GILEAD
Creating Possible

23 February 2024

Adjunct Professor Debora Picone AO
Chair
Reference Committee for the HTA Review
Department of Health and Aged Care

Dear Adjunct Professor Picone,

The Health Technology Assessment (HTA) Review presents a pivotal opportunity to fortify Australia's healthcare framework, enhancing the accessibility and affordability of cutting-edge treatments while advancing the objectives outlined in the National Medicines Policy (NMP). The NMP aims to achieve optimal health, social, and economic outcomes for all Australians by fostering a highly supportive medicines policy environment. However, the current proposals outlined in the HTA Review Options Paper are at odds with the NMP's vision, potentially leading to unintended consequences and erecting new barriers to patient access. Further, the presentation of options that propose the introduction of cost containment measures not only extend beyond the HTA Reviews scope, but are not sustainable for the health technology industry.

For these reasons, Gilead does not support the proposals in the Options Paper.

For more than 35 years, Gilead has delivered innovative therapies that offer new hope for patients around the world. Our ambitions have led us to a cure for hepatitis C and to helping transform the treatment and prevention of HIV.

Whilst not intended to represent the totality of our views across the Options Paper, this submission provides specific context with reference to some of the proposals. By considering Gilead's transformative treatments in hepatitis C and HIV we demonstrate the barriers created by the proposals in the Options Paper to making significant medical advances available to Australian patients.

HTA reform must protect the principle of value over cost.

The purpose of HTA is to "understand the benefits and comparative value of health technologies and procedures". It is therefore imperative to prioritise value in HTA reform efforts. Emphasising policies that encourage innovation in healthcare is paramount as innovation drives progress and improves patient outcomes by introducing new treatments that address unmet medical needs.

By valuing and incentivising innovation, we can stimulate ongoing investment in research and development, facilitate medical breakthroughs, and ultimately enhance health outcomes for patients nationwide. We can also guarantee that patients gain access to the most efficacious treatments while ensuring the responsible allocation of healthcare resources.

This approach maximises the benefits derived from healthcare investments and optimises patient outcomes, thereby enhancing the overall effectiveness and sustainability of the healthcare system. Additionally, a focus solely on cost may undermine the importance of incremental benefits and discourage competition, ultimately limiting patient options and innovation in the market.

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At the core of strong and evidence-based health technology assessment of value is the choice of the comparator. Regrettably, proposals in the Options Paper that address the selection of the comparator are discussed in the economic evaluation section (3.3). The selection of comparators in the assessment process should be a clinical assessment and reflect what is used or will be replaced in clinical practise rather than an intent to determine the comparator to be the lowest cost product available for an indication. With this in mind, Gilead Sciences believes the selection of comparator should be considered as part of the clinical evaluation, not the economic evaluation.

The Options Paper includes several further proposals that seek to undermine the principle of value over cost, not least of which is the streamlined pathway of cost-minimisation submissions (section 2.2). In many cases, studies conducted for regulatory approval, which form the basis of pivotal evidence for HTA submissions, are designed as non-inferiority studies. There are various reasons for this approach, including the fact that conducting superiority studies might necessitate significantly longer follow-up periods, delaying marketing authorization. This delay doesn't serve the best interests of patients.

It is crucial to recognise that just because a product demonstrates non-inferiority, it shouldn't automatically be valued less than existing medicines in the same therapeutic space. There may be incremental benefits associated with new treatments that don't necessarily meet the strict academic standards of Australian HTA, yet still advance patient care and treatment outcomes. Adopting a cost-minimization approach that solely incentivises lower prices could discourage the introduction of truly innovative therapies, leading to a market saturated with "me-too" products that offer little to no substantial advancement over existing options.

HTA reform must not create barriers to earliest possible patient access.

Gilead believes several proposals in the Options Paper may create barriers to earliest possible access to new medicines and fail to recognise the value of innovative health technologies.

Most clinical studies that have supported the regulatory approval and subsequent PBS listing of antiretroviral therapies, including all the single tablet regimens of TDF and TAF for the treatment of HIV have been based on non-inferiority studies. Both the comparator and streamlined pathway of cost-minimisation submissions proposals highlighted above would have resulted in an inability to replace TDF containing HIV treatments with the TAF regimens, which are globally considered the gold standard treatment.

Similarly, the pivotal clinical evidence for the hepatitis C treatment Epclusa (sofosbuvir with velpatasvir) was a cost minimisation submission. Epclusa was both a true innovation as the first pan-genotypic hepatitis C treatment and transformative in its simplicity as a single tablet and same duration for all patient characteristics. The introduction of the proposed streamlined pathways, specifically outlined in 4.1 “Recognising competition between new health technologies that deliver similar outcomes” options 1 and 2, would have been a barrier to Epclusa access that has now resulted in >100,000 people cured of HCV and delivered significant health care utilisation savings.

Therefore, it's essential HTA reform does not reduce the determination of value to only be through the demonstration of the cost-effectiveness of treatments. It must remove barriers that prevent recognition of broader clinical benefits and advancements they bring to patient care, either as an intended or unintended consequence. This ensures that patients have access to the most effective and innovative treatments available, fostering continual progress in healthcare delivery and outcomes.

Our concerns extend to health technologies that are jointly funded by the Commonwealth and state and territory governments through the National Health Reform Agreement (NHRA), specifically CAR T cell therapy. We acknowledge the intent in section 1.4 to enable timeliness and equitable adoption of new therapies funded through the NHRA, however the proposal lacks awareness of the current situation and ambition for genuine earliest possible access.

Even with a positive MSAC recommendation, we must wait 6-8 weeks post-MSAC meeting to receive a Public Summary Document. Only then can we enter into a price negotiation with the Commonwealth, a deed of agreement can take several more weeks to be sent to us by the Department of Health, and supply arrangement discussions with the states or specific treatment centres can comment once price negotiations with the Commonwealth have completed. Any framework to speed patient access must overcome these open-ended timeframes.

HTA reform must not introduce unpredictability.

The current Pharmaceutical Benefits Scheme (PBS) structure provides a crucial element of stability for the industry, ensuring predictability in access and pricing across the F1 and Combination Drugs Lists formularies. However, the proposed post-listing reassessment outlined in section 4.1 of the Options Paper threatens to disrupt this stability, introducing pricing volatility that could yield significant unintended consequences for patients, healthcare providers, and industry stakeholders.

Numerous mechanisms already exist within the purview of the Department of Health and Aged Care to manage the Australian Government's risk associated with funding new therapies. These include risk-share arrangements and post-market reviews, which effectively mitigate risk while furnishing the operational certainty and confidence necessary for pharmaceutical companies to bring new medicines to market. The Options Paper fails to justify the necessity for additional levers, nor does it provide concrete details on how these proposed measures would be implemented.

We firmly contend that post-listing reassessment of health technologies, with the intent to potentially delist medicines or address the ramifications of a sponsor withdrawing a medicine from the PBS, is unwarranted and superfluous. Such actions could set a troubling precedent, potentially resulting in the delisting of therapies relied upon by patients and clinicians, devoid of input, consultation, or transparency.

In light of these concerns, Gilead rejects the proposals outlined in section 4.1 of the Options Paper.

In conclusion, Gilead Sciences cannot support the proposals outlined in the Options Paper. While acknowledging the complexity of HTA reform, it is imperative to ensure that any changes align with the overarching goals of the National Medicines Policy and prioritise the interests of patients and healthcare stakeholders across Australia.

Yours sincerely,

Jaime McCoy
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Gilead Sciences

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