

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?

David Thomson

7

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

Pharmaceutical / Medical technology company

8.1

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

Amgen

9

Are you making feedback on behalf of your organisation?

Your organisation

13

Please select which chapter/s you would like to provide feedback on. You may provide feedback on as many or few chapters as you wish.

1. Transparency, communication, and stakeholder involvement in HTA, 2. Health technology funding and assessment pathways, 3. Methods for HTA for Australian government subsidy (technical methods), 4. Health technology funding and purchasing approaches and managing uncertainty, 5. Futureproofing Australia's systems and processes

14

Please select the topics within the chapter(s) you would like to provide feedback on. 1. Transparency, communication and stakeholder involvement in HTA

1.1. Transparency and communication of HTA pathways, processes and decisions, 1.2. Consumer, clinician and other stakeholder engagement and consideration in HTA, 1.3. First Nations people involvement and consideration in HTA, 1.4. State and territory government collaboration in HTA

15

Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways

2.1. Streamlining and aligning HTA pathways and advisory committees, 2.2. Proportionate appraisal pathways

16

Please select the topics within the chapter(s) you would like to provide feedback on. 3. Methods for HTA for Australian government subsidy (technical methods)

3.1. Determination of the Population, Intervention, Comparator, Outcome, 3.2. Clinical Evaluation Methods, 3.3. Economic evaluation

17

Please select the topics within the chapter(s) you would like to provide feedback on. 4. Health Technology funding and purchasing mechanisms and decisions

4.1. Approaches to funding or purchasing new health technologies, 4.2. Approaches to incentivise development of products that address antimicrobial resistance (AMR), 4.3. Understanding the performance of health technologies in practice

18

Please select the topics within the chapter(s) you would like to provide feedback on. 5. Futureproofing our systems and processes

5.1. Proactively addressing areas of unmet clinical need and gaps in the PBS, 5.2. Establishment of horizon scanning programs to address specific informational needs within HTA and the health system, 5.3. Consideration of environmental impacts in the HTA, 5.4. Mechanisms for continuous review and improvement, 5.5. Capacity and capability of the HTA system, 5.6. Strengthen international partnerships and work-sharing

21

Taking all Options within this section: 1.1. Transparency, communication and stakeholder involvement in HTA into account.

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

Mostly address the issue(s)

23.1

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

Positive

23.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Improvements to the HTA webpage including development of a dashboard

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

Positive

29.2

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

Positive

33

Taking all Options within this section: 1.3. First Nations people involvement and consideration in HTA into account.

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

Mostly address the issue(s)

34

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

If implemented well

35.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - First Nations peoples partnership in decision making

Positive

35.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Dedicated resource for HTA submissions and education

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)

40

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

Need to be implemented to be sure reforms don't delay access

41.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of central standardised data sharing system for utilisation and outcome data

Positive

41.2

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Increase opportunities for consultation and work sharing

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

46

Taking all Options within this section: 2.1. Streamlining and aligning HTA pathways and advisory committees into account.

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

Address some but not most of the issue(s)

48.1

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Pathway for drugs for ultra-rare diseases (Life Saving Drugs Program (LSDP))

Positive

48.2

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

Positive

48.3

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

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

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?

Address some but not most of 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

Positive

65.2

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

Positive

65.3

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

Alternative option 1: Introducing an optional resolution step before HTA committee consideration

Negative

65.4

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

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

Negative

65.5

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

Alternative option 3: Early Price negotiation

Negative

65.6

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

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

Positive

65.7

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Expanding resolution step to all relevant cost effectiveness submissions

Positive

65.8

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Development of a disease specific common model (reference case) for disease areas with high active product development

Negative

65.9

If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Decouple the requirement for the TGA Delegate's overview to support PBAC advice

Very positive

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)

It would be a disaster to expect price reduction for the sensible option of streamlining the cost minimization pathway. The purpose of this option should be to take unnecessary work and red tape out of the system.

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

This option is positive as long as the approach balances the incentives of the commonwealth and the sponsor and is not weaponized to push for lower prices. It should include an independent price arbitration process if the sponsor and the Commonwealth can not agree.

73