Response

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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?

Julia Norman

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

AbbVie Pty Ltd

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

1.2. 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)

3.2. 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

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,5.5. Capacity and capability of the HTA system,5.6. Strengthen international partnerships and work-sharing

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)

28

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

AbbVie is supportive in principle but cautions that implementation and operationalisation will be critical to ensuring that the overall submission process is not slowed down: the pilot program should include ways of measuring this.

Consumers will require more clarity around what type of information they will be able to input, what information is considered valuable and the ways in which they can provide input.

Clarity is needed requiring how a commitment to acting on consumer input and feedback will be assured. Consumers will need to see evidence that it influences decision-making and what input is most informative for decision making in order for this to be a constructive component of the HTA process.

AbbVie would like to see the pilot program for patient involvement in PBAC meetings pave the way for Sponsor presence, to support greater transparency around decision making and the PBAC's assessment of consumer evidence and the value of broader qualitative evidence.

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

48.3

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

Don't know

61

If you would like to expand on your answer above you can do so below -Expanding role of PBAC

When read in isolation, this Option appears reasonable and focused on creating a more efficient HTA system through the streamlining and alignment of HTA pathways and committees. In principle, this could reduce time to access for patients and reduce submission inefficiencies for Sponsors, such as duplication of work and delays due to the misalignment of submission cycles across different bodies, an issue raised by a number of stakeholders through Consultation 1.

In principle, AbbVie is supportive of the streamlining and alignment of HTA pathways given the potential to reduce duplication and existing inefficiencies across current processes and pathways for all stakeholders. The triaging of submissions (2.1) will be an important Option to co-implement in order to support the expanded PBAC scope and will need to be co-designed with Industry in order to ensure it is fit-for-purpose. It is important that this approach is adequately resourced, without impacting existing cost-recovery arrangements, and tested prior to full implementation to ensure that it achieves the desired outcome of faster, more efficient pathways.

However, AbbVie would oppose an increased remit that would transform the PBAC into a decision-making body.

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)

65.2

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)

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

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

Negative

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

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)

AbbVie is supportive in principle of a streamlined pathway for cost-minimisation submissions, however believes it imperative that existing pathways for cost-minimisation submissions remain, as this provides flexibility for Sponsors for more complex cost-minimisation submissions and those not based on a claim of non-inferiority.

However, AbbVie does not support review via a streamlined cost-minimisation pathway being contingent on the acceptance of a 'œdiscounted cost-minimisation'. This risks cost-minimisation submissions turning into a procurement process, by removing all principles of HTA from the assessment of new technologies and incentivising/mandating discounts for therapies that are considered equivalent in terms of safety and efficacy.

AbbVie also has strong concerns regarding the proposal for early price-sharing prior to PBAC consideration. It is not possible to implement a set of caveats and restrictions to effectively prevent price-seeking behaviour. Given the majority of submission related costs have been incurred and company resource expended at this point, the small benefit to Sponsors is vastly outweighed by the potential risks.

As per AbbVie's Consultation 1 response, AbbVie also urges the Reference Committee to consider improvements to post-PBAC pricing governance so that PBS listings are not unnecessarily delayed due to inconsistent or unclear pricing methodology or interpretation. This would in turn support more timely access for patients.

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

As demonstrated by NICE's adoption of a common model for technology appraisal of Covid-19 medicines, the development of disease-specific common models is a complex endeavour and challenging to implement. Ongoing revision of these models is critical as standards of care evolve and the understanding of long-term disease outcomes changes based on emerging evidence: they must be dynamic and are therefore highly resource intensive.

Common economic models require a degree of flexibility in order to allow Sponsors to account for unique clinical features (treatment administration, benefit and risk profile) and demonstrate the value of a specific product. A non-specific model could simply be a 'œblunt economic tool' that doesn't effectively recognise or value innovation of either a major or incremental nature.

The development of disease specific common models should be considered in the broader context of other Options intended to support a proportionate approach to submission appraisal. AbbVie considers that given the resourcing and capacity challenges within the current system, time and effort would be more appropriately allocated to better support the implementation of other Options that will have a greater impact on improving timely access to medicines for patients.

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

AbbVie is supportive in principle as it will assist in resolving the issues relating to parallel processing and delivers on the HTA Review objective of improving timely access for patients.

This Option is expected to reduce delays to patient access by removing the requirement to provide a TGA Delegate's Overview at least one week prior to the PBAC meeting. Currently, Sponsors are required to delay lodging their PBAC submission by a 4-month cycle when a Delegate's Overview may be received shortly after a PBAC meeting, where the TGA Evaluation phase (Milestone 5) may already be complete.

To ensure further predictability around timing, consideration could be given to making PBAC review contingent on availability of the Clinical Evaluation Report following TGA evaluation phase at Milestone 5.

86.5

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

Positive

93

If you would like to expand on your answer above you can do so below -Develop an explicit qualitative value framework

AbbVie is supportive of the development of a qualitative value framework to facilitate greater transparency and consistency around how evidence beyond clinical effectiveness, cost-effectiveness and budget impact is factored into HTA decision making. It is a crucial component in taking a holistic approach to value assessment and ensuring that Australia's HTA system is aligned with broader societal preferences regarding spending on health care and access to new health technologies.

The value framework must be developed independently by a coalition of all relevant stakeholders, separate from the PBAC, in order to ensure objectivity and alignment to patient and broader societal values. Consultation across a broad range of stakeholders during development of the framework will be essential to ensure all potential value domains are considered and represented fairly.

The value framework should be developed within one year of the start of HTA reform implementation, as there are other elements of reform that will need to be informed by the framework. Once finalised, the value framework should be embedded in legislation to ensure there is no conflict with the NHA.

-The PBAC's use of a flexible and implicit willingness-to-pay threshold when considering submissions that present cost-effectiveness analyses is an element of the current HTA approach that is working well, and should be retained as a priority.

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 little or none 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

Very negative

98.3

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

Positive

102

If you would like to expand on your answer above you can do so below -Valuing overall

AbbVie is supportive of HTA committees giving consideration to the circumstances in which higher prices for health technologies is justified, however opposes the need to introduce any additional measures, beyond the existing pricing policies, to offset higher costs over time.

If, through a robust assessment of clinical and cost effectiveness, the PBAC considers a higher price is justified then this should be commensurate with additional conferred benefit and therefore not offset later in the product's lifecycle.

The circumstances in which higher prices for health technologies is justified should be at least in part informed by the explicit qualitative value framework (3.2), with any additional input sought needing to be representative of the Australian population and all relevant stakeholders to ensure all potential elements that could justify higher prices are considered and there is no selection bias.

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 little or none 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

Negative

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

105.6

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

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

110

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

AbbVie does not support this Option as a tool for enabling and expediting the previously elaborated on Options 4.1 'œDiscounted cost-minimisation' and 2.2 Streamlined pathways for cost-minimisation submissions.

Any pricing offer and negotiation guidance framework should be with the procedural purpose of providing clear instruction and guidance with respect to pricing methods and improving transparency and certainty for Sponsors by outlining grey areas and policy nuance that Sponsors may be unaware of.

AbbVie's Consultation 1 response made the pragmatic recommendation to reintroduce a pricing methods manual as previously used prior to 2014 to ensure transparency and predictability of negotiated PBS prices. Furthermore, where there are different interpretations between Sponsors and the Department of Health and Aged Care (DoHAC) around the PBAC's pricing recommendations, there should be a pathway to clarify these matters with PBAC in an expedited manner.

111

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

AbbVie opposes the implementation of a new, enhanced rapid re-assessment program. The recently updated PMR framework which outlines a faster, more efficient process for health technology re-assessment, on which stakeholders have already been consulted.

AbbVie strongly opposes the implementation of an explicit disinvestment framework. This poses unknown and potentially sizeable risk to Industry as the intended scope of post-listing reassessment has not been defined, despite the significant potential impact to Sponsors which range from being used as leverage in price-lowering negotiations to complete delisting of products and the associated impact on patients including transitioning to alternative treatments or compassionate supply or self-funding.

AbbVie notes that any framework would be more acceptable if there were a symmetric, equivalent proposal to increase investment where patient outcomes are more favourable than expected or treatments contribute to raising the standard of care for patients.

112

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

While AbbVie is, in-principle, supportive of the establishment of a bridging funding program, AbbVie strongly opposes any legislative change that would permit the PBAC to make conditional recommendations.

AbbVie proposes that the co-development of a workable framework for Managed Access Programs (MAPs) to ensure they are more feasible and implementable would be an appropriate alternative with legislative change not required, and instead could be managed within a Deed.

AbbVie recognises that the establishment of a bridging funding program could present a potential opportunity to improve time to access for specific health technologies by closing the funding gap between provisional TGA approval and PBS listing by allowing PBAC submissions to be made earlier based on Phase I/II data.

Industry/Sponsors must be involved as a key partner in the co-design of any bridging funding program to ensure that the process of applying for, granting of and transition to and from bridging funding for specific products takes into account supply chain timing and the transition of trial patients and does not have any negative or unintended consequences for stakeholders.