Health Technology Assessment Methods and Policy Review

Consultation 2 Response: February 2024

AbbVie Pty Ltd

Introduction

AbbVie Pty Ltd (hereafter AbbVie) is a global, research-based biopharmaceutical company committed to discovering, developing, and delivering innovative new medicines with distinct and compelling benefits for people. Our therapeutic focus areas include immunology, oncology, eye care, virology, and neuroscience. Globally, approximately 57 million people are treated with AbbVie products annually across 60+ conditions and live in more than 175 countries.

In Australia, more than 125,000 Australians currently benefit from our medicines. In the 2022-23 financial year there were over 2 million PBS prescriptions written for AbbVie products. In 2023, over 2,500 Australians received compassionate access to our medicines. AbbVie is a member of the industry representative body, Medicines Australia.

Executive Summary

As one of the key commitments in the Strategic Agreement between the Commonwealth and Medicines Australia, the HTA Review provides an opportunity to improve upon the performance of Australia's HTA system and the policies that support it through purposeful, well-considered reforms that lead to transformational change. It is incumbent upon all members of the healthcare ecosystem to engage deeply with the Review to ensure that opportunities are realised and that proposed changes are analysed with the ambition of ensuring Australian patients have timely access to the best health technologies available.

In this context, AbbVie has reviewed the HTA Review Committee's Options Paper in terms of whether the proposed Options for reform address the issues raised by stakeholders through Consultation 1 and are aligned with the overarching goals and objectives of the HTA Policy and Methods Review and National Medicines Policy. The HTA reforms must ensure that there is earlier and sustainable access for patients, without being at the expense of treatment choice or equity considerations. Earlier and sustainable access for patients will only be achieved if the reforms are also viable for manufacturers. Australia is a small market (representing <2%[1]) within a global context, therefore appropriate value recognition is imperative to ensure the future sustainability of the Australian medicines industry.

In our evaluation of the Options, AbbVie has also considered the questions posed regarding:

- whether the proposed Option/s will achieve the intended outcome
- what the potential impact on stakeholders may be, and
- any unintended outcomes or challenges stemming from the proposed Options.

Many of the proposed Options for reform do not contain adequate detail regarding the scope and plans for implementation to enable a full and rigorous appraisal of potential risks and benefits. Therefore, when it comes to implementation of the final recommendations, priorities and details must be discussed and negotiated with all stakeholders in a collaborative, co-design approach. This is critical to ensuring that the resulting policies, processes, and methods are in accordance with the Strategic Agreement's intent to strengthen Australia's medicines

[1] https://defense.info/wp-content/uploads/2020/02/Australias-Medical-Supply-Chain.pdf

ecosystem in order to deliver better health outcomes for patients and keep Australia a global priority for the launch of new and innovative medical treatments.

AbbVie considers the following Options are unacceptable as they are at odds with the overarching goals and objectives of the HTA Policy and Methods Review and National Medicines Policy and do not address the issues raised through Consultation 1. These Options will limit patient access to a range of treatment options, impede the launch of new treatments by creating an unsustainable pricing environment, and jeopardise ongoing access to treatments for Australian patients.

- 3.3 Economic evaluation: *Selection of the comparator*
- 4.1 Approaches to funding or purchasing new health technologies: *Recognising competition between new health technologies that deliver similar outcomes ("Discounted cost-minimisations")*
- 4.1 Approaches to funding or purchasing new health technologies: *Post-listing re-assessment of health technologies (including an explicit disinvestment framework)*
- 5.6 Strengthen international partnerships and work sharing: *Collaboration with international jurisdictions to deliver sustainable access to health technologies (joint purchasing groups)*

The HTA Review is not an opportunity to (re-)negotiate or implement price reduction measures to deliver savings on health expenditure; this falls outside the HTA Review Committee's Terms of Reference[2] as well as the terms of the current Strategic Agreement.[3] It is therefore AbbVie's expectation that the final report provided to Government as part of this Review will not make any recommendations that would breach the Strategic Agreement or be outside the Terms of Reference.

AbbVie considers that significant amendments are required to the scope and implementation of the following Options. In their current form these options will not deliver on the overarching goals described above. AbbVie has recommended amendments to these options to ensure there are no negative and unintended consequences for stakeholders.

- 2.1 Streamlining and aligning HTA pathways and advisory committees: *Expanding role of PBAC*
- 2.2 Proportionate appraisal pathways: *Streamlined pathways for cost-minimisation submissions*
- 2.2 Proportionate appraisal pathways: *Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN*
- 2.2 Proportionate appraisal pathways: *Development of a disease-specific common model for disease areas with high active product development*
- 4.1 Approaches to funding or purchasing new health technologies: *Bridging funding coverage for earlier access to therapies of HATV and HUCN*
- 4.1 Approaches to funding or purchasing new health technologies: *Pricing offer and negotiation guidance framework*

AbbVie is supportive, in principle, of the following Options as through robust consultation and appropriate implementation, they are likely to improve time to access for Australian patients and maintain Australia's attractiveness as a launch country for new health technologies.

[2] https://www.health.gov.au/sites/default/files/2023-03/health-technology-assessment-policy-and-methods-review-terms-of-reference.pdf
[3] Strategic Agreement https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf

- 1.2 Consumer, clinician and other stakeholder engagement and consideration in HTA: *Develop an engagement; Strengthen consumer evidence*
- 2.2 Proportionate appraisal pathways: *Decoupling the requirement for the TGA Delegate's Overview to support PBAC advice*
- 3.2 Clinical evaluation methods: *Develop an explicit qualitative value framework*
- 3.3 Economic evaluation: *Valuing overall*
- 5.1 Proactively addressing areas of unmet clinical need and gaps in the PBS: *Development of a priority list; Identification of therapies to meet priority list*
- 5.4 Mechanisms for continuous review and improvement: *Mechanism for continuous review and improvement of current HTA policies and methods*
- 5.5 Capacity and capability of the HTA system: *Improve HTA capacity and workforce in Australia*

AbbVie is committed to supporting the implementation of Options that will clearly solve for current issues and deliver on the shared goals between Industry and the Commonwealth through achieving timely access for patients and maintaining the attractiveness of Australia as a launch country for future health technologies.

1. AbbVie's Position

AbbVie has a steadfast and long-standing commitment to ensuring that Australians have timely, sustainable and equitable access to innovative and new medicines that improve health outcomes. As a company that provides medicines for many thousands of Australians, we are deeply engaged in the Health Technology Assessment (HTA) Policy and Methods Review and provide the following response to the second round of consultation.

The HTA Policy and Methods Review (HTA Review) is one of the key commitments in the Strategic Agreement between the Commonwealth and Medicines Australia[4] and provides an opportunity to improve upon the performance of Australia's HTA system and the policies that support it through purposeful, well-considered reforms that lead to transformational change.

Despite significant initiatives implemented over the last 30 years,[5] further progress is still required, with a recent analysis showing that only 24% of globally approved medicines were Pharmaceutical Benefits Scheme (PBS) listed in Australia from 2012-2021, and only 12% of new medicines were PBS listed in Australia within one year of global first launch.[6] Patients still wait 466 days on average for PBS access to a new medicine following ARTG registration[7] therefore it is imperative that Australia's HTA system evolves to:

- resolve the existing issues,
- be primed to ensure patients have both timely and equitable access to all future health technologies, and
- ensure the attractiveness of Australia as a first-launch country through fostering a sustainable medicines industry that recognises value through the entire product life cycle.

On this basis, following review of the Options Paper released by the HTA Review Reference Committee, AbbVie is concerned that a number of the Options proposed do not deliver against the stated objectives of the HTA Review, which were to identify features that:

- are working effectively
- may act as current or future barriers to earliest possible access
- may act as current or future barriers to equitable access
- detract from person-centeredness
- may be creating perverse incentives

and will not support the transformation of Australia's HTA system that is required. It's important to note that the majority of Options proposed lack sufficient detail around implementation to enable a full assessment of potential risks and benefits. The absence of comprehensive referencing to supporting evidence has also made it challenging to understand the rationale behind the Options and identify which gaps identified in Consultation 1 are being addressed.

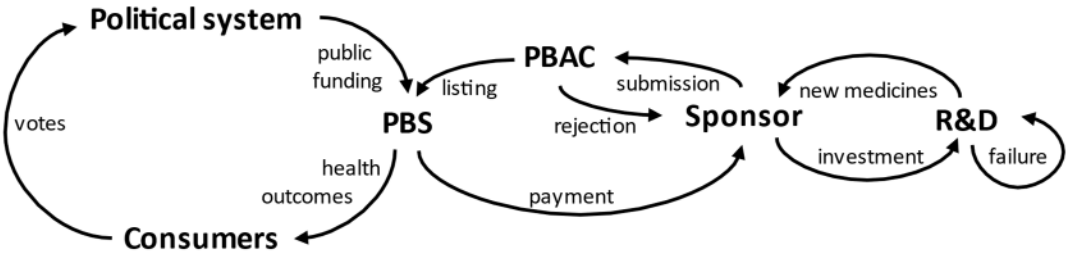
Certain changes proposed in the Options Paper, if implemented, could result in an ecosystem that is unviable for Sponsors to launch in and maintain patient access, leading to limited treatment options for clinicians and patients,

[4] Strategic Agreement https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf
[5] GSK https://au.gsk.com/media/6259/gsk-viiv-the-pbs-in-australia-feb-2018.pdf
[6] PhRMA https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report
[7] Medicines Australia https://www.medicinesaustralia.com.au/publications/medicines-matter/

and a treatment landscape that lags behind other comparable jurisdictions. With Australia being a comparatively small market within the global context, accounting for only 2% of the global pharmaceutical market and importing over 90% of medicines,[8] the wholesale devaluation of medicines within our single payer system has the potential to drive global organisations to prioritise launching new health technologies in other markets. The Industry has already delivered over $12 billion in budget savings through successive Strategic Agreements[9] which have contributed to Australia having some of the lowest prices for medicines in the world. AbbVie therefore cannot accept proposals within the Options Paper that lead to the further devaluing of medicines and reduce Australia's launch viability.

Improving time to access for Australian patients can be achieved through an efficient HTA system which appropriately values medicines, so that Sponsors are able to bring new technologies to patients as early as possible and continue to make them available post-launch. The complex dynamics and inextricable links which exist between all stakeholders within the Australian medicines' ecosystem are depicted in **Figure 1**. This diagram clearly illustrates the importance of the Australian Government's continued investment in medicines, with the downstream impacts of reduced spend being fewer reimbursed product launches and decreased research investment in Australia, both of which lead to a detrimental impact on health outcomes for patients. This is in direct conflict with the vision and aims of Australia's National Medicines Policy 2022 which is *to achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment*, including *support for a positive and sustainable policy environment to drive world-class innovation and research, including translational research.*[10]

Figure 1 The key dynamics and stakeholders in Australia's medicines ecosystem[11]



The Options Paper appropriately places a strong emphasis on measures to improve speed to access to innovative or disruptive health technologies through recommendations related to cost-effectiveness submissions for health technologies of high added therapeutic value (HATV) in areas of high unmet clinical need (HUCN). There is inadequate detail provided in the report to define how treatments of HATV and HUCN will be determined, however it is expected that these treatments will only apply to a very small number of Australian patients.

Contrastingly, a set of Options that would negatively affect the majority of Pharmaceutical Benefits Advisory Committee (PBAC) submissions (> 50%),[12] has been proposed for health technologies submitting on a cost-

[8] https://defense.info/wp-content/uploads/2020/02/Australias-Medical-Supply-Chain.pdf
[9] https://www.medicinesaustralia.com.au/media-release/governments-savings-on-pbs-far-outweighs-investment-in-new-medicines/
[10] https://www.health.gov.au/sites/default/files/2022-12/national-medicines-policy.pdf
[11] Image used with permission: Christian Sellars, Feb 2024.
[12] MAESTrO Database. Analysis of PBAC submissions and their related outcomes & timelines. December 2020; https://www.aph.gov.au/Document Store.ashx?id=95119276-cde3-4aa0-b784-8773ff3692a2&subId=693442. In the period 2010-2019, n=216 (ever CEA) vs n=266 (initial CMA).

minimisation basis, with cost-reduction measures embedded within the pathways proposed to accelerate patient access. Requiring or incentivising Sponsors of health technologies deemed to provide equivalent efficacy and safety to offer a lower price in order to be reviewed via a streamlined HTA pathway is not aligned with the fundamental objectives of the HTA Review, nor the overarching goals shared between the Industry and Commonwealth.[13] The Option proposing *"discounted cost-minimisations"* is not aligned with the assessment of comparative value, therefore represents a concerning deviation from the tenets of HTA on which funding of new technologies should be based. Mandating or incentivising companies to accept a price below parity at launch, along with accelerated price erosion over time due to reference pricing mechanisms could result in Australia being deprioritised or excluded from the launch sequence for new health technologies. This would mean a contraction in access for Australian patients, who benefit from being able to access a range of treatments with varied mechanisms of action, modes of administration and dosing schedules based on patient preference, treatment response and tolerability. Over time, this may also mean that Australian clinical practice will not be able to keep pace with evolving international consensus guidelines, and Australian patients would not be able to achieve the same treatment targets and goals as patients in countries where health technologies are valued appropriately.

Another Option focused on cost-reduction is the proposal for post-listing re-assessment of health technologies against an explicit disinvestment framework (4.1). While it is lacking in detail, the proposal of a new post-listing reassessment process is duplicative, given the recently revised post-market review (PMR) framework.[14] An explicit disinvestment framework, without any equivalent proposal to increase investment where patient outcomes are more favourable than expected, is asymmetric and lessens Australia's attractiveness as a market for new health technologies. The potential for re-assessment via a disinvestment framework to be leveraged to drive price reductions in order to avoid de-listing represents a perverse incentive and is not aligned with the goals of the HTA Review and could have broader implications when considered alongside other Options described below. Importantly, AbbVie notes that this Option does not address the potential impact to patients and how continuity of treatment will be managed in the event of a product no longer being funded through the PBS.

The Options Paper also did not propose an acceptable solution to the long-standing issue of comparator selection. The misalignment between the definition of comparator in the PBAC Guidelines and the PBAC's interpretation of "alternative therapy" in the National Health Act 1953 (Section 101(3B)) was identified as a specific method-related challenge creating perverse incentives in the Consultation 1 Report[15] and the immediate implication that *in practice this means that alternative therapies that are not the therapy most likely to be replaced may be relevant to the assessment for the purposes of pricing* was articulated in the Draft paper: HTA Methods: Economic Evaluation.[16] However, the Options paper did not propose any amendments to the legislation to address this issue and as such it will continue to impact the ability of new treatments to launch and maintain access in Australia and limit patient access to a range of treatment options.

The possible expansion of the PBAC's authority is posed throughout the Options Paper, including an expanded scope for the PBAC to make recommendations across a broader range of funding pathways, potential legislative

[13] Strategic Agreement https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf
[14] https://www.pbs.gov.au/info/reviews/subsidised-medicines-reviews#framework
[15] https://www.health.gov.au/resources/publications/health-technology-assessment-policy-and-methods-review-consultation-1-report
[16] https://www.health.gov.au/sites/default/files/2024-01/hta-policy-and-methods-review-draft-paper-hta-methods-economic-evaluation.pdf

change to permit the PBAC to apply conditionality to recommendations, and a framework for disinvestment and possible de-listing. These Options include:

- 2.1 Streamlining and aligning HTA pathways and advisory committees: *Expanding role of PBAC*
- 4.1 Approaches to funding or purchasing new health technologies: *Bridging funding coverage for earlier access to therapies of HATV and HUCN*
- 4.1 Approaches to funding or purchasing new health technologies: *Post-listing re-assessment of health technologies (including an explicit disinvestment framework)*

While AbbVie would, in principle, support an expansion of scope to make recommendations across multiple funding pathways, the PBAC must remain an independent advisory body that provides advice to the Minister for Health as to which products should be funded based on a comparative assessment of efficacy, safety and cost effectiveness. It is critical that the Minister for Health remains the final decision-maker for all determinations pertaining to the funding of health technologies in Australia.

Overall, some of the Options presented throughout the Paper appear to proliferate, rather than streamline, current processes while also introducing additional rigidity and stringency into the system. the Options presented to improve upon existing early re-entry pathways (*2.2*) place restrictions on resubmissions, which will leave Sponsors optionless in the event of being unable to satisfactorily address deficiencies or when pricing negotiations reach an impasse. A set of pathways that result in treatments exiting the HTA review cycle with no pathway for resubmission is clearly not in the best interests of patients. It is unclear how these proposed pathways deliver on the goals of the HTA review when they could ultimately lead to reduced access.

It is therefore AbbVie's position that the Options Paper presents a set of recommendations with varying potential to deliver the transformative system-level change required to meet the overarching objectives of the review. AbbVie is supportive, in principle, of a number of constructive Options that have been proposed that relate to enhanced consumer input, equitable access to health technologies, an explicit qualitative value framework, decoupling of regulatory advice from PBAC submission consideration and improving HTA capacity. These potential benefits are contrasted with the significant risks associated with Options addressing *proportionate appraisal pathways* (*2.2*) and *approaches to funding or purchasing new health technologies* (*4.1*), which serve to contain PBS spend instead of being founded on the principles of HTA. AbbVie is unable to accept these Options, as they will not improve the timeliness of patient access and maintain Australia's attractiveness as a first-launch country for new health technologies.

Note: The written response prepared by AbbVie focuses on the Options which may present the greatest risk, or may lead to greatest potential benefit, for all relevant stakeholders. AbbVie has also responded to the online survey; a table summarising AbbVie's survey responses can be found in ***Appendix 1****.*

2. Options not supported by AbbVie

AbbVie considers the following Options unacceptable as they:

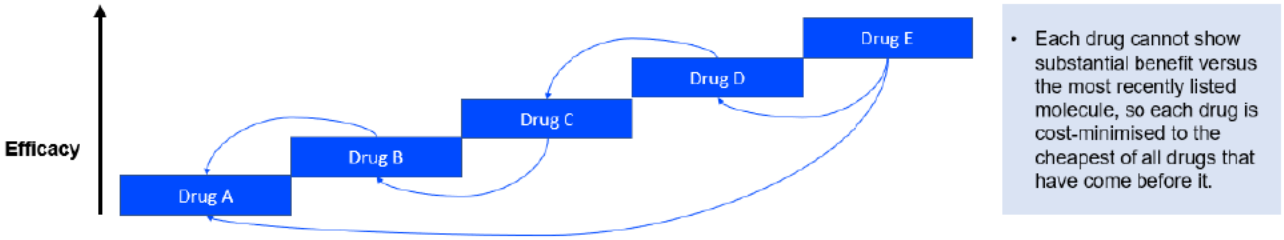
- Are not aligned with the overarching goals of the HTA Policy and Methods Review and National Medicines Policy;
- Do not solve for the issues identified in the first round of consultation of this review; and/or
- Have negative and/or unintended consequences for stakeholders.

These Options will limit patient access to a range of treatment options, impede the launch of new treatments by creating an unsustainable pricing environment, and jeopardise ongoing access to treatments for Australian patients.

Subject:	3.3 Economic evaluation
Option:	Selection of the comparator
Comments:	

- The issue of comparator selection was raised in the Industry and AbbVie's response to Consultation 1 of this HTA Review and was identified as a specific method-related challenge creating perverse incentives in the Consultation 1 Report.[17]
- The Options Paper recommends the development of guidelines to distinguish between comparator selection for submissions claiming superiority vs non-inferiority, however this will not resolve the existing comparator issues as long as Section 101 (3B) of the National Health Act (NHA) 1953 remains unchanged. The PBAC Guidelines on Comparator Selection state that the comparator should be the therapy most likely to be replaced in clinical practice and the legislation must be changed to reflect how this may apply.
- Without legislative change, the PBAC will continue to make recommendations based on the interpretation of NHA 1953 Section 101(3B) i.e. *where a health technology is non-inferior to alternative therapies, funding can only be recommended on the basis that it will cost no more than the cheapest of those alternative therapies* as being the lowest cost comparator (LCC).

Figure 2 The "daisy chain" effect of requiring each new medicine to cost-minimise to the LCC



- Because of the conservatism and high evidentiary requirements of the PBAC, it is highly challenging to establish clinical superiority of new medicines over existing ones, despite a new medicine conferring a small yet meaningful incremental therapeutic benefit that may address a specific unmet patient need. As a result, new medicines are price-referenced to the LCC, which in most instances is a multi-branded F2 medicine that has been subject to significant price erosion through statutory price reductions and price disclosure cuts.

[17] https://www.health.gov.au/resources/publications/health-technology-assessment-policy-and-methods-review-consultation-1-report

The LCC price is then flowed onto existing price-linked medicines in F1 through reference pricing. The use of LCC therefore does not reflect the improvements in patient outcomes associated with incremental innovation over time and undervalues new medicines, resulting in the "daisy chain" effect depicted above in **Figure 2.**

Recommendations and considerations:

- **AbbVie opposes this Option and upholds that amendments to the legislation are required to rectify the existing issues, as per the following possible Options:**
    - **Option 1:** Section 101(3B) of the NHA 1953 should be repealed in its entirety to enable the selection of comparator(s) to be based on the PBAC Guidelines Section 1.1.3 i.e. *the medicine/intervention most likely to be replaced in clinical practice*. For indications where multiple therapeutic options are available, this would allow for recommendations to be made based on a derived weighted price.
    - **Option 2:** Addition of the following clause to Section 101(6) of the NHA 1953: *'In situations where there are multiple alternative therapies, Section 101(3B) need not apply'*. This would enable better recognition of the value of incremental innovation through appropriate comparator-based pricing and effectively de-link the "daisy chain" illustrated in Figure 2, such that F1 medicines are no longer linked through reference pricing to older, F2 medicines.
- The PBAC's current interpretation of the NHA's definition of "alternative therapy" for pricing purposes is not aligned to HTA best-practice and contributes to making Australia increasingly unviable with respect to launch and maintaining patient access through immediate and downstream pricing impacts.

Subject:	4.1 Approaches to funding or purchasing new health technologies
Option:	Recognising competition between new health technologies that deliver similar outcomes

Comments:

- The Options Paper proposes what is effectively a "discounted cost-minimisation" pathway, whereby new treatments demonstrating equivalent efficacy and safety would either be required or incentivised to provide a discount on price relative to already PBS-listed equivalent drugs in order to be PBS listed. **AbbVie fully opposes this Option for both mandated and incentivised discount proposals** and notes that this Option, when considered in conjunction with Options *2.2 Streamlined pathways for cost-minimisation submissions and 4.1 Pricing offer and negotiation guidance framework,* highlights proposals that focus on securing discounted prices for new medicines at the expense of patient access.
- The justification for this Option is based on the perceived absence of normal free market forces driving competitive price reduction for Commonwealth-funded health technologies. This Option attempts to mimic an unsubsidised market, however this is not appropriate given a) healthcare is not a free-market due to heterogeneity of patients, providers, and varying access to healthcare, b) competitive forces still exist between therapies considered equivalent in efficacy and safety and drive market share, and c) Australia is a single-payer market with a price setting system that delivers net prices that are lower than nearly every other system in the world, whether market-driven or price-controlled.
- Furthermore, HTA is an assessment of the incremental benefit that a particular technology confers to the patient, and if two medicines confer similar benefit there is no HTA-based reason justifying a lower price.
- This Option does not solve for any of the issues that have been identified through the HTA Review process in terms of proportionate HTA assessment or economic evaluation; in fact, this was not raised in any of the

draft HTA Expert Papers published as part of this Review. Instead, it proposes a procurement-like process that delivers on cost-reduction. The proposal to "incentivise" Sponsors to offer a price discount in order to list on the PBS could effectively result in a tendering process and cannot be accepted.

- Sequential new listings of comparable therapies at a price below the lowest cost comparator (LCC) would result in accelerated price erosion through cascading price reductions triggered by cumulative reference price cuts as each new treatment establishes a new LCC which is flowed-on to all comparable F1 products. The rate of price erosion would be further intensified through existing anniversary and first new brand statutory price reductions, as well as price disclosure cuts impacting F1 treatments with pricing links to products in F2. As the price reduction measures outlined in the latest Strategic Agreement have already been implemented, the additional price erosion that will occur through this Option will result in the Commonwealth deriving additional cost-savings beyond what was agreed to by Industry.
- This Option fails to recognise patient heterogeneity, and that it is important for patients and their clinicians to have access to a range of treatment options to choose from in order to optimise patient outcomes. The availability of different treatment options is critical in many chronic conditions to account for progressive and lifelong disease courses, loss of response over time, and need for different modes of administration to support equity for rural and remote patients. The implementation of a discounted cost-minimisation approach may serve as a barrier to global organisations launching new treatments in Australia, due to the unviability of launching below price parity and inability to accept the uncertainties related to price erosion from further new entrants post-launch, especially as Australian prices are already amongst the lowest in the world.
- Ongoing and deepening undervaluing of new health technologies is not in the best interests of patients or maintaining the attractiveness of Australia as a first-launch country through sustainable pricing. This Option fails to address the objectives of the HTA Review in terms of reducing time to access for patients or securing Australia's position as an early-launch country as it will instead reduce treatment options for patients through having an effect on the ability of global organisations to bring new products to Australia or maintain them in the market post-launch.

Recommendations and considerations:

- **AbbVie opposes this Option proposing a "discounted cost-minimisation" pathway and calls for it to be removed entirely. Australia's HTA system must continue to allow cost-minimisation submissions with listing at price parity to the comparator.** With >50% of submissions recommended by the PBAC between 2010-2019 being on a cost-minimisation basis, the potential impact of this Option on Australia's treatment landscape is far-reaching and likely to disproportionately impact treatments for chronic disease, which represent >75% of cost-minimisation submissions.[18] This is misaligned with the Government's focus on improving the prevention, management and treatment of chronic conditions.[19]
- It is important that the Government acknowledges that it is in patients' best interest to have access to a range of treatment options, and that this ensures security of supply. This Option would only serve to increase the risk of products not launching or de-listing due to unacceptable post-launch pricing erosion.

[18] MAESTrO Database. Analysis of PBAC submissions and their related outcomes & timelines. December 2020; https://www.aph.gov.au/DocumentStore.ashx?id=95119276-cde3-4aa0-b784-8773ff3692a2&subId=693442. In the period 2010-2019, n=216 (ever CEA) vs n=266 (initial CMA).
[19] https://www.health.gov.au/topics/chronic-conditions/what-were-doing-about-chronic-conditions;
https://www.health.gov.au/sites/default/files/documents/2019/09/national-strategic-framework-for-chronic-conditions.pdf

Subject:	4.1 Approaches to funding or purchasing new health technologies
Option:	Post-listing re-assessment of health technologies (including an explicit disinvestment framework)

Comments:

- The Options Paper proposes the introduction of a systematic and enhanced, rapid reassessment program that (re-) reviews health technologies to provide funding/purchasing and disinvestment advice to the HTA committee. **AbbVie opposes the implementation of a new re-assessment program** given 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** as this could potentially allow the PBAC to compel disinvestment, rather than provide advice to the Minister for Health as per their current remit.
- Notwithstanding the above, this Option 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.
- For patients, it is not just a "perceived" loss of clinical choice as stated in the Options Paper, disinvestment that removes a particular health technology from the market unequivocally means fewer options for patients. While the Options Paper notes the impact to stakeholders broadly, due to a "range of expectations and sensitivities", AbbVie is deeply concerned about the lack of detail on consideration given so far to the patient impact.
- Post-listing re-assessment against an explicit disinvestment framework alongside other proposed Options may lead to significant negative consequences across multiple stakeholders. Specifically, if implemented in conjunction with *2.1 Expanding the role of the PBAC* and *4.1 Approaches to Managing Uncertainty (legislative change to enable conditional listings on the PBS)* this would transform the PBAC or future HTA body into a decision-making body. AbbVie considers decision making must remain with the Minister for Health as removing medicines from public access must be subject to Ministerial scrutiny.

Recommendations and considerations:

- **AbbVie opposes the implementation of a new, enhanced rapid re-assessment program. AbbVie strongly opposes the implementation of an explicit disinvestment framework.**
- There is already a new PMR framework, which can systematically review therapies post-launch. There is therefore no need to establish a separate program for the re-assessment of funded health technologies nor develop an explicit disinvestment framework against which to measure them, especially without any 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.

Subject:	5.6 Strengthen international partnerships and work sharing
Option:	Collaboration with international jurisdictions to deliver sustainable access to health technologies

Comments:

- AbbVie is supportive of measures that deliver sustainable access to health technologies; however, the measures must be sustainable for all stakeholders, including manufacturers. The proposal to *form joint-common markets… to increase market share and purchasing power* does not represent a sustainable or viable option for manufacturers and would result in new health technologies not launching in Australia.

The fact that *Australian access to innovative medicines can depend on prices of certain innovative medicines being subject to special pricing arrangements* is acknowledged by the Commonwealth in the latest Strategic Agreement,[20] with current agreements and processes serving this purpose effectively.

- As acknowledged in the Options Paper, *Australia is a small market within a global context*. Australia has also been reported as having some of the lowest prices in the world compared to similar jurisdictions.[21, 22] If the Australian government were to join a buying group with other markets, it is expected that manufacturers would need to waive rights to special pricing arrangements among the payers within the buying group to generate a common price. This would have detrimental international reference pricing implications that is expected to be unviable for manufacturers.

Recommendations and considerations:

- **AbbVie strongly opposes this Option as it would impede products launching in Australia. The proposal is also in direct conflict with the Commonwealth's commitment to maintaining confidential pricing.**

[20] Strategic Agreement https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf
[21] https://www.sciencedirect.com/science/article/pii/S0277953620302616
[22] https://www.medicinesaustralia.com.au/media-release/australia-has-lowest-prices-for-new-medicines-uk-govt/

3. Options requiring significant amendments

AbbVie considers that significant amendments are required to the scope and implementation of the following Options as in their current form they:

- Will not deliver on the overarching goals of the HTA Policy and Methods Review and National Medicines Policy;
- May not fully address the issues identified in the first round of consultation of this review.
- May have negative and/or unintended consequences.

While many of these options reflect recommendations put forward by stakeholders and represent an opportunity for meaningful benefit to patients, AbbVie has recommended amendments to these options to ensure there are no negative and unintended consequences for stakeholders.

Subject:	2.1 Streamlining and aligning HTA pathways and advisory committees
Option:	Expanding role of PBAC

Comments:

- The Options Paper proposes that, in the short-term, the PBAC's advisory role be further expanded to enable it to make HTA recommendations to the Minister for Health and Aged Care for a broader range of health technologies i.e. provide advice across funding programs including NIP, LSDP, PBS, MBS (co-dependent technologies), NHRA (medicines not services).
- 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.
- However, the proposed expansion of the PBAC's role, when considered together with language in Option *4.1 Approaches to Managing Uncertainty (legislative change to enable conditional listings on the PBS),* could have unintended consequences. AbbVie's position is that it is imperative that the PBAC (or future appropriate resourced HTA committee) remains an advisory body whose remit is to provide advice, not make decisions on the funding of health technologies. The PBS is a public health program and therefore any decision-making body must be accountable to the Australian public.

Recommendations and considerations:

- **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.** Being a statutory committee, the PBAC is not subject to the same level of scrutiny and accountability to the Australian public regarding health technology funding decisions. This would

inherently limit expression of sentiment by the general public as the PBAC is not subject to political forces in the same manner as a member of parliament or political party representative. It is critical that the Minister for Health remains the final decision-maker for all determinations pertaining to the funding of health technologies in Australia.

Subject:	2.2 Proportionate appraisal pathways
Option:	Streamlined pathways for cost-minimisation submissions

Comments:

- AbbVie's response to Consultation 1 of the HTA Review described the existing cost-minimisation pathways as working well, as the economic and budget-impact modelling requirements are reduced relative to a cost-effectiveness submission, but still permit Sponsors to make clinical claims beyond non-inferiority based on improved efficacy, safety, modes of administration or other improvements that matter to patients.
- The proposal for a streamlined cost-minimisation pathway for all treatments considered clinically non-inferior will mean that these submissions undergo an abbreviated submission process and be fast-tracked to the price agreement stage. Taken in isolation, this accelerated pathway aligns with the HTA review's overarching goal of improving time to access for patients through expedited review and early launch compared to global counterparts.
- A streamlined cost-minimisation pathway would be consistent with the expedited cost-minimisation pathways for treatments considered non-inferior in other comparable jurisdictions, namely the UK (NICE) and Singapore (ACE).[23]
- However, if considered with other proposals presented in the Options Paper, this would fast-track submissions into pricing negotiations where the Sponsor is either required or incentivised to offer a price below LCC (according to Options Paper *4.1 "Discounted cost-minimisation"* proposal and the PBAC's interpretation of "alternative therapy" as per NHA 1953 Section 101(3B)). **AbbVie does not support this.**

Recommendations and considerations:

- **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 "discounted 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.

[23] https://www.health.gov.au/sites/default/files/2024-01/hta-policy-and-methods-review-draft-paper-hta-methods-economic-evaluation.pdf

- 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.

Subject:	2.2 Proportionate appraisal pathways
Option:	Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN

Comments:

- The proposed eligibility criteria for early resolution specifies that the submission must have been lodged with the PBAC within 6 months of receiving first regulatory approval from a comparable overseas regulator (FDA/EMA). Mandating such a narrow window relative to overseas agencies is not practical given the difference between TGA and PBAC evaluation timeframes (14 vs 4 months respectively), timing of availability of internal Clinical Study Reports to inform a PBAC submission, and challenges around timing for submission of consumer comments. At a minimum, a broader window for submission following the first overseas regulatory approval is required. However to avoid the criteria being so restrictive that virtually no drug qualifies, it would be more appropriate to remove any timing-related criteria and make early resolution pathways available to all therapies of HATV in areas of HUCN.
- The Options Paper proposes four alternative options that do not appear to present significant improvement compared to existing early re-entry pathways, although the faster facilitated resolution-like pathway proposed in Alternative Option 4 (17 vs the current 34 weeks) could support earlier access for patients. All four of the alternative options impose restrictions on Sponsors undertaking a resubmission in the event that perceived deficiencies/technical concerns cannot be resolved. AbbVie asserts that there should be no pathway in the HTA system which would leave Sponsors without an option to resubmit in the event of a PBAC rejection.
- Alternative option 3 is the only pathway that proposes an "early price negotiation" step which introduces the final negotiated price into the consideration/assessment of the submission and economic model post-ESC evaluation and ahead of consideration by the HTA committee. This undermines the HTA process and, in a similar vein to other Options already discussed, presents as a procurement-like process rather than being an assessment of cost effectiveness.
- AbbVie notes that the key objective for PBS Stage 2 process improvements, a reduction in the number of resubmissions by 50%, has not yet been achieved.[24] While in principle, stringent re-entry pathways could reduce the number of resubmissions through increased opportunity for dialogue and issue resolution during the submission process, the unintended consequence of these inflexible pathways is that Sponsors may be left in an untenable position where they must decide between accepting a sub-optimal recommendation or exit the submission process permanently. Neither of these outcomes delivers on the goals of improving patient access or enhancing Australia's attractiveness as an early-launch country.

Recommendations and considerations:

- **AbbVie is supportive in principle of there being additional early resolution mechanisms/pathways for Sponsors, providing current re-entry pathways are retained. However, AbbVie is opposed to any**

[24] DoHAC https://www.health.gov.au/resources/publications/national-medicines-policy?language=en

proposed pathways which remove or minimise process elements that provide flexibility for Sponsors, namely the ability to undertake a resubmission.

- Any new pathways that seek to improve upon existing early re-entry must ensure that flexibility for Sponsors is preserved, and that it remains at the Sponsor's discretion as to whether or not they undertake a resubmission.

Subject:	2.2 Proportionate appraisal pathways
Option:	Development of a disease-specific common model for disease areas with high active product development

Comments:

- As demonstrated by NICE's adoption of a common model for technology appraisal of Covid-19 medicines,[25] 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 "blunt economic tool" that doesn't effectively recognise or value innovation of either a major or incremental nature.
- The use of a common model in conducting PMRs may potentially result in increased transparency for Sponsors, however Sponsors and other stakeholders must be able to have early input into model design, which is likely to result in a protracted, cyclical process which would not be conducive to the efficient and rapid conduct of PMRs as per the recently revised PMR framework.

Recommendations and considerations:

- 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** such as those described elsewhere in AbbVie's response.

Subject:	4.1 Approaches to funding or purchasing new health technologies
Option:	Bridging funding coverage for earlier access to therapies of HATV and HUCN

Comments:

- This Option proposes to "*Establish bridging funding through a capped special funding program (separate and distinct from the PBS special appropriations) or legislate to enable conditional listings on the PBS.*"
- 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

[25] https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisal-guidance/Updating-technology-appraisal-recommendations-for-COVID-19-medicines-finalised-process.docx

I/II data. The opportunity for earlier PBS-listing via a bridging funding program should be based on the expected value for a given treatment, and not incentivise or require Sponsors to offer a lower price.

- The alternative option presented – *legislate to enable conditional listings on the PBS* – could allow the PBAC to impose conditions on recommendations, with the risk that listing conditions may be unreasonable and data collection requirements not feasible for Sponsors and put ongoing patient access at risk.

Recommendations and considerations:

- **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.
- 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.

Subject:	4.1 Approaches to funding or purchasing new health technologies
Option:	Pricing offer and negotiation guidance framework

Comments:

- The Options Paper describes that the proposed pricing offer and negotiation framework may be designed to apply to *all health technologies submitted for HTA evaluation, health technologies submitted for HTA evaluation on a cost-minimisation basis, or specific health technologies that meet defined criteria,* and will *account for the comparative/incremental health benefit of the health technologies compared to existing available subsidised products.* The Options Paper also refers to Germany as an example of where more explicit guidance is provided to Sponsors around the *expectations and/or requirements for lower prices for health technologies that are evaluated on a cost-minimisation basis and provide only marginal (or no) added clinical benefit vs existing treatments.*
- The introduction of a pricing offer and negotiation guidance framework will only be useful if it is developed with the intent of reducing the amount of time spent on the post-recommendation negotiation process and time to listing. Industry has previously advocated for greater pricing method transparency and consistency however this Option, when considered in conjunction with Options *2.2 Streamlined pathways for cost-minimisation submissions and 4.1 "Discounted cost-minimisation",* both of which AbbVie opposes, brings into sharp focus proposals set on securing discounted prices for new medicines and reducing the cost of the PBS and does not address the issues raised relating to timeliness of access as part of Consultation 1 of this review.

Recommendations and considerations:

- **AbbVie does not support this Option as a tool for enabling and expediting the previously elaborated on Options *4.1 "Discounted 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.

4. Options supported in principle by AbbVie

The below options are supported by AbbVie, in principle, as through robust consultation and appropriate implementation, have the potential to:

- Contribute to achieving the overarching goals of the HTA Policy and Methods Review and National Medicines Policy;
- Solve for the issues identified by stakeholders in the first round of consultation of this review; and/or
- Be unlikely to result in negative and/or unintended consequences.

Subject:	1.2 Consumer, clinician and other stakeholder engagement and consideration in HTA
Options:	Develop an engagement framework Strengthen consumer evidence

Comments:

- The proposed development of a consumer engagement framework may provide a greater opportunity to strengthen clinician and patient input into submissions and represents further progress towards a person-centred approach to HTA.
- This may be a significant ask of patients and patient advocacy groups (PAGs). There may be a degree of distortion towards patient groups who are well resourced and already mobilised being able to contribute significantly greater input.

Recommendations and considerations:

- **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.

Subject:	2.2 Proportionate appraisal pathways
Option:	Decoupling the requirement for the TGA Delegate's Overview to support PBAC advice

Comments:

- With respect to Category 1 and Category 2 submissions, the PBAC submission cycles and TGA milestones are currently sub optimally aligned to maximise the opportunity that parallel processing presents for improving timely access for patients.
- This 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.

Recommendations and considerations:
- **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. - 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.

Subject:	3.2 Clinical evaluation methods
Option:	Develop an explicit qualitative value framework
Comments:	
- An explicit qualitative value framework has the potential to address some of the issues stemming from the implicit elements that exist within the HTA submission and consideration process by concomitantly increasing transparency and reducing perceived subjectivity. The explicit nature of the value framework is key in order to increase transparency for all stakeholders around what the value elements considered are, how they inform deliberations and the overall impact they have on PBAC decision making. - This framework would also provide a basis for Sponsors to demonstrate the unique value of a specific product (including in specific populations), however will not lead to improved patient access and Australia's attractiveness for new health technologies unless there is a corresponding willingness to invest more in new technologies that deliver against broader patient and societal value elements. - The formalisation of an explicit qualitative value framework is consistent with international HTA best practice, with the draft Expert Paper on Clinical Evaluation Methods in HTA describing their use by expert committees and organisations including NICE, ICER, SMC and ISPOR.[26]	
Recommendations and considerations:	
- **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, as per the Clinical Evaluation Methods in HTA Expert Paper.[23] - Critically, 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. - Not discounting the need for robust consultation, elements relating to the domains that should be part of the framework may include: wider societal benefits (e.g. non-patient outcomes), patient and carer experience (e.g. improvements in convenience and adherence), treatment choice (e.g. alternative mechanism of action or mode of administration), equity (e.g. reduces geographical inequity if hospital admission not required), and real option value (e.g. life-extending treatments may allow for additional treatment options in the future). - While the Options Paper makes specific mention that there will be no pre-weightings or scores to allow flexibility for the deliberation process itself to add value to the decisions, a score or ranking method to	

[26] https://www.health.gov.au/sites/default/files/2023-10/hta-policy-and-methods-review-draft-paper-clinical-evaluation-methods-in-hta.pdf

collect quantitative information could, over time, generate an informative dataset on PBAC decision making. Sponsors could therefore make better-informed decisions regarding the prioritisation of evidence generation activities to ensure specific value domains are addressed in PBAC submissions.

- 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 *National Health Act*.
- 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, as detailed in AbbVie's response to Consultation 1. AbbVie believes the current implicit and flexible threshold should be retained as a priority, as it allows for the ICER threshold to be considered in light of the value elements which would comprise the explicit qualitative value framework such as contextual issues, equity, and person-centredness, providing there is a commitment to consider higher ICER values for treatments that perform well against the value framework.

Subject:	3.3 Economic Evaluation
Option:	Valuing overall

Comments:

- The Options Paper recommends conducting workshops to understand if and where it may be reasonable for HTA committees to accept higher prices for health technologies, including *what measures would be appropriate to offset the higher costs over a product's lifecycle*.
- 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.
- Products in Australia already experience significant price erosion over their life cycle through anniversary and first new brand statutory price reductions, reference pricing mechanisms, as well as price disclosure cuts impacting F2 products. As the original assessment of cost-effectiveness for health technologies does not account for price erosion through the product lifecycle, treatments essentially become more cost-effective over time, rendering additional offset measures unnecessary.

Recommendations and considerations:

- **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.**
- 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.

Subject:	5.1 Proactively addressing areas of unmet clinical need and gaps in the PBS
Options:	Development of a priority list Identification of therapies to meet priority list

Comments:

- AbbVie is concerned that a priority list of areas of HUCN could negatively impact submissions for other health technologies which are ranked as lower priority. Australia's medicines funding budget is not capped, therefore this would not be an appropriate approach to adopt if used to prioritise which therapeutic areas and treatments to fund.

Recommendations and considerations:

- **AbbVie's position is that a priority list should be created and maintained for the purpose of forward-focused horizon scanning only,** and not be related to any value and/or funding decisions. This would present an unacceptable level of risk for Sponsors and patients, particularly if this led to the deprioritisation of what would be considered "non-priority" treatments. It is vitally important that there is sufficient capacity within the HTA evaluation process to adopt an "and" not an "or" approach to the consideration of submissions.
- The potential for company-specific pipeline discussions should be explored in order to truly adopt a forward-focused approach to understanding future health technologies and to support operational and capacity planning. AbbVie would welcome the opportunity to enter into an open dialogue at regular cadence with the PBAC and DoHAC on pipeline technologies.

Subject:	5.4 Mechanisms for continuous review and improvement
Option:	Mechanism for continuous review and improvement of current HTA policies and methods

Comments:

- The Options Paper proposes the implementation of a program of continuous review and improvement for current HTA policies and methods. This program is described as one which would be transparent, with predictable timeframes for reviews, and informed by international best practice as well as internal and external consultation.
- This option also suggests that HTA Guidelines, including the PBAC Guidelines, could be used as 'living guidelines' which can be continuously updated.

Recommendations and considerations:

- **AbbVie agrees in principle that the continuous evaluation of Australia's HTA policies and methods is required** in order to keep pace with our rapidly changing landscape in terms of health technologies, evidence bases, and assessment methods.
- **AbbVie also supports in principle the features proposed for any future HTA policies and methods continuous review and improvement program**, and specifically considers robust internal and external consultation to be crucial. This will provide key stakeholders, including Sponsors, the opportunity to provide input into improving the policies, processes, capabilities and methods with which they work .
- AbbVie notes that the concept of "living guidelines" may be particularly useful in allowing Australia to keep pace with technology and methodology changes. However, it is essential that robust consultation and consideration of changes is undertaken on an ongoing basis.
- This section of the Options Paper also describes the current state for PMRs, PBS metrics, and recent process improvement initiatives, yet is silent on how these specific elements could be improved. AbbVie

believes that effective and regular reporting of PBS and PBAC metrics as key performance indicators (KPIs) is vital to ensure that any changes to HTA policies and methods are having an impact. This should include changes recommended and implemented from this HTA Review.

Subject:	5.5 Capacity and capability of the HTA system
Options:	Improve HTA capacity and workforce in Australia

Comments:

- Many of the Options proposed throughout this options paper will require additional capacity in the HTA system to perform additional roles. For example, the proposed approaches to triaging submissions and setting up a single point of contact for HTA in Australia will require reallocation and an increase to existing resources.
- The Options Paper proposes to improve HTA capacity and workforce in Australia through the support of students to undergo formal training and internships. AbbVie notes that several members of the Medicines Industry currently support and fund similar programs, contributing to the development of HTA knowledge and competencies in Australia. For example, many Sponsors operate internship programs or support local health economic research through scholarships such as the Macquarie University Australian Pharmaceutical Scholarship (MUAPS) Program.[27]

Recommendations and considerations:

- **As capacity will be fundamental to the successful implementation of many of these Options, AbbVie supports the proposal to improve HTA capacity and workforce in Australia** and considers that industry is a key partner in achieving this goal. Industry can share insights and successes from prior programs and could also be involved in designing and executing future scholarships, internships, and training programs. HTA capacity and capability building should not incur additional costs to industry through changes to current cost-recovery arrangements.

[27] Macquarie University Australian Pharmaceutical Scholarship Program (MUAPS). Available at: https://www.mq.edu.au/__data/assets/pdf_file/0005/1275989/MUCHE-MUAPS-brochure-2023.pdf

5. Final Remarks

The HTA Review, one of the key commitments in the Strategic Agreement between the Commonwealth and Medicines Australia,[28] provides a unique opportunity to improve upon the performance of Australia's HTA system and the policies supporting it. This can only be achieved through purposeful, well-considered reforms that focus on accelerating patient access and maintaining Australia's attractiveness as a first-launch country for new health technologies without resulting in negative and/or unintended consequences for stakeholders.[29]

AbbVie is in principle supportive of Options which raise and strengthen the consumer, i.e. patient, carer and clinician voice in the HTA process, and place a greater emphasis on the importance of incorporating broader patient and societal values into the evaluation of new health technologies however this must not be at the expense of speed to listing. The key to achieving this will be in the implementation of a number of these Options, including broad and comprehensive consultation with relevant stakeholders, and ensuring that the appropriates KPIs and measures are in place to assess the success of their implementation.

Subsidising new life-saving and life-improving therapies should be viewed as the investment that it is, reaping broad societal benefits as demonstrated in the 2019 research paper: Measuring the Impact of Pharmaceutical Innovation in Australia 1998–2018, authored by economist, Professor Frank Lichtenberg. The paper showed that PBS-listed pharmaceutical innovation improves patient outcomes, reduces hospital demand, and is cost-effective.[30] While focused on cancer medicines, the findings and concepts are applicable to any treatment that generates improvements in health outcomes.

To date, Industry has delivered over $12 billion in budget savings through successive Strategic Agreements[31] with the result that Australia has some of the lowest prices for medicines in the world. While this is beneficial for the Australian government, further erosion of price will endanger the viability of the industry in the AU market. While PBS expenditure has grown in nominal terms by $3 billion over 10 years, it has decreased from 20% to 17% of overall healthcare expenditure.[32] Government scrutiny of PBS spending is focussed on growth in the costs rather than the efficiency and value delivered through Australia's HTA system. A more appropriate measure of the overall impact of the Government's investment in medicines on the PBS would be examining expenditure in terms of the health benefits delivered (e.g. comparing total costs with national health targets).

AbbVie upholds that the allocation of funds and investment in the PBS should be concordant with the health outcomes it delivers, therefore the introduction of additional reforms to limit spending through Options focused on price reduction and cost-containment is both counterproductive and damaging for the Australian medicines industry. The (re-)negotiation or implementation of price reduction measures to deliver savings on health expenditure falls outside the HTA Review Committee's Terms of Reference[33] as well as the terms of the current Strategic Agreement.[34] AbbVie's expectation that the final report provided to Government as part of this Review

[28] Strategic Agreement https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf
[29] https://www.health.gov.au/sites/default/files/2023-03/health-technology-assessment-policy-and-methods-review-terms-of-reference.pdf
[30] Measuring the Impact of Pharmaceutical Innovation in Australia 1998–2018: https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2020/11/Med-Aus-Lichtenberg-Report-12pg-Booklet.pdf
[31] https://www.medicinesaustralia.com.au/media-release/governments-savings-on-pbs-far-outweighs-investment-in-new-medicines/
[32] https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/06/Funding-Innovative-Medicines-1.pdf
[33] https://www.health.gov.au/sites/default/files/2023-03/health-technology-assessment-policy-and-methods-review-terms-of-reference.pdf
[34] Strategic Agreement https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf

will not make any recommendations that would breach the Strategic Agreement terms or be outside the Terms of Reference.

Many of the proposed Options for reform will require significant discussion and negotiation with all stakeholders in a collaborative, co-design approach in order to determine how the final recommendations are prioritised and implemented in order to deliver the best possible outcomes for Australian patients and uphold the sustainability of the Australian medicines ecosystem. AbbVie remains committed to this process through supporting the implementation of a subset of Options, as described above, that deliver on the goals of the HTA Review by achieving timely access for patients and maintaining the attractiveness of Australia as a launch country for all health technologies.

Appendix 1

	Overall, to what extent could the options (if implemented) address the issues that relate to them? *(completely/mostly/ some but not most/little or none/don't know)*	Expand on answer	If implemented, would the Options have a positive or negative impact on your organisation? *(very negative/ negative/neutral/positive/very positive/don't know)*	Expand on answer	Do you have any further comments or concerns to add specific to this topic that should be considered? (Including intended consequences or overlooked considerations)	To what extent could the alternative options (if implemented) address the issues that related to them? *(significant/ moderate/ limited/not at all/don't know)*	What comments do you have on the relative strength and weaknesses of these potential reform options?	Which of the proposed reform options do you think offers greatest scope to improve the HTA process?	Why?
1. Transparency, communication, and stakeholder involvement in HTA									
1.1 Transparency and communication of HTA pathways, processes and decisions	-	-			-				
Publish plain language summaries			-	-					
Improvements to the HTA webpage including development of a dashboard			-	-					
1.2 Consumer, clinician and other stakeholder engagement and consideration in HTA	**Mostly**	**As per response**			**As per response**				
Develop an engagement framework			**Positive**	-					
Strengthen consumer evidence			**Positive**	-					
1.3 First Nations people involvement and consideration in HTA	-	-			-				
First Nations people partnership in decision making			-	-					
Dedicated resource for HTA submissions and education			-	-					
1.4 State and territory government collaboration in HTA	-	-			-				
Development of central standardised data sharing system for utilisation and outcome data			-	-					
Increase opportunities for consultation and work sharing			-	-					
Health technologies that are jointly funded by the Commonwealth and state and territory governments			-	-					
2. Health technology funding and assessment pathways									
2.1 Streamlining and aligning HTA pathways and advisory committees	-	-			-				
Pathway for drugs for ultra-rare diseases (LSDP)			-	-					
Vaccine pathway			-	-					

Expanding role of PBAC			Negative	As per response					
Unified HTA pathway for all health technologies with Commonwealth funding			-	-					
2.2 Proportionate appraisal pathways	Some but not most	-			As per response				
Triaging submissions			-	-					
Streamlined pathway for cost-minimisation submissions (therapies not claiming a significant improvement in health outcomes or reduction in toxicity)			Negative	As per response					
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	-		Limited	As per response	None in current form	As per response
- Alternative option 2: Introducing an optional resolution step before HTA committee consideration, with additional post committee resolution			Negative	-		Limited	As per response		
- Alternative option 3: Early Price negotiation			Negative	-		Limited	As per response		
- Alternative option 4: Introducing an optional resolution step after HTA committee consideration but before advice is finalised			Negative	-		Moderate	As per response		
Expanding resolution step to all relevant cost effectiveness submissions			-	-					
Development of a disease specific common model (reference case) for disease areas with high active product development			Negative	As per response					
Decouple the requirement for the TGA Delegate's overview to support PBAC advice			Positive	As per response					
Case manager			-	-					
3. Methods for HTA for Australian Government Subsidy (technical methods)									
3.1 Determination of the Population, intervention, Comparator, Outcome	-	-			-				
Increased early stakeholder input			-	-					
Increased transparency for stakeholders			-	-					
Updated guidance			-	-					
3.2 Clinical evaluation methods	-	-			-				
Overarching principles for adopting methods in Australian HTA			-	-					
Methods for the assessment of non-randomised and observational evidence			-	-					
Methods for the assessment of surrogate endpoints			-	-					

Generate a curated list of methodologies that are preferred by decision-makers, in collaboration with evaluation groups and sponsors			-	-					
Develop an explicit qualitative value framework			Positive	As per response					
Therapies that target biomarkers (e.g. tumour agnostic cancer therapies, therapies that target particular gene alterations)			-	-					
Pharmacogenomic technologies			-	-					
3.3 Economic evaluation	Little or none	-			As per response				
Selection of the comparator			Very negative	As per response					
Valuing of long-term benefits			-	-					
Valuing overall			Positive	As per response					
4. Health technology funding and purchasing approaches and managing uncertainty									
4.1 Approaches to funding or purchasing new health technologies	Little or none	-			-				
Recognising competition between new health technologies that deliver similar outcomes									
- Alternative option 1: "discounted cost-minimisation" required			Very negative	-		Not at all	As per response	Neither	As per response
- Alternative option 2: "discounted cost-minimisation" incentivised			Very negative	-		Not at all			
Investigate further options to address budget impact implications of high-cost/high impact health technologies			-	-					
Pricing offer (PO) and negotiation guidance framework			Negative	As per response					
Post-listing re-assessment of health technologies			Very negative	As per response					
Approaches for managing uncertainty - bridging funding coverage for earlier access to therapies of likely HATV and HUCN			Negative	As per response					
Approaches for managing uncertainty - revised guidance on the uses of different managed entry tools			-	-					
4.2 Approaches to incentivise development of products that address AMR	-	-			-				
HTA Fee exemptions for products that address AMR			-	-					
HTA Policy and Guidance changes for products that address AMR			-	-					
Funding and reimbursement-related changes to support availability of antimicrobials			-	-					
4.3 Understanding the performance of health technologies in practice	-	-			-				
Oversight – reforms to optimise access to and use of RWD in HTA			-	-					

Develop a strategic approach to increase confidence, awareness, and acceptance of cross-jurisdictional and cross-sectoral RWD access and use in HTA			-	-					
Data infrastructure			-	-					
Methods development			-	-					
Develop Guidance framework			-	-					
Collection of utilisation and outcome data for provisionally listed health technologies			-	-					
5. Futureproofing Australia's systems and processes									
5.1 Proactively addressing areas of unmet clinical need and gaps in the PBS	-	-			-				
Development of a priority list			**Positive**	**As per response**					
Identifying therapies to meet priority list (horizon scanning)			**Positive**	**As per response**					
Early assessment and prioritisation of potentially promising therapies			-	-					
Proactive submission invitation and incentivisation			-	-					
Early PICO scoping			-	-					
5.2 Establishment of horizon scanning programs	-	-			-				
Horizon scanning for advanced therapies (including high cost, HSTs funded through the NHRA) and other potentially disruptive technologies			-	-					
Horizon Scanning to meet priority areas (including addressing equity and HUCN)			-	-					
Horizon Scanning to help operational and capacity planning for HTA and health systems			-	-					
5.3 Consideration of environmental impacts in the HTA	-	-			-				
Environmental impact reporting			-	-					
5.4 Mechanisms for continuous review and improvement	-	-			-				
A program of continuous review and improvement for current HTA policies and methods			**Positive**	**As per response**					
5.5 Capacity and capability of the HTA system	-	-			-				
Improve HTA capacity and workforce in Australia			**Positive**	**As per response**					
5.6 Strengthen international partnerships and work-sharing	-	-			-				
Harmonisation of HTA evaluations			-	-					
Work sharing for individual submissions			-	-					
Collaboration with international jurisdictions to deliver sustainable access to health technologies			**Very negative**	**As per response**					