Eli Lilly Australia's Submission to the HTA Policy and Methods Review - Consultation 2

February 2024

About Eli Lilly Australia

Eli Lilly Australia was established in 1960 at West Ryde, NSW.

For more than 60 years, we have remained committed to bringing life-changing, innovative medicines to people across Australia and New Zealand.

We currently employ approximately 200 employees in ANZ. Our employees are committed to our purpose of making life better, starting with the people who take our medicines and extending to the communities in which we live.

We are passionate about enhancing patient care in Australia. Patients play a critical role in our mission as a company and we never lose sight of that.

As a company that has worked to pioneer medical discoveries that make life better, we recognise the importance of optimising access to life-changing and life-saving medicines and ensuring that medicines and health technology assessment policies are fit for purpose.

This submission is designed to help shape policies that prioritise patient needs, while also recognising and rewarding pharmaceutical innovation.

[redacted]

Introduction

Lilly cares about the health of Australians and Australia's health system and welcomes the opportunity to contribute to the formulation of reform via the HTA Review. Lilly is committed to working together with the Government to build on the reputation of the PBS in providing affordable universal access to medicines for all Australians regardless of where they live or their financial situation.

Lilly is a proud member of the industry association Medicines Australia and is broadly aligned to their position on the HTA Policy and Methods Review – Consultation 2 as outlined in their submission. Lilly believes that the process improvements suggested in the Consultation Options paper will improve efficiencies if they are approached as a package of integrated reforms and resourced with the appropriate expertise with sufficient capacity. However, Lilly remains concerned that the proposed options do not sufficiently recognise the value of medicines and this lack of recognition creates delays to, or prevents, patients' access to medicines in Australia.

We have structured our submission by areas where Lilly believes that there may be unintended outcomes or challenges stemming from the proposed options or where Lilly believes that the option should be strengthened to reduce time to patient access to medicines. The numbers below reference those in the Consultation Options paper. Lilly has also completed the ongoing survey.

1.2 Consumer, clinician and other stakeholder engagement and consideration in HTA

Lilly believes that medicines and health technology assessment policies must be informed by the views of a range of stakeholders, including but not limited to patients, caregivers, patient advocacy groups, clinicians and professional societies of clinicians. Research commissioned by Eli Lilly Australia, *The Medicines Waiting Room*, explored the perceptions of medicines access, use and supply among a sample of 100 Australian clinicians from varying medical specialities. More than 70% of clinicians that participated in this research would like greater input to decision-making about which medicines are listed on the PBS and eligible patient populations. 70% of clinicians believe that patient outcomes would improve significantly if reimbursement criteria for certain medicines already PBS-listed were relaxed to allow for earlier or wider use. Nearly two-thirds (64%) of clinicians believe that the comparatively low dollar value assigned to a life and health outcomes in Australia's health technology assessment processes could deny or delay patients access to medicines, vaccines and other health technologies.

Note: *The Medicines Waiting Room* research project explored the perceptions of medicines access, use and supply among a sample of 100 Australian clinicians from varying medical

specialities who keep up to date with overseas trends in their area of expertise. The survey was conducted in February-March 2023 by Ipsos Research on behalf of Eli Lilly Australia.

2.2 Early resolution mechanisms for submissions of major new therapeutic advances in areas of HUCN: *Alternative Option 4*

Lilly broadly supports alternative Option 4: *introducing an optional resolution step **after** HTA committee decision but **before** advice is finalised.* Lilly believes that this option would be effective at reducing time to access, assuming that the provisional negative recommendation by the HTA committee is on the basis that they are not going to recommend all that the sponsor has requested. The value of this option is negated if the committee provides a positive recommendation with no resolution step if they do not agree with all of the sponsor's requests.

An example of where this approach could have improved speed to access is with Lilly's early breast cancer medication, Verzenio (abemaciclib), which is still yet to be listed at the time of this submission. Verzenio was first considered by the PBAC in March 2022 for the early breast cancer indication, and has been considered twice since, with the primary concern of the PBAC being aspects of the cost-effectiveness. A resolution step after that first HTA committee decision could have enabled these cost effectiveness concerns to be addressed before the HTA advice was finalised, and would have enabled around 3,400 patients to be treated with this medicine. Whereas currently, these patients are still waiting to access PBS reimbursed Verzenio, and may have missed the opportunity for treatment with their disease progressing to a metastatic state. This is in stark contrast to the many countries that have government-subsidised patient access for Verzenio for early breast cancer, including the UK, Germany, Scotland, Sweden, Finland, Belgium, Spain, Bulgaria, Slovenia, Czech Republic and Romania.

3.2 Clinical Evaluation: *Development of a qualitative value framework*

Lilly is aligned with Medicines Australia in believing that the development of a qualitative value framework will be crucial for ensuring that Australia's HTA system delivers on societies needs and preferences for medicines. Impacts on patients and their caregivers, such as social welfare, carer impacts and productivity benefits, should be included in the HTA assessment process. The qualitative value framework should also include workable methodologies for the transparent inclusion of second-order effects or patient and caregiver benefits in a way that supports early and equitable access to medicines. One example, where Lilly strongly believes that the addition of societal input into the HTA assessment process will be key is in the Alzheimer's Disease therapy area. In addition to a dependence on medical care, patients with Alzheimer's Disease have substantial dependence on social care and carer support. Emerging

therapies are showing potential to modify disease and slow disease progression, which could lead to significant impacts on the degree of carer and social care burden. Such impacts should be taken into account when considering the value of these medicines and consequently, carer and social care burden should be factored in to the HTA assessment process. Importantly, this should not only be captured in a qualitative framework but quantified in the base case economic evaluation and incorporated in the valuation of medicines.

Lilly believes that the development of the qualitative value framework should be elevated to an independent policy initiative led by a coalition of all relevant stakeholders and not be run by the HTA committee. Once finalised the value framework should be embedded in legislation to ensure there is no conflict with the National Health Act (NHA).

3.3 Economic Evaluation: *Selection of the comparator*

Lilly is aligned with the position of Medicines Australia in believing that this option needs to be significantly strengthened. Lilly's recommendations for HTA comparator policy are that:

- The comparator should be the treatment most likely to be replaced in practice by the proposed medicine, which would reinstate the intent of the original PBAC guidelines
- If a new medicine is non-inferior to multiple comparators that it could replace, and a cost-minimisation approach is appropriate, the cost-minimised price of the new medicine should be the average price of the other alternative medicines weighted by market share, rather than the price of the lowest price alternative. This is a fair and balanced solution that achieves a comparator price which more accurately represents the average cost to the PBS of current treatment

The 'lowest cost comparator' policy is a key barrier to reimbursement of innovative medicines in Australia, and indirectly links the prices of F2 medicines to F1 medicines. A recent example for Lilly where this impacted commercial viability and therefore patients' access to medicine was for Omvoh (mirikizumab) for ulcerative colitis. Despite the positive recommendation Omvoh received when the PBAC met in July 2023, the requirement to price Omvoh at the level of the lowest cost comparator – a competitor therapy that went off patent almost a decade ago – has made the launch commercially unviable for Lilly. Lilly was unable to accept the eroding 'lowest cost comparator' price resulting from ongoing price disclosure policies. Lilly believes that, as with other international HTA systems, the principle for the comparator should be 'the therapy most likely to be replaced in practice'.

3.3 Economic Evaluation: *Valuing overall*

Lilly believes that the current HTA system has a disconnect between the value attributed to a medicine by the government and the value attributed by a patient. This disconnect results in lower recommended medicine prices compared to the value placed on these by patients.

A recent example of this is demonstrated by GLP-1 agonists in type 2 diabetes. There is a global shortage of GLP-1 agonists due to high consumer demand despite the relatively high price point for GLP-1 agonists. The disproportionate impact on Australian supply relative to other markets is due, at least in part, to the low price of GLP-1 agonists in Australia. Furthermore, as production is increased to meet global demand over time, a low effective price will likely extend the time until supply is restored in Australia as other markets with higher prices receive new supplies preferentially. Eli Lilly cannot share confidential effective pricing, but we confirm that the effective PBS price of Trulicity is the lowest within Lilly's International Business Unit.

4.1 Health technology funding and purchasing approaches and managing uncertainty

Lilly broadly supports *4.1: Approaches for managing uncertainty - bridging funding coverage for early access to therapies of likely HATV and HUCN*. Lilly believes that this option will facilitate earlier access to these medicines. One example of where this could have benefited patients is Lilly's targeted therapy Retevmo (selpercatinib) for the treatment of adult patients with locally advanced or metastatic RET fusion positive non-small cell lung cancer (NSCLC), which received TGA provisional approval in July 2023. A submission utilising the same clinical evidence as that upon which the TGA provisional approval was granted (LIBRETTO-001, a phase II single arm trial) was reviewed by the PBAC in July 2023. The PBAC did not recommend Retevmo due to uncertainty in the comparative clinical effectiveness. In contrast, Retevmo is reimbursed for the treatment of RET fusion positive NSCLC in 20 countries, including HTA based jurisdictions such as the UK and Canada. A small gene panel testing for NSCLC, which included testing for RET genetic alterations has been recently listed on the MBS, meaning that patients who are eligible for Retevmo can now be identified, but do not have reimbursed access to the appropriate targeted therapy.