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?
Jerome Higgins
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
MSD Australia
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.
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
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
4.1. Approaches to funding or purchasing new health technologies
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
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))
Neutral
48.2
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Vaccine pathway
Very 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
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
60
If you would like to expand on your answer above you can do so below -Vaccine pathway
The proposed streamlined vaccine pathway should be sufficiently flexible to accommodate new technologies. Whilst MSD supports the proposed streamlined Vaccine pathway (short term), MSD advocates for expanding the language in point 2. of this proposed pathway to include wording specific to novel technologies as follows: Horizon scanning for vaccines, and vaccine-like technologies that may require legislative changes, is established including appropriate stakeholders to ensure that ATAGI can be prepared to provide advice.
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
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**
Neutral
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**
Very 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
Don't know
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)
The appraisal process should be proportionate to the type of evaluation as proposed; however, competitor pricing should not be released until a positive recommendation is obtained. MSD agrees with the Reference Committee who identified that for low-risk applications, the appraisal process should be '"more flexible to ensure time and resources of Government, evaluators, and Sponsors is directed to the submissions where it is most beneficial' (Health Technology Assessment Policy and Methods Review - Consultation 2, p81). However, MSD has significant concerns regarding the proposal to share the price of the comparator with the Sponsor of the proposed therapy before PBAC consideration as it poses the risk of competitors exploiting the processes to gather market intelligence without any intention of listing. Therefore, MSD purports that Sponsors must receive a positive PBAC recommendation before receiving competitor pricing information. Unintended consequences: Releasing pricing information to competitors prior to a PBAC recommendation may impact the launch of new health technologies in Australia due to concerns regarding confidentiality.
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**
Although there may be efficiency benefits in the Sponsor obtaining early ESC advice before HTA committee consideration (Alternative Option 1), MSD does not support limiting the number of resubmissions to one. There are multiple instances where ESC advice was not supported by PBAC, so conducting this process early may not resolve key economic disputes.
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**

The proposed early resolution process (Alternative Option 4) should occur after HTA committee consideration but before advice is finalised. Current early re-entry pathways are working well and must be retained alongside any new early resolution mechanisms for technologies that address areas of HUCN.
MSD is supportive of early resolution pathways for HUCN after HTA committee consideration but before advice is finalised as per Alternative Option 4.
Different perspectives between MSD and the PBAC on clinical and economic uncertainties have been the key driver of submission churn. The PBAC has frequently adopted the most conservative, but not necessarily the most plausible, economic modelling assumptions regarding time horizon, extrapolation methods and treatment. This perspective was echoed by several stakeholders in Consultation 1, who noted that conservative adjustments during the evaluation process have resulted in multiple resubmissions, delaying access and increasing costs for Sponsors and the government.
In its current form, the proposal will not speed up access due to the lack of a separate and independent process to resolve disputes on key clinical and economic uncertainties, andmay have low uptake due:
1.The limit of one re-submission confers the PBAC excessive power in setting conditions that may be difficult or impossible to meet.
2.It is unclear how a resolution process of lasting up to 17 weeks would facilitate faster access than existing pathways.

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

Earlier and more frequent interactions with evaluators are much needed but the current case management role in Pricing Pathway A will need to be improved to achieve this.
MSD welcomes the opportunity for more interactions with evaluators. Currently the limited opportunity for Sponsors to address questions during the commentary response process can result in issues that have not been clarified by the time of PBAC consideration. This is particularly true for new disease areas, where treatment pathways and clinical considerations are not well understood. The lack of early and ongoing interactions between evaluators, committee members, Sponsors and other stakeholders contributes to submission churn and delays in access. This issue was highlighted by the Reference Committee, who noted that Sponsors frequently rely on the PBAC decision from their first submission as a form of early advice to inform the development of a more fulsome latter submission.
MSD also support resourcing a case manager to facilitate communication between MSD and the Department regarding key economic issues.

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?

Mostly address 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

Don't know

100

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

This option needs to include legislative change to the NHA definition of alternative therapies, otherwise it will not resolve the issue of comparator selection.
The Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee outline that '"the main comparator should be the therapy that prescribers would most replace with the proposed medicine'. However, the PBAC has frequently applied a lowest cost comparator approach based on its interpretation of the National Health Act (NHA), Section 101(3B). The Reference Committee also identified '"concerns about choice of comparator, and the different pricing-related implications and consequences that feed into the PBAC's HTA recommendation to the Government'. To address these concerns, MSD recommends legislative changes to the NHA definition of alternative therapies to incorporate the PBAC Guideline definition and aligned with the intent of the Strategic Agreement.
The lowest cost comparator approach means that PBAC decision making is not always based on the most clinically relevant comparator. This has the impact of undervaluing new innovations that should be compared to the therapy most likely to be replaced. Over time, this can erode pricing for entire classes of medicines or therapeutic areas leading to the Australian standard of care falling behind other similar nations and further disincentivise manufacturers from listing new medicines on the PBS, such as the recent example with Eli Lilly's OMVOH.

101

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

The discount rate should be lowered as recommended by the PBAC in 2022 to align with comparable international HTA countries. There is no need for further workshops.
MSD supports the PBAC advice that a lower discount rate should be considered alongside other relevant factors in HTA decision making. The discount rate should be informed by a social values framework so that discount rates reflect societal preferences and national priorities for healthcare. MSD supports maintaining flexibility in application of the discount rate across different types of technologies, in particular vaccines to ensure that the long term benefits are fairly factored into the cost effectiveness.
Unintended consequences
Given PBACs consideration of discount rate in July 2022, MSD supports inclusion of a lower base case discount rate of 3.5% (sensitivity at 5%) in PBAC guidelines, rather than further workshops which are likely to create administrative burden and further delay implementation.

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 some but not most 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 benefit

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

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

Alternative options 1 and 2 which require a lower price for medicines with no added therapeutic value must be removed from consideration as this stifles innovation and devalues patient benefits.
The option to 'œrequire offers of a lower price' is in direct conflict with shared goals of the HTA review and contradicts the price certainty clauses of the Strategic Agreement which outlines '"the Commonwealth will not pursue any additional PBS policies or measures to generate new price based savings from the innovative medicines sector during the Term without first consulting with Medicines Australia'. The HTA Review and this short public consultation does not constitute an appropriate consultation on such a significant policy.
Current cost-minimisation arrangements must be retained as they support innovation with no additional cost to government. This feature recognises that therapies deemed non inferior can have meaningful differences from a patient perspective in terms of side effect profiles, mode of administration and dosing regimen.
Imposing lower prices for cost-minimisation submissions discourages companies from introducing medicines that are not first-in-class or first-in-indication for Australia. This could lead to an increased risk of medicine shortages, delays in timely access to innovative treatments and limited choice for patients and clinicians.
This approach may be particularly detrimental for access to vaccines in Australia

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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

See above response to Option 1

111

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

The '"explicit disinvestment framework' should be re-framed as an explicit re-assessment framework with clear decision criteria against which technologies will be considered for continued funding or disinvestment.
MSD welcomes a '"systematic and enhanced, rapid' program to provide advice on funding and disinvestment of technologies. However, the focus on '"an explicit disinvestment framework' should be broadened to encompass funding of cost-effective technologies where there is unmet clinical need. The Commonwealth already has measures in place to '"disinvest' from technologies, such as statutory price cuts and a rapid post-market review framework (updated Feb'24).
The barriers for disinvestment should be set at a level at least as high as those for investment; e.g. levels of evidence such RCTs.
Re-assessment is particularly important for the NIP to ensure that the schedule continues to protect Australians from preventable diseases. The nationally negotiated price of some vaccines currently on the NIP were set over 10 years ago (with some prices set prior to the 2005 PBAC review of vaccines). There is currently no mechanism to adjust the nationally negotiated price to reflect increased manufacturing and distribution costs which have occurred since NIP listing without presenting a cost effectiveness argument to PBAC. This discourages Sponsors from continuing to supply the market when vaccines are not commercially viable, thus compromising the integrity of the NIP.

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

Don't know