

Response

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Please publish my submission anonymously (personal and organisational names will be removed and the submission will be marked as "Name withheld") (Note: if you select this option and your submission contains identifying information, your submission may not be published).

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What is your name?

7

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

8.1

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

9

Are you making feedback on behalf of your organisation?

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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.

4. Health technology funding and purchasing approaches and managing uncertainty

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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

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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)

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

It is encouraging that bridging funding for earlier access to therapies of likely HATV and HUCN is being considered. However, it is discouraging that the funding and governance structure of a special funding program is outside the remit of the current HTA review.

The Government has in place excellent opportunities to fund development of innovative Australian medical device manufacturers. However, in the absence of bridging funding proposed in this review, Australian manufacturers must either seek further Government funding to support Australian roll-out and adoption, or first launch overseas where such bridging funding programs are in place. Unfortunately it often the latter that occurs, leading to overseas citizens experiencing the benefit of Australian innovation, while the Australian population waits.

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

Don't know

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

Don't know

105.3

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

Don't know

105.4

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

Don't know

105.5

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

Don't know

105.6

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

Neutral

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

Don't know

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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

The proposed program would benefit from additional consideration of the following:

- 1) Applicants should be allowed an opportunity to justify that their technology addresses a HUCN. A central body identifying areas of HUCN may not capture all opportunities in a priority list or via horizon scanning. Applicants, who include experts intimately involved in their area of clinical need, may identify opportunities that a central body would not.
- 2) It is my understanding that under HATV, therapies or therapeutic value would also include diagnostic devices. Clarification on this point would be appreciated.
- 3) The great majority of medical device manufacturers in Australia seek first regulatory clearance from a comparable overseas regulator, which expedites TGA review. Therefore, parallel application to MSAC and TGA is of little benefit since the MSAC review would continue long after TGA review. It is recommended that the MSAC application is allowed at the time of application to a comparable overseas regulator, while maintaining that any MBS listing would require ARTG listing first.
- 4) I am unclear how capped reimbursement would apply to medical devices. The cost-benefit decision to purchase capital medical equipment is directly impacted by the availability of reimbursement. If a hospital purchases equipment dependent on receipt of the reimbursement, what would happen when the cap is met? How would they know?

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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

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

The need for bridging funding coverage for earlier access to therapies of likely HATV and HUCN is immediate as Australia falls behind USA, Canada and Western European countries. Excluding such reform in this review delays implementation.

238.1

Under the subject 'Recognising competition between new health technologies that deliver similar outcomes', there are two options that provide different alternative mechanisms to address the issues that relate to them.

To what extent could the below different alternative options (if implemented) address the issues that relate to them? - Alternative option 1: In conjunction with options for proportionate assessment of cost-minimisation submissions, require offers of a lower price for health technologies that provide no added benefit

Don't know

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.

Don't know