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23 February 2024

MSD submission to the HTA Policy & Methods Review – Consultation 2

MSD welcomes the opportunity to provide feedback on the *HTA Review - Consultation 2: options paper* currently being considered to strengthen Australia's Health Technology Assessment (HTA) system.

The HTA Review is an important milestone to deliver on the Minister's stated vision of bold and ambitious reform for HTA and align Australia's HTA framework with the objectives contained in the National Medicines Policy.

MSD supports many of the proposals put forward in the options paper (see Table 1). However, MSD strongly opposes mandating upfront price discounts for cost-minimisation submissions as proposed in *Option 4.1: Recognising competition between new health technologies that deliver similar outcomes.* Issues of pricing, as proposed in this option, are clearly outside the scope of the reform agenda. This proposal will hinder the Commonwealth's ability to deliver on its shared goals with Medicines Australia for the HTA Review, outlined in the Strategic Agreement, to reduce time to access and maintain the attractiveness of Australia as a first launch country.[1]

MSD strongly supports the development of a broader qualitative value framework (Option 3.2). An Australian social value framework, like that included in NICE's methods and process manuals, [2] is required to provide guidance for advisory committees when making judgements about the equitable distribution of resources. These principles can also inform decision-makers so that judgements on important HTA issues mentioned in the options paper better reflect society's preferences for healthcare.

MSD endorses the position put forth by Medicines Australia (MA) in their submission to Consultation 2. Furthermore, MSD emphasises the importance of faster access to new health

[1] Australian Government (2021). Strategic Agreement - Clause 5.1. Department of Health. https://www.pbs.gov.au/general/medicines-industry-strategic-agreement-files/MA-Strategic-Agreement-Signed.pdf

[2] NICE (2024). The principles that guide the development of NICE guidance and standards. https://www.nice.org.uk/about/who-we-are/our-principles

technologies. Our submission aims to offer ways to reduce the access gap and increase the availability of innovative treatments to Australians.

The body of MSD's submission discusses options that should either not be retained or require amendments to achieve their intended purpose. Table 1 summarises our positions on what MSD considers are the key options.

Table 1. MSD's position on key options proposed in Consultation 2.

Options to be retained	• Expanding the role of the PBAC (2.1) • Unified HTA pathway for all health technologies with Commonwealth funding (2.1) • Decouple the requirement for the TGA Delegate's overview to support PBAC advice (2.2) • Develop an explicit qualitative value framework (3.2) • Bridging funding coverage for earlier access to therapies (4.1) • Revised guidance on the uses of different managed entry tools (4.1) • Early PICO scoping (5.1) • Consideration of environmental impacts in the HTA (5.3)
Options to be removed	• Recognising competition between new health technologies that deliver similar outcomes (4.1)
Options to be amended	• Vaccine pathway (2.1) • Early resolution mechanisms (2.2) • Streamlined pathway for cost-minimisation submissions (2.2) • Case Manager (2.2) • Selection of the comparator (3.3) • Valuing of long-term benefits (3.3) • Post-listing re-assessment of health technologies (4.1) • Horizon scanning (5.2) • A program of continuous review and improvement (5.4)

MSD is dedicated to contributing to this important review process and supporting the development of a stronger, more effective and equitable HTA system.

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Options for reform to be removed due to unintended consequence or perverse incentives

4.1 Approaches to funding or purchasing new health technologies:

Recognising competition between new health technologies that deliver similar outcomes: 'require offers of a lower price' or 'accept offers of a lower price'.

Alternative options 1 and 2 which require a lower price for medicines with no added therapeutic value must be removed from consideration as this stifles innovation and devalues patient benefits.

The option to "require offers of a lower price" is in direct conflict with shared goals of the HTA review[3] and contradicts the price certainty clauses of the Strategic Agreement which outlines 'the Commonwealth will not pursue any additional PBS policies or measures to generate new price based savings from the innovative medicines sector during the Term without first consulting with Medicines Australia'.[4] The HTA Review and this short public consultation does not constitute an appropriate consultation on such a significant policy.

Current cost-minimisation arrangements must be retained as they support innovation with no additional cost to government. This feature recognises that therapies deemed non inferior can have meaningful differences from a patient perspective in terms of side effect profiles, mode of administration and dosing regimen.

Although this perspective was echoed by multiple industry stakeholders in their submissions to consultation 1,[5] it was not captured in the Consultation 1 Summary Report or the Consultation 2 options paper. As none of the stakeholder recommendations from Consultation 1 suggested lower prices for cost-minimisation submissions[6] it is unclear why this option is now being considered. Australia already has multiple pricing policies (e.g., F1/F2, Anniversary price cuts) that result in price erosion over time. It is not appropriate to overlay additional pricing policies that are adopted in some other markets.

Unintended consequences:
Imposing lower prices for cost-minimisation submissions discourages companies from introducing medicines that are not first-in-class or first-in-indication for Australia. This could

[3] Australian Government (2021). Strategic Agreement - Clause 5.1: The Commonwealth and Medicines Australia shared goals
[4] Strategic Agreement - clause 7.3: Price certainty
[5] HTA Review - Consultation 1 submissions from Abbvie (p8), Pfizer (p9), MA (p16)
[6] HTA Review - Consultation 1 Summary Report, Appendix 5

lead to an increased risk of medicine shortages, delays in timely access to innovative treatments and limited choice for patients and clinicians.

This approach may be particularly detrimental for access to vaccines in Australia. It will discourage Sponsors of second to market vaccines from commercialising the vaccine, potentially limiting the National Immunisation Program (NIP) to only one brand. This compromises security of supply, which is a key strategic priority in the National Immunisation Strategy.[7]

Furthermore, for some innovative vaccines which have the potential to offer benefits over existing vaccines, PBAC approval based on cost minimisation is the most likely outcome, due to challenges generating evidence required to show clinical superiority. For instance, for pneumococcal disease, pneumococcal conjugate vaccine 13-valent (PCV13) was cost minimised to the earlier 7-valent PCV7 due to lack of clinical outcomes, despite having significantly broader coverage. However, the low disease incidence meant that a clinical outcomes trial was not feasible.

This pattern has continued with the approval of PCV15 and PCV20 in paediatrics. If higher valency vaccines are required to take an additional reduction on the nationally negotiated price with the potential for further reductions during the tender process, it is likely that companies will not seek reimbursement in Australia. As a result, Australians will be denied access to the most innovative vaccines as diseases evolve.

Options for reform which require amendment

2.1 Streamlining and aligning HTA pathways and advisory committees:

Vaccine pathway (short term)

The proposed streamlined vaccine pathway should be sufficiently flexible to accommodate new technologies.

Whilst MSD supports the proposed streamlined Vaccine pathway (short term), MSD advocates for expanding the language in point 2. of this proposed pathway to include wording specific to novel technologies as follows (MSD recommendations in *italics*):

> Horizon scanning for vaccines, *and vaccine-like technologies that may require legislative changes,* is established including appropriate stakeholders to ensure that ATAGI can be prepared to provide advice.

[7] National Immunisation Strategy for Australia 2019-2024, Department of Health, Australian Government, https://www.health.gov.au/sites/default/files/national-immunisation-strategy-for-australia-2019-2024_0.pdf

Monoclonal antibodies (mAbs) for respiratory syncytial virus (RSV) have been accepted by many international NITAGs for inclusion in their NIPs, including in Canada. However, in Australia, vaccine-like therapies such as mAbs are out of scope to be considered by ATAGI for NIP inclusion and legislative changes are required in the National Health Act to amend ATAGI's scope. This will lead to delayed access to efficacious vaccine-like agents in Australia compared to similar HTA countries, even with the proposed streamlined vaccines pathway.

Unintended consequences:
If the vaccines pathway does not accommodate new technologies such RSV monoclonal antibodies, there will be delays in access to these technologies in Australia.

2.2 Proportionate appraisal pathways:

Streamlined pathway for cost-minimisation submissions

The appraisal process should be proportionate to the type of evaluation as proposed; however, competitor pricing should not be released until a positive recommendation is obtained.

MSD agrees with the Reference Committee who identified that for low-risk applications, the appraisal process should be '*more flexible to ensure time and resources of Government, evaluators, and Sponsors is directed to the submissions where it is most beneficia*l' *(Health Technology Assessment Policy and Methods Review - Consultation 2, p81)*.

However, MSD has significant concerns regarding the proposal to share the price of the comparator with the Sponsor of the proposed therapy before PBAC consideration as it poses the risk of competitors exploiting the processes to gather market intelligence without any intention of listing. Therefore, MSD purports that Sponsors must receive a positive PBAC recommendation before receiving competitor pricing information.

Unintended consequences:
Releasing pricing information to competitors prior to a PBAC recommendation may impact the launch of new health technologies in Australia due to concerns regarding confidentiality.

Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN

The proposed early resolution process (Alternative Option 4) should occur after HTA committee consideration but before advice is finalised. Current early re-entry pathways are working well and must be retained alongside any new early resolution mechanisms for technologies that address areas of HUCN.

MSD is supportive of early resolution pathways for HUCN after HTA committee consideration but before advice is finalised as per Alternative Option 4.

Different perspectives between MSD and the PBAC on clinical and economic uncertainties have been the key driver of submission churn. The PBAC has frequently adopted the most conservative, but not necessarily the most plausible, economic modelling assumptions regarding time horizon, extrapolation methods and treatment. This perspective was echoed by several stakeholders in Consultation 1, who noted that conservative adjustments during the evaluation process have resulted in multiple resubmissions, delaying access and increasing costs for Sponsors and the government.[8]

Although there may be efficiency benefits in the Sponsor obtaining early ESC advice before HTA committee consideration (Alternative Option 1), MSD does not support limiting the number of resubmissions to one. There are multiple instances where ESC advice was not supported by PBAC, so conducting this process early may not resolve key economic disputes.

MSD also advocates for maintaining the current early re-entry pathway for cost-effectiveness analyses in the event of an interim period where an early resolution pathway is trialled for areas of HUCN.

Unintended consequences:

In its current form, the proposed early resolution mechanism will not speed up access due to the lack of a separate and independent process to resolve disputes on key clinical and economic uncertainties. This proposed option is likely to have low uptake due to:

1. The limit of one re-submission confers the PBAC excessive power in setting conditions that may be difficult or impossible to meet.
2. It is unclear how a resolution process of lasting up to 17 weeks (HTA cycle length) would facilitate faster access than existing pathways. Currently Applicants who proceed down the early re-entry pathway are eligible for PBAC consideration at the immediate next meeting, whilst applicants who procced down the early resolution pathway are considered out-of-session before the next meeting.

Case Manager

Earlier and more frequent interactions with evaluators are much needed but the current case management role in Pricing Pathway A will need to be improved to achieve this.

MSD welcomes the opportunity for more interactions with evaluators. Currently the limited opportunity for Sponsors to address questions during the commentary response process can result in issues that have not been clarified by the time of PBAC consideration. This is particularly true for new disease areas, where treatment pathways and clinical considerations are not well understood. The lack of early and ongoing interactions between evaluators, committee members, Sponsors and other stakeholders contributes to submission churn and delays in access. This issue was highlighted by the Reference Committee, who noted that

[8] HTA Review - Consultation 1 - Summary report, p25

Sponsors frequently rely on the PBAC decision from their first submission as a form of early advice to inform the development of a more fulsome latter submission.

MSD also support resourcing a case manager to facilitate communication between MSD and the Department regarding key economic issues.

This would have expedited access to an innovative therapy for first-line head and neck cancer. In this situation, a major reason that the therapy was not recommended by the PBAC at its first consideration was that MSD's model had not factored in the health benefits of a second-line treatment comparator. MSD became aware of the issue in the evaluator's commentary (Week 10), by which time it was too late to update the model before a PBAC decision was made.

Furthermore, MSD was unable to meet the earliest possible resubmission deadline since the issue, which was of a technical nature, required time to address. A case manager could have communicated the issue earlier in the evaluation (e.g., Week 3-5 of the cycle rather than Week 10). The earlier interaction would have brought the resubmission forward by a cycle, reducing the access gap by 4 months. Ideally, through greater dialogue, the case manager could have even facilitated a pragmatic solution that both the evaluator and the Sponsor could have supported in the original submission process, potentially expediting access by 8+ months.

Unintended consequences:
It was suggested that the use of a case manager is 'modelled off the current case management approach for positive PBAC recommendations that progress through pricing pathway A'. However, in MSD's experience the case manager in Pricing Pathway A has not substantially improved the nature or frequency of Sponsor-Department interactions and has rarely achieved the intended accelerated listing, despite being associated with higher cost-recovery fees.

3.3 Economic Evaluation

Selection of the comparator

This option needs to include legislative change to the NHA definition of alternative therapies, otherwise it will not resolve the issue of comparator selection.

The Guidelines for preparing a submission to the Pharmaceutical Benefits Advisory Committee outline that '*the main comparator should be the therapy that prescribers would most replace with the proposed medicine'*. However, the PBAC has frequently applied a lowest cost comparator approach based on its interpretation of the National Health Act (NHA), Section 101(3B). The Reference Committee also identified 'concerns about choice of

comparator, and the different pricing-related implications and consequences that feed into the PBAC's HTA recommendation to the Government'.[9] To address these concerns, MSD recommends legislative changes to the NHA definition of alternative therapies to incorporate the PBAC Guideline definition and aligned with the intent of the Strategic Agreement.[10]

The lowest cost comparator approach means that PBAC decision making is not always based on the most clinically relevant comparator. This has the impact of undervaluing new innovations that should be compared to the therapy most likely to be replaced. Over time, this can erode pricing for entire classes of medicines or therapeutic areas leading to the Australian standard of care falling behind other similar nations and further disincentivise manufacturers from listing new medicines on the PBS, such as the recent example with Eli Lilly's OMVOH (mirikizumab).[11]

Unintended consequences:
In the absence of the proposed legislative change, this option is unlikely to resolve the issue of comparator selection and prices will remain prohibitively low for certain therapies. Consequently, some medicines will continue to be delayed or may not be launched in Australia, thereby preventing patient access to novel therapies.

Valuing of long-term benefits

The discount rate should be lowered as recommended by the PBAC in 2022 to align with comparable international HTA countries. There is no need for further workshops.

MSD supports the PBAC advice that a lower discount rate should be considered alongside other relevant factors in HTA decision making. The discount rate should be informed by a social values framework so that discount rates reflect societal preferences and national priorities for healthcare. MSD supports maintaining flexibility in application of the discount rate across different types of technologies, in particular vaccines to ensure that the long term benefits are fairly factored into the cost effectiveness.

Unintended consequences
Given PBACs consideration of discount rate in July 2022, MSD supports inclusion of a lower base case discount rate of 3.5% (sensitivity at 5%) in PBAC guidelines, rather than further workshops which are likely to create administrative burden and further delay implementation.

[9] HTA Review - Consultation 2, p91
[10] Australian Government (2021). Strategic Agreement. Clause 6.6: Lowest cost comparator.
[11] BioPharmaDispatch (2024). Lilly says no based on current policy – the new proposals would make it even worse. Feb 1 2024. https://pharmadispatch.com/news/lilly-says-no-based-on-current-policy-the-new-proposals-would-ma

4.1 Approaches to funding or purchasing new health technologies

Post-listing re-assessment of health technologies

The 'explicit disinvestment framework' should be re-framed as an explicit re-assessment framework with clear decision criteria against which technologies will be considered for continued funding or disinvestment.

MSD welcomes a 'systematic and enhanced, rapid' program to provide advice on funding and disinvestment of technologies. However, the focus on 'an explicit disinvestment framework' should be broadened to encompass funding of cost-effective technologies where there is unmet clinical need. The Commonwealth already has measures in place to 'disinvest' from technologies, such as statutory price cuts and a rapid post-market review framework (updated February 2024).

The barriers for disinvestment should be set at a level at least as high as those for investment; e.g. levels of evidence such RCTs which are usually required for investment should also be required for disinvestment decisions.

Re-assessment is particularly important for the NIP to ensure that the schedule continues to protect Australians from preventable diseases. The nationally negotiated price of some vaccines currently on the NIP were set over 10 years ago (with some prices set prior to the 2005 PBAC review of vaccines). There is currently no mechanism to adjust the nationally negotiated price to reflect increased manufacturing and distribution costs which have occurred since NIP listing without presenting a cost effectiveness argument to PBAC. This discourages Sponsors from continuing to supply the market in Australia when vaccines are not commercially viable, thus compromising the integrity of the NIP.

Unintended consequences:
A focus on 'disinvestment' in a post-listing re-assessment framework will lead to poorer outcomes for consumers and less choice for consumers and clinicians.

5.2 Establishment of horizon scanning programs

Horizon scanning options should be expanded to include not only technologies and stakeholders but also the methods by which new technologies will need to be assessed.

Where possible, guidance should be provided for HTA evaluators and Sponsors on accepted extrapolation methods when modelling the effects of new technologies in economic evaluations of submissions. This would avoid unnecessary discourse and delay during the evaluation stage.

5.4 Mechanisms for continuous review and improvement

A program of continuous review and improvement for current HTA policies and methods

Continuous review and improvement programs should be embedded with agreed key performance indicators that meet the objectives of the Strategic Agreement so that processes can be meaningfully measured.

The implementation of co-designed key metrics was highlighted as a facilitator of earlier patient access in the Strategic Agreement (clause 6.1: Continuous process improvement). These metrics include 'Reduce time to PBS listing, including time from TGA registration to PBS listing within the Term of the Agreement'. A baseline measure will be established, and specific metrics will be reported on an ongoing basis. The implementation and publication of performance indicators was also raised through the Parliamentary Inquiry's *The New Frontier*[12] report.

In line with MSD's recommendation from Consultation 1, these metrics should be categorised as:

i. domestic; capturing the following milestone dates:
   - ARTG listing to PBS listing,
   - TGA submission to PBAC submission,
   - PBAC submission date to PBAC recommendation, and
   - PBAC recommendation to PBS listing.

ii. international; from the date of the earliest marketing or regulatory authorization amongst OECD countries (or another pre-specified group of countries) until PBS listing date.

These metrics should be published on a PBS webpage such as the Medicine Status Website (MSW) and updated routinely (at least twice per year).

Unintended consequences:
Without the introduction and regular reporting of time-to-access metrics benchmarked against other nations, there is no accountability to continuously improve current HTA processes.

[12] Commonwealth of Australia (2021), The New Frontier, https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Newdrugs/Report