GSK Australia Submission:
Health Technology Assessment Policy and Methods Review Consultation 2

Introduction

GSK Australia welcomes the invitation to comment on the Health Technology Assessment (HTA) Policy and Methods Review Options Paper (the Paper). The Review and its extensive consultation process are critical to delivering timely access to innovative medicines and vaccines for Australian patients. However, the Options proposed in this paper do not currently maximise this opportunity to bring the health system into the 21st century and improve HTA for the betterment of Australian patients.

A patient representative attending the HTA Review Consultation 2 workshop on 13 February 2024 commented on the Paper saying it was focused on saving money and not saving lives.

Australian patients must be at the centre of any reform.

GSK supports the Paper's intent, however the Options proposed do not go far enough to deliver on the objective of the Review or for Australians. The Paper also does not reflect the Government's broader vision set out in the National Medicines Policy: "To achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment".[1]

GSK recognises there needs to be a balance between robust systems that ensure quality, safety, patient and community benefit, and manage expenditure. Getting this balance right is essential to ensuring Australians have access to the medicines and vaccines they need, encouraging innovation and ensuring the sustainability of the health system. The HTA Review provides an avenue to find that balance and embed recognition that healthcare is an investment.

As a global leader in preventative medicine, vaccine development and supplier of the National Immunisation Program (NIP), we have focused our submission on areas of our experience. In addition to completing the survey, we have provided comments on key Options.

As detailed in GSK's submission to Consultation 1, we continue to call for greater recognition of healthcare as an investment through:

- Implementing the Pharmaceutical Benefits Advisory Committee (PBAC) recommendation of lowering the discount rate to a maximum of 3.5% immediately and considering the feasibility of lower discount rates
- Applying the same "willingness to pay" for lives saved through prevention as for therapeutic medicines
- Improving early and equitable access to innovative medicines and vaccines for all Australian patients
- Ensuring Australia is regarded as a 'first launch' country for innovations such as precision medicine
- Supporting patient-centredness by ensuring PBAC decision making reflects all value elements relevant to patients and society.

Option 2.1 - Streamlining and aligning HTA pathways and advisory committees: Vaccine pathway

Recommendation: Do not progress 2.1: Vaccine pathway option 1 as proposed. Streamline process while retaining the comprehensive independent input of the Australian Technical Advisory Group on Immunisation (ATAGI), recognising the value of vaccines on patient outcomes.

It takes an average of 1375 days for a vaccine to be listed on the NIP.[2] As noted in the Options Paper, there are ways to "remove duplication, reduce administrative burden, increase consistency and improve timely access."[3]

GSK supports streamlining the vaccine process but we do not support the proposed option of consolidating ATAGI advice into the PBAC's evaluations and sub-committee reports. Streamlining the vaccine pathway without ensuring proper valuation of patient and community benefits (discussed below) or by limiting specialist input from ATAGI will not result in better access to prevention in Australia.

ATAGI has a unique and important role to provide expert clinical advice on immunisation. GSK is aware of circumstances where ATAGI has taken a more evidence-based and holistic view on key decision inputs than other evaluators and sub-committees, which has supported improved PBAC decision making. If included as just one input to the PBAC economic decision framework as proposed, this independent advice could be potentially lost.

To drive efficiencies in the HTA pathway for vaccines and better access for Australians, the Review would be better placed to recommend mechanisms that embed recognition of the value of prevention. This includes taking a broader view of the health, economic and societal impact of interventions, an updated 'willingness to pay' and reduced discount rate.

An example detailed in GSK's submission to Consultation 1 is access to meningococcal B vaccination.[4] Despite four submissions to the Federal Government to date, GSK has been unsuccessful in securing NIP access for all Australian children to our meningococcal B vaccine, Bexsero® (Multicomponent Meningococcal group B vaccine (recombinant, absorbed)). Bexsero was approved for use in Australia by the Therapeutic Goods Administration (TGA) in 2013, with an ATAGI recommendation in 2014. It is a cost-effective intervention with strong evidence underpinning the community health benefits of wider access to meningococcal B vaccination. State programs are in place for infants and adolescents in South Australia and Queensland, creating significant inequality for families in other states and territories.

Option 3.3 – Economic evaluation: Valuing of long-term benefits

Recommendation: Immediately reduce the discount rate for vaccines to a maximum of 3.5% as recommended by PBAC in 2022, with a view to reduce to 1.5% in the medium term.

A higher discount rate biases against products that accrue benefits over many years but with upfront costs. When combined with PBAC's focus on minimising uncertainty in extrapolation of benefits and time horizons, the Australian methodology is unfavourable to prevention or generation of long-term benefits for patients. Curative or preventative treatments and vaccines are particularly disadvantaged as their costs are typically upfront and their benefits are longer term. As GSK explained in our submission of the Review of the Discount Rate in PBAC Guidelines, a 5% discount rate effectively values an average Australian lifespan at only 20.7 years, compared to 48.3 years with a 1.5% discount.[5]

The Paper notes PBAC published advice from 2022 proposing that Australia's discount rate could be lowered to between 3.5% – 4%, providing a "mandatory 5% discount rate sensitivity analysis be conducted for purpose of being explicit about the impact on opportunity cost and budget, and to ensure consistency with prior decisions by allowing

advisory committees to compare ICERs for new listing requests with previously considered items based on the 5% rate."[6] This advice recognises the need for a lower discount rate and that Australia is out of step with international best practice.

While GSK recommends a discount rate of 1.5%, implementing the PBAC's recommended 3.5%-4% discount rate would begin to better reflect the Government's health policy and priorities around preventative health. GSK asks that this be implemented immediately.

According to Clause 5.2 of the Strategic Agreement, PBAC guidelines were to be updated with a reduced discount in line with international best practice rate by July 2022.

Australia's discount rate has remained unchanged since 1990. The discount rate is the highest of 40 countries with established HTA practice and equal highest of 20 comparable OECD country HTA agencies.[7] For example, the discount rate is 1.5% in Canada, 2% in Japan, 3% in Germany and Singapore, 3.5% in Scotland, England and New Zealand, and 4% in Ireland and France.[8]

Acting to amend the discount rate for vaccines now will support Australia's assessment processes to keep pace with the rapid advances in health technology and minimise barriers to access.

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

Recommendation: Do not progress. Alternative Option 1 and Alternative Option 2 will negatively impact patient access.

GSK is aligned with Medicines Australia's response to Option 4.1 - Approaches to funding or purchasing new health technologies: Recognising competition between new health technologies that deliver similar outcomes.

Requiring offers of a lower price for cost-minimisation submissions does not address the objective or challenges identified in in the Review and will not result in improved access for Australians.

In the current system, cost-minimisation submissions often provide innovation that benefits patients at no additional cost to the Government. The proposed option of requiring or incentivising offers of a lower price for cost-minimisation submissions will reduce competition, leaving patients and clinicians with fewer treatment options.

As outlined in Medicines Australia's response; the option contradicts the entire premise of F1/F2 formulary split which has delivered significant savings to Government. The option would reintroduce pricing uncertainty for F1 medicines, contradicting the commitment to price certainty in Clause 7.3 of the Strategic Agreement. In the case of F2 medicines, it has the potential to decrease competition, thereby diminishing the savings derived from price disclosure.

The proposed option also does not reflect existing price controls, such as statutory price reductions, reference pricing and post market reviews. The introduction of new price saving, or price reduction measures would work against the Reviews objective and broader Government health policy. It would negatively impact Australia's attractiveness as a first launch market and Australian patient access to innovative medicines and vaccines.

Option 4.2 – Approaches to incentivise development of products that address antimicrobial resistance (AMR): Funding and reimbursement-related changes to support availability of antimicrobials

Recommendation: Government to implement a pilot subscription model. A workshop or consultative approach be delivered to refine the pilot details.

GSK is proud to be recognised by the Access to Medicines Foundation as having the world's strongest AMR pipeline. [9] We welcome the Reference Committee's acknowledgment that AMR is an emerging issue that the HTA Review provides an avenue to address and call for action.

The threat of AMR is more urgent than recognised in Option 4.2:

- AMR is a global health emergency, recognised by the WHO as one of the top ten public health threats facing humanity[10]
- 5200 Australian deaths per year are associated with AMR[11]
- By 2050, 10,000 Australians per year are expected to die from drug-resistant infections[12]
- AMR will also have severe economic impacts; a 50% increase in resistance to first-line antimicrobials for urinary tract infections (UTIs) could see an increase of cost the Australian Government $1.6 billion[13]
- Australia's lack of access to novel antimicrobials is well-documented by the Australian Antimicrobial Resistance Network[14]

The Government has invested $27.3 million into understanding AMR and potential solutions, including surveillance, stewardship, and a funding model scoping study commissioned by the Department of Health and Aged Care. In addition, in its inquiry into approval processes for new drugs and novel medical technologies in Australia, the Parliamentary Standing Committee on Health Aged Care and Sport recommended: "In partnership with the states and territories, develop and implement a pilot scheme for value-based payments for new antimicrobial drugs."[15]

Piloting a subscription fund that delinks reimbursement from volume of sales is the established solution. A workshop or consultative approach that brings together Australian and international experts and stakeholders to refine the pilot details would better address the Review's objectives. It would support Australia to keep pace with the urgent threat of AMR.

Option 5.3 – Consideration of environmental impacts in the HTA: Environmental impact reporting

Recommendation: Implement this option in alignment with global HTA leaders.

GSK supports exploration of approaches to consider environmental impacts within the HTA process. Alignment between Government, industry and other stakeholders locally and globally will be essential to seeing this Option deliver on the Review's objectives and environmental benefits to be realised.

Medicines manufacturing and its supply chains are global in nature, and so it is critical that Australian initiatives in this space are aligned with other HTA leaders to ensure that reporting is consistent and not onerous for sponsors. This includes a clear understanding of mechanisms for measurement, weighting, and associated value in HTA processes.

For example, GSK's environmental initiatives stretch from our R&D approaches, to production operations and business facilities, to logistics and distribution. We are focused on achieving reduction in our carbon emissions, energy, and managing water and waste in our own operations.

In addition, we are striving to drive positive change across our value chain, from our service providers and contractors to contract manufacturers and suppliers. We will also look to include eco-design considerations into products and packaging for sustainability, while maintaining high quality and safety standards.

Consideration of environmental impacts in the HTA environment will further encourage innovation and support patient access to better medicines and vaccines.

Conclusion

GSK Australia recognises the importance of the HTA system and this Review in ensuring timely access to innovative medicines and vaccines for Australian patients, now and into the future. We ask that Options proposed in the Review reflect this importance. The Review has an opportunity to modernise Australia's HTA system and improve processes for the betterment of Australian patients.

It is clear the Review has consulted broadly and the Paper does capture current challenges and strengths within the system. However, the Options proposed do not reflect this understanding and will not deliver on the Review's objectives.

GSK recognises there must be balance between robust systems that ensure quality, safety, patient and community benefit, and expenditure. The HTA Review provides an avenue to get this balance right. Embedding the value of investment in medicines and vaccines within the HTA system will result in better access for Australians, encourage innovation and support the ongoing sustainability of the health system.

In addition to providing the views of GSK Australia via the survey, this submission includes comments on highly important Options that we are best positioned to provide insights into. We also want to take this opportunity to highlight the critical importance of continued engagement with Australian patients and consumers. It is Australian patients and consumers who must be at the centre of the Review and any Options implemented.

GSK Australia will continue to advocate for greater recognition that healthcare is an investment in the community and economy.

About GSK

GSK is a biopharma company with the ambition and purpose to unite science, technology, and talent to get ahead of disease together. We aim to impact the health of 2.5 billion people over the next 10 years. At the centre of this is our R&D focus on the science of the immune system, human genetics and advanced technologies, and our world leading capabilities in vaccine and medicines development. In Australia, we offer a broad portfolio of innovative and established vaccines and medicines in respiratory disease, HIV, and oncology. Our vaccines have been at the heart of the Australian National Immunisation Program from the time it began, helping to protect infants and children from multiple serious diseases. Beyond childhood, our vaccines help to protect Australians throughout life whether at home or travelling overseas. Across the country, we employ approximately 500 Australians in many areas of expertise from graduates to senior managers. We have committed to accelerate our progress on inclusion and diversity and seek to make a meaningful and lasting contribution to reconciliation in Australia. We have ambitious environmental sustainability goals in both climate and nature: aiming to have a net zero impact on climate and a net positive impact on nature by 2030.

For further information please visit au.gsk.com.

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