and utilisation; the involvement and consideration of First Nations peoples in HTA and decision-making (1.3); and supporting collaborative HTA working practices with state and territory governments through the development of a central and standardised data sharing system and increased opportunities for consultation and work sharing (1.4) are also supported. Painaustralia emphasises that the aforementioned proposed reforms must ensure engagement of all relevant or affected stakeholders and mitigate any potential for uneven influence or an overreliance on the views of some individuals, organisations or groups. Painaustralia considers that stakeholder engagement mechanisms must be designed to ensure that all relevant organisations, irrespective of size, have the capacity and opportunity to be involved in and participate in consultations. Any co-design engagement process must support the capture of voices at an early stage in the review process to support decision making that has a full " understanding of issues arising from new technologies, innovations and associated implications for consumers'. Painaustralia suggests that the values developed by the Health Technology Assessment International (HTAi) special interest group, for patient and citizen participation are inst
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?

Mostly address 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

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

63

Taking all Options within this section: 2.2. Proportionate appraisal pathways into account

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

Mostly address the issue(s)

65.1

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

Neutral

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)

Neutral

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

Positive

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 positive

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

Negative

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

Neutral

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

Neutral

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

With regard to early resolution mechanisms for submissions of major new therapeutic advances in areas of unmet clinical need Painaustralia supports the proposal detailed in Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution (2.2).

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

Regarding the development of a disease specific common model (reference case) for disease areas with high active product development (2.2)¹ Painaustralia supports the development and adoption of a consistent model structure for specified disease areas where there are several potential therapies/ technologies under development (as identified through horizon scanning). Painaustralia emphasises that this will require input from a wide range of stakeholders to ensure a comprehensive representation of the disease area. In Painaustralia's view the development of disease specific models would strengthen and support consistency in decision-making as models across different technologies for the same disease/condition will be more easily comparable. Further, the investigation of international collaboration on the development of disease-specific common models is supported.

It is Painaustralia's view that the development of a disease specific common model would assist formal HTA approaches to recognise the nature and complexity of pain. Chronic pain is considered to be 'one of the most difficult conditions to treat'. Contributing factors for this include that it is challenging 'to assess the short-term and long-term effects of any particular treatment that you use. Pain is very individual'.

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 some but not most 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

Neutral

98.2

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

Very positive

98.3

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

Positive

101

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

Regarding economic evaluation (3.3) Painaustralia supports the valuing of long-term benefits for interventions. Painaustralia reiterates its view that HTA assessment processes must consider the complexity of pain. To effectively do this, cost assessments must adopt societal cost based perspectives that include evaluation of: (i) direct costs and outcomes including direct costs borne by the health care system (for example, drug costs, costs of hospitalisation) and direct outcomes (quality of life impact) on the patient; and (ii) indirect costs, outcomes and effects including productivity loss of patients due to illness and gains due to participation in the workforce due treatment interventions; and indirect outcomes (quality of life impact) on those affected by caring for an ill patient (for example, carers, parents). Formal HTA processes must also fully value preventative interventions in assessment processes. Assessment processes in addition to reviewing the costs and benefits to the patient and health system must also consider broader societal impacts (including productivity and socio-economic considerations). When the impact of interventions outside the scope of the health system are not factored into assessments the full value of preventative interventions remains unaccounted and those consumers who the community expects to receive the benefit of advances in technology and treatments will actually miss out.

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?

Address some but not most of the issue(s)

123.1

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

Positive

123.2

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

Neutral

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

Neutral

123.5

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

Neutral

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

Regarding understanding the performance of health technologies in practice (4.3) Painaustralia supports reforms to optimise access to and use of real-world data (RWD) in HTA. The proposed establishment of a multi-stakeholder advisory group, reporting to government, to co-design and oversee the development and implementation of enabling systems, pathways, evaluation, and research to optimise access to and use of RWD in HTA would be a constructive measure.

131

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

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

Mostly address the issue(s)

133.1

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

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)

Positive

133.3

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

Very positive

133.4

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

Very positive

133.5

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

Positive

135

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

Painaustralia supports measures to proactively address areas of unmet clinical need and gaps in the PBS (5.1). Painaustralia concurs that any such measures would "require methodological development, implementation planning, and adequate resourcing including joint investment across stakeholder groups". It is Painaustralia's view that the development of a priority list of high unmet clinical need; identification of therapies to meet priority lists; and early assessment and prioritisation of potentially promising therapies would assist in this regard.

136

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

Formal HTA approaches must identify and accommodate major therapeutic advances for the treatment and management of chronic pain that may enter the regulatory or reimbursement systems (or both). The contemporary evidence base underpinning therapeutic innovations for pain management supports the use of therapies that include consideration of the pain experience from a biomedical and biopsychosocial perspective. This includes both pharmacological and nonpharmacological therapies.

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?

Completely 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

Very 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

Regarding mechanisms for continuous review and improvement (5.4) Painaustralia strongly supports a program of continuous review and improvement for current HTA policies and methods. The effective implementation of the five proposed program components will facilitate earlier patient access to therapeutic innovations in a timely, equitable, safe and affordable way.

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?

Somewhat confident

168

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

The reform options if implemented properly and with consumers consulted at a much earlier stage and their views considered than Painaustralia is confident that health technology assessments could improve.

Painaustralia looks forward to the final recommendations and report of the HTA Review Reference Committee. It is vital that the outcome of such a review future-proofs formal HTA approaches for the next 30 years.

Importantly, for Australian's suffering from chronic pain"reforms to HTA policy and methods must consider: (i) advancements in therapeutic innovations available for treating and managing pain; (ii) the nature and complexity of pain; (iii) current and emerging models of care for people living with chronic pain; (iv) the use of current and emerging technologies to support access, self-management and care processes; (v) economic evaluation of the cost-effectiveness of multidisciplinary chronic pain management interventions; (vi) reduce disparities in access to pain treatment and management; and (vii) prioritise the perspectives from individuals living with pain.

It is Painaustralia's view that consideration of these important factors in a consistent way will strengthen formal HTA processes for Australians affected by chronic pain. The proposed reform option areas and associated actions as developed by the Review Reference Committee through the Health Technology Assessment Policy and Methods Review are a positive and critical step in achieving this goal.

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.

Painaustralia supports measurement outcomes of economic evaluation modelling (3.3) that includes: overarching impacts to the budget; changes to variables such as the incremental cost-effectiveness ratio (ICER) that may require adjustment in response to any changes to the base case discount rate.

Further, any workshops conducted, as proposed, to assist in this regard must ensure that participants are representative of the Australian population, workshops/consultation should include a population representative sample (including representation of key stakeholder groups) and ensure measurement is free from selection bias. Further, as proposed, workshops of this kind could be assisted through use of the explicit qualitative value framework.

f

233.1

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

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 1: Introducing an optional resolution step before HTA committee consideration

To a moderate extent

233.2

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

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution

To a significant extent

233.3

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

Under the subject 'Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN', there are some options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 3: Early Price negotiation

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

Not at all

236

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

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

237

Why did you select that response above?

We believe this is the best option for consumers and to include consumer views at an early stage which is vital.