Pfizer Australia and New Zealand
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HTA Review Secretariat
Department of Health and Aged Care
Via Email: htareviewconsult@health.gov.au

Thank you for providing Pfizer Australia with the opportunity to contribute to the second round of consultations on the HTA Review.

Pfizer Australia is one of the nation's leading providers of prescription medicines. We research, develop and manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives.

Pfizer has had operations in Australia since 1956. Our Australian business operates across two commercial sites in Sydney and Melbourne, and a manufacturing facility in Melbourne that exports to more than 60 countries worldwide.

Pfizer commends the Government on the release of the Wellbeing Budget Statement in 2023 which recognised the importance of measuring and benchmarking a broader range of social and environmental factors and broadening the conversation about quality of life. Medicines and vaccines provide obvious benefits to the health of individuals – and, as the COVID years demonstrated, they also make a significant contribution to productivity and societal well-being.

Pfizer is pleased to raise issues related to ensuring the options proposed achieve the goals of accelerating patient access to innovative health technologies and retaining Australia's place as a first launch country.

Yours sincerely

Anne Harris
Managing Director

Australian patients wait too long to access new medicines. It takes on average 466 days for a new medicine to go from TGA registration to PBS listing.[i] This is almost 100 days slower than the OECD average and more than 300 days slower than Japan, Germany or the UK.[ii] This delay negatively impacts patients, their families and society, and our economy as treatment is delayed.

Similarly, there are medicines that Australian patients will never access because companies elect to deprioritise Australia when our HTA policies, processes and methods systematically undervalue innovative medicines and vaccines. This means patients are denied equitable, timely and affordable access to access some of the most innovative medicines.

The Commonwealth agreed to undertake the HTA review in recognition of the shared goals of the Strategic Agreement:

1. reducing time to access for Australians so that they can access new health technologies as early as possible; and
2. maintaining the attractiveness of Australia as a first-launch country to build on Australia's status as a world leader in providing access to affordable healthcare,

and to ensure "that our assessment processes keep pace with rapid advances in health technology and barriers to access are minimised".[iii]

With those goals in mind, Pfizer called for the HTA Review to been used as an avenue to bold reform. The Options for presented by the Reference Committee should have been grounded in two fundamental policy reforms:

- A commitment to recognise the value of health technologies; and
- A commitment to significant improvement in time to access for patients.

These core policy undertakings, in combination with enabling policies, processes and methods, should be the foundation of HTA reform in Australia.

Australia's approach to HTA fails to recognise expenditure associated with keeping people well and in the workforce as an investment. Vaccinations prevent millions of deaths globally from infectious diseases and also vastly reduce the numbers of hospitalisations. Medications such as anticoagulants can prevent strokes and other serious and disabling events. Australia underspends on medicines and preventative health and then pays more to respond when people inevitably present in the acute care and other health settings.

Savings measures should be antithetical to health thinking as health spending should be categorised as an investment rather than a cost. Pfizer is alarmed by the presence and prominence of pricing policy, namely price reduction policy, in the options paper given this was not part of the scope of the review and does not align with its goals.

<u>Pfizer high level reflections on the options paper</u>

While there are parts of the options paper that we can support as having the potential to achieve faster access we are disappointed by the lack of alignment between the options proposed and the goals of the review, in particular the lack of bold reform to improve the value attributed to innovative medicines.

We have provided a separate response to the survey that considers each of the options separately. In that response the lack of detail in the options paper has been raised, which made engaging with options challenging as well as options where there was a lack of clarity on how the option would interact with existing arrangements. We have raised in particular issues relating to value and time to access as outlined below as well as other matters of priority for Pfizer as an innovative medicines company.

We are using this paper to outline the policy reforms needed to achieve the HTA review's goals.

A commitment to recognise the value of health technologies

Australia's approach to HTA systemically diminishes and undermines the value of innovative health technologies and is out of step with comparable countries like the UK, France, Japan, Germany and Canada. Adequately valuing innovation is foundational to whether Australia is a first-wave launch country and thereby to delivering rapid access for patients. It is a fact that when Australia does not ascribe adequate value to their health technologies, it will be de-prioritised for launch of new medicines and vaccine launches.

Recognition of value must be broadened to include patient experience, equity, wellbeing, innovation and non-health elements like carer burden. A new value framework is essential to ensure value considerations are explicit and transparent and is instrumental in shifting decisions from a focus on cost to investment. We believe the options paper fails to adequately address these ideas.

- Vaccines – The current framework undervalues vaccines and must be reformed. This is due to high discount rates, exclusion of broader societal benefits, under-accounting for benefits accrued over many budget cycles, low ICERs, and limited acceptance of real-world evidence.
- Rare disease treatments – Decision-making should rely less on ICERs and incorporate a wider range of evidence demonstrating clinical benefit, along with more flexible considerations of rarity, severity, burden of disease, scientific advancement, budget impact and societal benefits. The present approach has an overreliance on data sources that may not be available in rare disease because of small patient cohorts.
- Cell and gene therapies – Recommendations should be based on appropriate ICERs, a lower discount rate and recognition of societal and economic benefits.
- Innovative medicines used in combination – HTA policies must be revised to deliver value assessment that can support predictable and sustainable subsidised access to effective combinations that include two or more innovative medicines that advance the health outcomes of patients.
- Anti-infectives – The rapid establishment of a reimbursement model that de-links revenue from volume. Australia's response should recognise the value of the antimicrobial to the health system. The information about reforms that address the long-standing problem is already available and implementation of a new approach must be undertaken with urgency.

Enablers for recognising value:

A different approach to **comparator selection** that addresses the current long-standing problem must be implemented. The proposal (option 3.4) adds additional complexity to comparator selection without addressing the fundamental issues with Australia's choice of comparators for HTA, namely lowest cost comparator and comparator price erosion. Use of the lowest cost comparator means new medicines are priced in comparison to the cheapest alternative rather than the most used in

clinical practice for a particular condition. This fails to recognise the value of innovation and incremental improvements of therapies over time. It also fails to recognise the expertise of prescribers, given the most prescribed therapy represents contemporary Australian therapeutic practice. This practice jeopardises the integrity of HTA in Australia.

Use of the lowest cost comparator instead of the comparator most commonly used in clinical practice also causes innovative medicines to frequently be priced against low-cost F2 medicines which may have been subject to substantial price reductions. Demonstrating cost-effectiveness of a new medicine compared to an old F2 comparator medicine is particularly challenging when the price of the latter has been eroded. This represents a significant barrier to access to new medicines in Australia. This problem is compounded when those low prices are flowed on to all related innovative medicines via the reference pricing policy in F1, failing to recognise the incremental improvements of various therapies over years. This represents a significant barrier to access to new medicines in Australia because medicines are not listed in the first place or because they are withdrawn due to price erosion over time.

There must be greater acceptance of **non-RCT evidence** in decision-making, for example real world evidence, not just more guidance on preferred methods for inclusion in submissions. Without agreement that additional flexibility is required where RCT evidence is very limited or not available, for example diseases with small patient cohorts, therapies will continue to be undervalued because of the way that uncertainty associated with available evidence is treated in decision making.

We strongly believe the base case **discount rate** must be reduced to 1.5%. The current base case discount rate of 5%, has been in place since 1990 and is the highest of 40 countries with established HTA methods. Using 5% as the base case rate means that Australia systematically undervalues vaccines, medicines and other novel treatments that have up-front costs and/or longer-term health benefits. In practice, the use of a higher discount rate means that Australians face delayed access to a range of vaccines and treatments and in some cases, reimbursed access does not occur at all. A discount rate in line with international best practice would be an important and overdue reform. The proposal (option 3.4) is too marginal and does not address the problem. The option defers the decision resulting in further delay with no timeline for implementation. This is in stark contrast to the Strategic Agreement commitment (Clause 5.2.1) to reduce the discount rate by 2022. The decision to reduce the discount rate should be made and commence by July 2024.

We need to **recognise the broader social and economic value** of health technologies. This includes second order effects like productivity benefits, reduced strain on social welfare systems, reduced carer burden, equity and disease severity. This should be part of a transparent value framework and should be more explicitly reflected in decision-making, including in ICERs.

<u>A commitment to achieving faster patient access</u>

The options paper seems to question whether time to access is a problem, because Australia's time to access was around the middle of the range of OECD countries.[iv] This means a newly diagnosed cancer patient could need to wait 18 months for a breakthrough therapy; time they don't have. This does not align with Australia's Long Term National Health Plan goal: to make Australia's health system the world's number one.[v] It is similarly misaligned with the goal of the HTA review that

patient access be achieved as fast as possible. Australia being placed in the middle of the pack highlights that, by definition, faster is possible.

Medicines Australia called for reimbursement within 60 days of TGA registration as a benchmark timeframe for HTA processes in Australia.[vi] While there are options in the paper that seek to accelerate time to access, we believe without a commitment on timing, Australian patients will continue to wait and potentially miss out on access to medicines and vaccines. We therefore reiterate our call for the government to adopt a target of 60 days from registration to reimbursement.

New policies and approaches are required to address the delays in our HTA system. We propose:

- A front loaded and empowered office of HTA – We support the proposal (option 2.1) for a single-entry point for HTA, it should provide oversight of the system, offer PICO guidance, triage applications down the appropriate pathway (as proposed in option 2.1) and conduct horizon scanning (as proposed in option 5.2).
- Provisional listing pathway with bridging funding – Creation of an early resolution mechanism for submissions in areas of HUCN (as proposed in option 2.1) is an important step but access likely won't be accelerated as pricing considerations will take time to resolve without bridging funding.
- Proportionate assessment for cost-minimisation submissions – The creation of a proportionate assessment approach is an important step in removing unnecessary pressure on our HTA bodies. However, building in a price reduction (as proposed in option 4.1) cannot be supported. Seeking to create a quid pro quo where faster processing can be achieved in exchange for cost reductions fails to solve the key problem that evaluation for low budget impact medicines is overly cumbersome. There is clearly an opportunity to create efficiencies and improved timelines. Proportionate assessment is an opportunity to create efficiencies in HTA evaluation and get health technologies to patients faster.
- Creation of therapy area specific pathways – Addressing delay in current HTA processes is important. Creation of new pathways for vaccines (option 2.1) and drugs for ultra-rare diseases (option 2.1) are sensible and must be designed to ensure expert advice is available at the correct points to inform modelling, submissions and decision making, to ensure no new delays are created.

Enablers for faster access:
Clear and predictable timelines for post-PBAC processes including good faith price negotiations is also essential. In some cases, a PBAC recommendation is just the beginning of a slow negotiation process. In delivering on the goals of the Strategic Agreement, this is also an area in need of urgent reform.

[i] Medicines Australia, 2023, 'Medicines Matter 2022: Australia's access to medicines 2016-2021', https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/04/Medicines-Matter-2022-FINAL.pdf Accessed 5 February 2024.
[ii] Ibid.
[iii] Department of Health, 2024, 'HTA Review: Terms of Reference', https://www.health.gov.au/sites/default/files/2023-03/health-technology-assessment-policy-and-methods-review-terms-of-reference.pdf pg 3.
[iv] Department of Health, 2024, 'HTA Review Options Paper', https://ohta-consultations.health.gov.au/ohta/hta-review-consultation-2/, pg 12.
[v] Department of Health, 2019, 'Australia's Long Term National Health Plan, https://www.health.gov.au/sites/default/files/australia-s-long-term-national-health-plan_0.pdf, pg 3.
[vi] Medicines Australia, 2023, 'Submission to HTA review consultation 1', https://ohta-consultations.health.gov.au/ohta/hta-review-consultation1/consultation/view_respondent?uuId=539488271.