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?
Sarah Bridge
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
Bayer Pharmaceuticals ANZ
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
15
Please select the topics within the chapter(s) you would like to provide feedback on. 2. Health technology funding and assessment pathways
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,5.3. Consideration of environmental impacts in the HTA,5.4. Mechanisms for continuous review and improvement,5.6. Strengthen international partnerships and work-sharing
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)
64
If you would like to expand on your answers above you can do so below:
65.1
If implemented, overall would these Options have a positive or negative impact on you (/your organisation)? - Case manager
Positive
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)
Very negative
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
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 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
67
If you would like to expand on your answer above you can do so below -Triaging submissions
Bayer supports in principle this option, however further clarity is required regarding; the pathway criteria, the level of information required by sponsors to facilitate triaging, and the options for sponsors to make submissions should they disagree with the determined pathway.
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)
Bayer supports streamlining cost-minimization submissions however not if this requires offering a lower price or incentives offers of a lower price as set out in Option 4.1. Bayer does not support sharing of price early in process prior to HTA committee consideration as this erodes pricing confidentiality.
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** Bayer is in principle supportive of introducing an optional resolution step after HTA committee consideration but before advice is finalised. We agree with other stakeholders that this approach requires further co-design and reconsideration of the proposed criteria for this option. The criteria to insist submissions are made to the PBAC and TGA at the same time is overly restrictive and fails to recognize that it is not always possible to submit to TGA and PBAC in parallel; the choice and speed of regulatory pathway is an important consideration and not necessarily under the decision-making authority of the Australian subsidiary of a sponsor company. While it is recognised multiple resubmissions are burden to all parties, Bayer suggests capping the maximum allowable number of submissions risks reducing patients access.
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
Noting that the above resolution step requires further co-design, Bayer is supportive of this being expanded to all cost-effectiveness submissions.
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
Bayer does not support this option and would agree with other stakeholders that is not required and will not deliver on reducing time to access for Australian patients or ensure our assessment processes keep pace with rapid advances in health technology. Seeking input from stakeholders to ensure the model is comprehensive in its representation of the disease area will require resources that could be better directed to other options designed to speed access. Where disease specific models have been developed in other jurisdictions, it has been difficult to create a model that captured sufficiently the complexity to enable use by multiple sponsors; this is especially problematic where parameters are different in relation to patient population, lines of therapy or disease stage. To accommodate parameter differences can require simplification assumptions that adds to parameter uncertainty and risks the full value of the therapeutic benefit not being captured. Where there is continued changes in disease management and/or standard of care; disease-specific common models will, without updates, become redundant.
75
If you would like to expand on your answer above you can do so below -Decouple the requirement for the TGA Delegate's overview to support PBAC advice
Bayer supports this option has the capacity to reducing time to access for Australian patients assuming in situations where PBAC would be minded to recommend, that this allows for post PBAC recommendation processes to be commenced while awaiting either the delegate's overview or ARTG listing.
76
If you would like to expand on your answer above you can do so below -Case manager
Bayer supports the concept of a case manager; however, the remit of this role should be co-designed with industry and other sponsors to ensure this role will add value. It will be important to take learnings from the use of the current case management approach used to progress pricing pathway A in order to enhance a case manager role for submissions. It is unclear whether this case manager would act as an end-to-end facilitator, most value would come from a single person facilitating communication and information sharing prior to submission and also to assist in progressing pricing.
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

Negative

98.2

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

Negative

98.3

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

Negative

100

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

This option requires further consideration and significant change. The selection of comparator should be based upon the principle of "the therapy most likely to be replaced in practice" regardless of the clinical claim being made. The current option proposed does not change current approach to comparator selection or address concerns with use of the lowest cost comparator (LCC).

Flow-on pricing impacts through reference pricing due to the PBAC's current application of Section 101(3B) of the National Health Act to cost-minimization submission, has the consequence of devaluing F1 through price erosion over time. Price erosion of F1 medicines risks access to future innovation in Australia.

Bayer supports Medicines Australia's recommendation for legislative change to amend the National Health Act to address issues with comparator selection.

101

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

This option requires significant change. Further consideration to reduce the discount rate is not required. Medicines Australia has already made a submission calling for the base case discount rate to be reduced from 5% to 1.5% in line with the discount rates of comparable countries. As proposed this option would further delay a decision on this topic.

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

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 negative

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

Neutral

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

Such a measure should not appear in the Reference Committee's final report. Price-reduction measures are outside the terms of reference for this Review. Implementation of such an option, risks fewer medicines coming to market and consequently less choice for patients and clinicians.

This approach ignores that two medicines with a similar efficacy or safety benefit may have other benefits that justify similar pricing rather than a lower price.

The Australian system already has many price controls, statutory price reductions, reference pricing and post-market reviews; it not necessary for this review to introduce new price saving or price reduction measures.

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

Such a measure should not appear in the Reference Committee's final report. Price-reduction measures are outside the terms of reference for this Review. Implementation of such an option, risks fewer medicines coming to market and consequently less choice for patients and clinicians.

The Australian system already has many price controls, statutory price reductions, reference pricing and post-market reviews; it not necessary for this review to introduce new price saving or price reduction measures.

110

If you would like to expand on your answer above you can do so below -Pricing offer (PO) and negotiation guidance framework

Such a framework should only be implemented if it will speed access and not create additional steps that slow this down. If this framework is to proceed it should be aligned with cost-effectiveness principles and co-designed with industry stakeholders.

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