GSK Australia Submission:
Health Technology Assessment Methods and Policy review Consultation 1

Introduction

GSK Australia welcomes the opportunity to have input into the Health Technology Assessment (HTA) Methods and Policy Review. Australian HTA frameworks have been slow to adapt to emerging technologies and issues, seeing Australia become unaligned with international best practice, especially on access to preventative health.

The COVID-19 pandemic has shown that healthcare is an investment, with vaccines and antivirals allowing us to move beyond lockdowns, while still preventing deaths and long-term complications. Traditional HTA approaches were unable to deliver the timely care and prevention Australia needed, and the Government needed to apply more flexible, expedited processes. This highlights the inequity faced by Australians affected by many other illnesses – from meningococcal B to endometrial cancer – who may experience avoidable death or disability while waiting for HTA processes to deliver access.

We now have a unique opportunity to bring the system into the 21st century and improve its processes for the betterment of Australian patients.

Revised HTA methods and policies are needed to better recognise healthcare as an investment through:

- Implementing the Pharmaceutical Benefits Advisory Committee (PBAC) recommendation of lowering the discount rate to 3.5% immediately and considering the feasibility of lower discount rates
- Applying the same "willingness to pay" for lives saved through prevention as 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

In addition to the issues highlighted in this document, GSK Australia supports Medicines Australia's recommendations in their submission 'A Healthcare System for the 21st Century.'

Bringing the National Medicines Policy to life

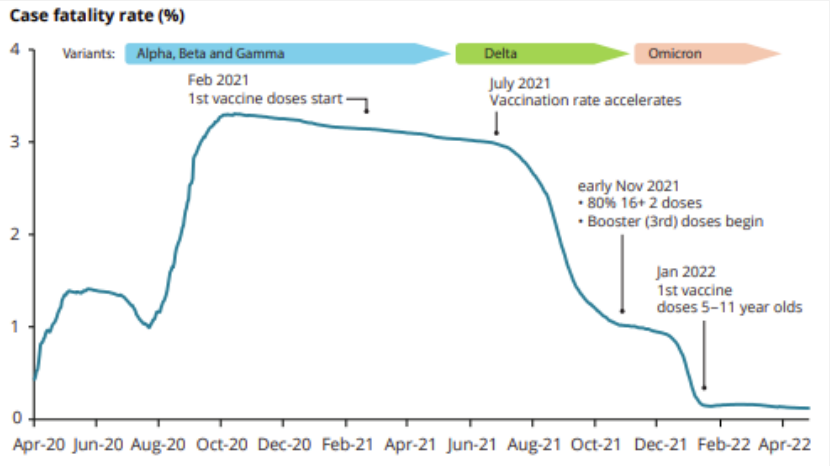
HTA in Australia should align with the principles of the National Medicines Policy (NMP) and its overarching vision to achieve the world's best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment. The aim of the NMP is to provide:[1]

- Equitable, timely, safe and affordable access to a high-quality and reliable supply of medicines and medicines-related services for all Australians
- Safe, optimal and judicious use of medicines, with a focus on informed choice and well-coordinated patient-centred care
- Support for a positive and sustainable policy environment to drive world-class innovation and research – including translational research – and the successful development of medicines and medicines-related services in Australia

Case study: COVID-19

- If the first COVID-19 vaccines had followed the standard process for the National Immunisation Program, they would have not been available before 2023 – a 2-year delay. If they had experienced multiple PBAC rejections as for other innovative vaccines, the delay may have been another 2+ years. The case would be similar for treatments and antivirals seeking PBS funding through standard pathways.
- The vaccines rollout reduced the case fatality rate for COVID-19 from a peak of 3.3% in October 2020 to 0.1% in April 2022.[1] Without timely access, lockdowns and other restrictive measures could have been in place for longer, with significant impacts on community wellbeing and the economy.

Impact of COVID-19 vaccines on fatality rates, Australia

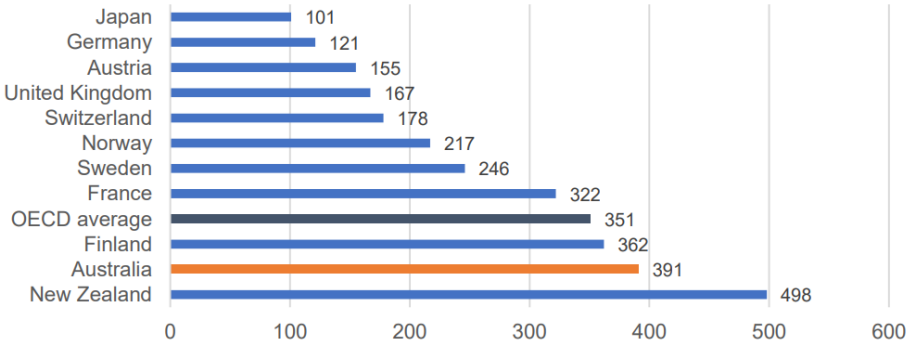


Source: AIHW. 2022. Australia's Health 2022: In Brief. p13

Recognising that there are not unlimited resources for healthcare, HTA must strike a balance to optimise outcomes for Australians in alignment with these principles. The HTA Methods and Policy Review is an opportunity to find a better balance. This submission will address key areas where the HTA system is not meeting our NMP goals, especially around timeliness, equity and patient-centredness.

The NMP has an objective of "timely access to the medicines that Australians need, at a cost individuals and the community can afford". However, Australia ranks 13th out of 20 comparable nations for the average time from registration to reimbursement of First in Class Medicines and New Molecular Entities. This means many Australians are missing out on early access to innovative interventions.[2]

Average days from registration to reimbursement (2014-19)



Source: Medicines Australia. 2020. Medicines Matter: Australia's Access to Medicines 2014-2019, Figure 4

On average it takes 1375 days for a vaccine to be listed on the National Immunisation Program (NIP) and 391 days for reimbursement of a medicine, once approved by the Therapeutic Goods Administration (TGA).[3] This is more than twice the amount of time than in Japan, the United Kingdom or Germany.[4] GSK acknowledges there have been several improvements in processes aimed at reducing waiting periods for patients, however, more is needed to align Australia with international standard in similar countries.

Similarly, delays in listing/reimbursement have meant that some vaccines and medicines are only available on the private market to those who can afford them. GSK Australia's 'Risk to Resilience: a roadmap to vaccine access for older Australians' report, found that Australians with higher average incomes had less presence of co-morbidities and better overall health outcomes than those with lower average incomes, yet have better access to health interventions and services.[5] This does not deliver on the NMP objective of equitable access.

Some medicines never make it to Australia. Systemic benefits from developing new antimicrobials to combat resistance are not captured in an HTA process centred on incremental cost-effectiveness ratios (ICERs). As explained in Medicine Australia's submission, novel antimicrobials are undervalued by the current system relative to their socioeconomic benefits, due to the low-cost comparators which are still effective for many infections, and the inherently narrow focus of HTA on direct health costs and benefits.

The system is also not achieving its objective of patient-centredness. The Enhanced Consumer Engagement Process aims to capture consumer and patient perspectives earlier in HTA processes to allow enough time for consumer representatives to gather feedback and influence outcomes.[6] However, the HTA frameworks for assessing the value of medicines and vaccines such as cost-per-quality-adjusted life year (QALY) and health system perspective are narrow, meaning that many areas of input from patients on issues that matter to them (e.g. being able to work, reduced dependence on carers, improved convenience) rarely influence decision-making.[7] This then influences technologies that are developed and brought to Australia.

This review must ensure that our HTA system supports all aspects of the NMP.

Medicines and vaccines as investments

Innovative medicines and vaccines keep people well, reducing demands of primary care and hospitals, while increasing productivity and benefiting the community and economy.

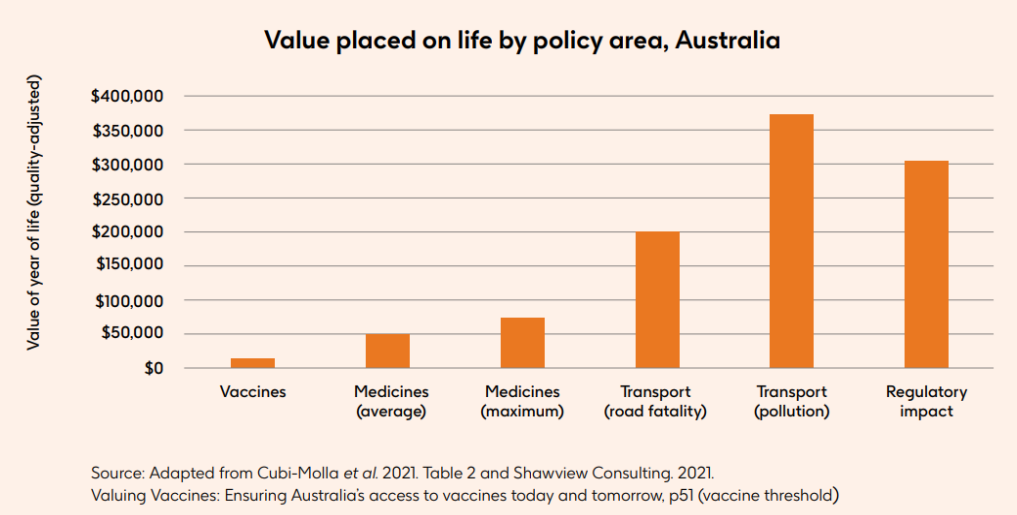
> "Immunization is a global health and development success story, saving millions of lives every year... Immunization is the foundation of the primary healthcare system and an indisputable human right. It's also one of the best health investments money can buy."
>
> **World Health Organization**
> World Health Organisation. (2023). Immunization Agenda 2023: A Global Strategy to leave No One Behind. From Immunization Agenda 2030

The Australian Government has recognised the value of prevention in various policy frameworks such as the National Preventative Health Strategy 2021-2030,[8] the National Immunisation Strategy for Australia 2019 to 2024,[9] and the National Medicines Policy.[10]

However, the policies and methods used to attribute value to new medicines and vaccines in the Australian HTA framework limit the ability to recognise long term benefits and savings to patients and the health system. Current processes do not allow for indirect socioeconomic benefits (such as to carers, productivity, and the economy) to be considered. Such considerations may be presented in submissions to Government HTA bodies as supplementary information but are rarely influential on outcomes.

Globally, our HTA system has become out of step with international best practice. Germany, the Netherlands and Spain have recently taken steps to include public health benefit/value and social productivity value in their HTA assessments, recognising the importance of indirect benefits of medicines and proven interventions.[11]

Australia also applies a lower value to gains in length and quality of life than similar countries overseas, and even than other sectors of the Australian Government such as transportation. This means that the Australian Department of Health will not pay the same price for extending life or improving quality of life with a vaccine as other countries, or even another Australian Government Department via a road safety measure.



Source: Adapted from Cubi-Molla *et al.* 2021. Table 2 and Shawview Consulting. 2021. Valuing Vaccines: Ensuring Australia's access to vaccines today and tomorrow, p51 (vaccine threshold)

The COVID-19 pandemic demonstrated in real time the link between the health of the nation and the economy. As shown in the COVID-19 case study above, the introduction of vaccines reduced the fatality rate from 3.3% in October 2020 to 0.1% in April 2022.[12] Throughout the pandemic we saw our healthcare system under immense pressure. Hospitals, carers and other health and welfare services were not able to cope with the severity and volume of COVID-19 related patients, coupled with pre-pandemic patient numbers and needs. COVID vaccines were approved and funded through processes approximately two years faster than other innovative vaccines. It is this timely access to vaccinations and treatments that enabled other public health measures such as lockdowns to ease, allowing the community and economy to begin to recover. COVID-19 is a clear example of the benefits of medicines and vaccines that are often undervalued in our HTA system. A broader healthcare perspective, higher willingness to pay and lower discount rate can all benefit the community and economy significantly through better access.

Valuing lives saved through prevention

Australia's discount rate has remained unchanged since 1990. It is the highest of 40 countries with established HTA practice and equal highest of 20 comparable OECD country HTA agencies.[13] 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.[14]

A higher discount rate biases against products that accrue benefits over many years. 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 therefore undiscounted) 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.[15]

Aim no. 4 of the National Preventive Health Strategy 2021-2030 states that "prevention is valued and viewed as a worthwhile and important venture – funding is rebalanced towards prevention."[16] However our current discount rate of 5% and approach to managing uncertainty balances funding *away* from prevention.

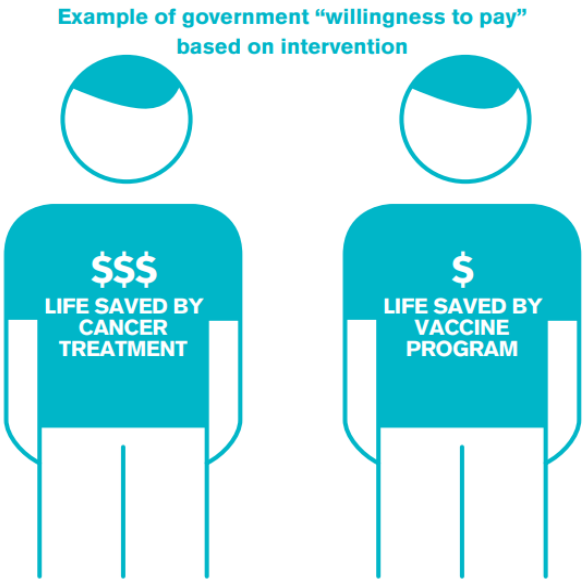
In 2022 the PBAC published advice recommending Australia's discount rate could be lowered to between 3.5% – 4%, providing a "mandatory 5% discount rate sensitivity analysis be conducted for purpose of being explicit about the impact on opportunity cost and budget, and to ensure consistency with prior decisions by allowing advisory committees to compare ICERs for new listing requests with previously considered items based on the 5% rate."[17] This new advice recognises the need for a lower discount rate and that Australia was previously 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 at least begin to better reflect the Commonwealth Government's health policy and priorities around preventative health. GSK asks that this be implemented immediately.

The discount rate issue is compounded further by the Government's low willingness to pay for the health gains from prevention. While the PBAC does not have an explicit ICER threshold (as used in some international HTA bodies), the PBAC's repeated view is that the ICER threshold for population-level programs with large opportunity costs should be at the lower end of the range it uses.[18]

Several studies have assessed the probability of a medicine/vaccine being listed based on its cost per QALY ratio. Approximately half of PBS submissions were accepted when the cost per QALY was less than $45,000, 33% when between $45,000 and $75,000, and 16% once above $75,000.[19,20]

In contrast, the initial submission for Shingrix® (varicella zoster virus recombinant vaccine) in 2018 was rejected by PBAC due to high and uncertain cost-effectiveness. In all cases, the ICERs presented were below thresholds typically accepted for medicines but above $15,000/QALY. The PBAC noted that "the threshold of incremental QALYs gained for treatments with large opportunity costs, such as population preventative interventions including lipid-lowering, anti-hypertensive drugs and vaccines, was at the lower end of the



Source: GSK Australia. (2019). The Value of Vaccines: Ensuring Australia keeps pace with community values and international practice recommendations. GlaxoSmithKline Australia, p2 https://au.gsk.com/media/6218/infographic-valueofvaccines-digital-final.pdf

ICER range. The PBAC considered that the ICERs proposed in the submission were highly uncertain and suggested that lower ICERs would be more appropriate."[21]

It is unclear why the PBAC applies a lower willingness to pay threshold for preventative interventions such as vaccines. This is inconsistent with international practice, misaligned with principles of health maximisation, and conflicts with recent research suggesting greater societal preferences for avoidance of rare but serious/catastrophic risks in young and healthy populations, and stated/observed willingness to pay for vaccines and immunisation programs.[22]

Case study: Shingrix®

- Shingles (herpes zoster) is triggered by the reactivation of the chickenpox virus and up to 1 in 3 Australians risk getting shingles in their lifetime. The risk increases with age.[1]
- Shingles typically produces a painful rash. In most cases, shingles resolves on its own and people recover fully. For some, shingles can lead to ongoing pain (which can last for months) or damage to the eyes, ears or nose.
- GSK estimates the annual cost of shingles to the Australian healthcare system is approximately $125 million in GP, hospital and prescription costs. These costs do not include transport/parking to GP, hospitals or other ongoing support requirements such as carers. For the working population, there is also a potential loss of productivity and income.
- In 2018, Shingrix (varicella zoster virus recombinant vaccine) was approved by the TGA.[2]
- It is recommended by ATAGI for immunocompetent adults aged over 50 years and immunocompromised adults aged over 18 years.[3]
- In 2019 Shingrix was rejected by PBAC due to cost effectiveness concerns and was recommended in 2023 in a sub-set of the proposed population.[4] The vaccine currently remains available to the private market only.

Shingrix is a cost-effective intervention, which is evidenced by the strong and broad recommendations that have been made in other countries, including the US, Canada and Germany. As well as being widely used globally, Shingrix is recommended for use by ATAGI[1] but is currently only available to those who can afford it privately.

The Federal Budget 2023-24 announced funding in adults aged 70, Aboriginal and Torres Strait Islanders over 50 and highly immunocompromised patients. However, many patients who are recommended to receive Shingrix by ATAGI will still need to pay out of pocket, including immunocompromised groups who are not eligible for Zostavax.

1. ATAGI. (2022). Statement on the clinical use of zoster vaccines in adults in Australia. Australian Government Department of Health and Aged Care https://www.health.gov.au/resources/publications/statement-on-the-clinical-use-of-zoster-vaccine-in-older-adults-in-australia
2. TGA. (2018). SHINGRIX Recombinant Varicella Zoster Virus glycoprotein E antigen vaccine 50 micrograms powder vial and suspension vial for suspension for injection (289257). Australian Government Department of Health and Aged Care. https://www.tga.gov.au/resources/prescription-medicines-registrations/shingrix-glaxosmithkline-australia-pty-ltd
3. ATAGI. (2022). Statement on the clinical use of zoster vaccines in adults in Australia. Australian Government Department of Health and Aged Care https://www.health.gov.au/resources/publications/statement-on-the-clinical-use-of-zoster-vaccine-in-older-adults-in-australia
4. PBAC. (2018). ZOSTER VIRUS VACCINE, Injection [1 vial] & adjuvant substance diluent [0.5 mL vial], Shingrix®", Pharmaceutical Benefits Scheme. https:// www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2018-11/files/varicella-zoster-virus-recombinant-vaccinepsd-november-2018.pdf

Case study: Bexsero®

- Invasive meningococcal disease (IMD) is a rare bacterial infection, which can progress rapidly.
- Up to 1 in 10 of those infected may die, and around 1 in 5 may suffer serious long term disabilities including brain damage, deafness or loss of limbs.[1]
- Children (less than two years of age) and adolescents (15–19 years of age) are most vulnerable to the disease, which is spread by secretions from the nose and throat of a person who is carrying the bacteria.[2]
- Strains B, W and Y cause the majority of IMD in Australia.[3]
- It is estimated that a severe case of meningococcal disease-causing lifelong disability could cost the Government an estimated $10 million per patient. The majority of costs include educational assistance, NDIS support, direct Government support and lost tax revenue.[4]
- In 2013, Bexsero (multicomponent meningococcal group B vaccine) was approved by the TGA.[5]
- Since 2014, ATAGI has strongly recommended Meningococcal B vaccination for infants and young children aged <2 years, healthy adolescents aged 15-19 years and other high risk groups.[6]
- Bexsero is currently funded for Indigenous infants up to 12 months and a small group of medically at-risk individuals and South Australian infants up to 12 months and adolescents in year 10 via a State Government Funded program.[7]
- Bexsero was rejected for broader funding by the PBAC due to cost effectiveness concerns. The vaccine currently remains available via the private market to those not included in funding.[8]

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).

It is a cost-effective intervention with strong evidence underpinning the community health benefits of wider access to meningococcal B vaccination, which is supported by recommendations in other countries that currently fund Bexsero on their vaccination programs, including New Zealand, the United Kingdom and France.

1. ATAGI. (2022). Australian Immunisation Handbook, Australian Government Department of Health and Aged Care. immunisationhandbook.health.gov.au
2. World Health Organization. (2023). Meningitis key facts. https://www.who.int/news-room/fact-sheets/detail/meningitis
3. ATAGI. (2022). Australian Immunisation Handbook, Australian Government Department of Health and Aged Care. immunisationhandbook.health.gov.au
4. Wright C, Wordsworth R, Glennie L. (2013). Counting the cost of meningococcal disease : scenarios of severe meningitis and septicemia. Paediatric Drugs.;15(1):49-58. DOI: 10.1007/s40272-012-0006-0. PMID: 23322553.
5. TGA. (2013). BEXSERO - multi-component meningococcal B vaccine (recombinant, adsorbed) suspension for injection 0.5 ml pre-filled syringe with needle (190719).Australian Government Department of Health and Aged Care.
6. ATAG. (2022). Australian Immunisation Handbook, Australian Government Department of Health and Aged Care. immunisationhandbook.health.gov.au.
7. The University of Adelaide. (2023). News Room Life-saving meningococcal B vaccination program continues indefinitely | Newsroom | University of Adelaide.
8. PBAC. (2019). MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE, Injection 0.5 mL, Bexsero®, Pharmaceutical Benefits Scheme. https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2019-11/files/multicomponent-meningococcal-b-vaccine-psd-november-2019.pdf

Managing uncertainty

As noted earlier, an additional barrier to access is the PBAC's conservative approach to managing 'uncertainty', whether clinical or economic. While there is a risk in HTA that the Government may overpay for a new medicine or vaccine that delivers less benefit than predicted, in practice the PBAC seeks to minimise this risk by seeking price reductions. Unfortunately, where price agreement cannot be reached, access to medicines or vaccines may be delayed for medicines or vaccines that would have delivered *more* value than modelled.

The PBAC is particularly cautious with drugs being registered with preliminary data or data with no comparator (single arm), even when supported by other regulatory bodies.[23] Preliminary data and single arm data is often common in therapy areas such as oncology, especially in rare cancers.

For example, in 2022, Jemperli® (dostarlimab) was rejected by the PBAC for advanced endometrial cancer (EC) despite the committee recognising the high need for new EC interventions and the community benefit it would provide.[24] The PBAC were conservative in their benefit modelling noting the "cost-effectiveness of dostarlimab (Jemperli) versus standard of care (SoC) was unable to be reliably assessed due to the uncertain magnitude of benefit for dostarlimab (Jemperli), based on data from a relatively small single arm study."[25]

Case study: Jemperli®

- Endometrial cancer is found in the inner lining of the uterus, known as the endometrium.[1]
- Endometrial cancer is the most diagnosed gynaecological cancer in Australia – followed by ovarian and cervical cancer.[2]
- In 2021, it is estimated that more than 3,200 new cases of endometrial cancer were diagnosed (approximately 8 women every day), and an estimated 660 women died from the disease.[3]
- It is most common in women over 60 and in post-menopausal women.[4,5]
- Fewer than 1 in 5 women with advanced endometrial cancer will survive 5 years or longer after the cancer is found.[6]
- In 2022, Jemperli received provisional approval from the TGA for adult patients with recurrent or advanced mismatch repair deficient (dMMR) endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.[7]
- In 2022 and again in 2023, Jemperli was rejected by the PBAC due to cost effectiveness concerns in terms of uncertainty of benefit.[8]
- There are currently no other treatment options available.

1. Australian Institute of Health and Welfare & Cancer Australia. (2012). Gynaecological cancers in Australia: an overview. Cancer series no. 70. Cat. no. CAN 66. AIHW
2. Ibid
3. Cancer Australia. (2023). Uterine Cancer Statistics. https://www.canceraustralia.gov.au/cancer-types/uterine-cancer/statistics
4. American Cancer Society. (2023) Endometrial Cancer.https://www.cancer.org/cancer/endometrial-cancer/about/key-statistics.html
5. TGA. (2022). Jemperli. Australian Government Department of Health and Aged Care https://www.tga.gov.au/resources/auspmd/jemperli
6. Cancer Australia. (2023). Uterine Cancer Statistics. https://www.canceraustralia.gov.au/cancer-types/uterine-cancer/statistics
7. TGA. (2022). Jemperli. Australian Government Department of Health and Aged Care https://www.tga.gov.au/resources/auspmd/jemperli
8. PBAC. (2022). Public Summary Documents: DOSTARLIMAB Solution concentrate for I.V. infusion 500 mg in 10 mL, Jemperli®, GlaxoSmithKline Australia Pty Ltd." Pharmaceutical Benefits Scheme. https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-11/files/dostarlimab-psd-11-2022.pdf

This second submission presented new economic modelling that lowered the ICER from its previous submission from $55,000 to < $75,000/QALY to $45,000 to < $55,000/QALY.[26] However, the PBAC considered that the ICER still remained unacceptably high given the level of uncertainty in the magnitude of benefit and long-term overall survival (OS). A third application to the PBAC in 2023 provided a revised pricing proposal to mitigate the uncertainty in the ICER, but was still rejected. Overall, there was no ICER threshold that could adequately mitigate the uncertainty for the PBAC to recommend funding, despite the PBAC recognising the superior clinical efficacy and high clinical need for new treatments – meaning that patient access would be delayed indefinitely.

Benlysta® (belimumab) was also rejected by the PBAC in 2019 and 2020 for systemic lupus erythematosus (SLE).[27] The PBAC considered that the evidence provided did not provide a substantial enough benefit or certainty of benefit to patients.[28] In this case, over seven years of long-term clinical data was supplied in the submission. However, while the PBAC acknowledged the "clinical need for effective treatments for SLE, particularly for the group of patients who are not responding to current therapies" they noted that the estimated QALY were "not adequately justified."[29] As a result, GSK is currently unable to resubmit to the PBAC for patients living with SLE. It should be noted that the PBAC has the flexibility to accept data uncertainty where there is a large clinical need with no alternative treatment options available and at a relatively small cost to the government.

Case study: Benlysta®

- Systemic Lupus Erythematosus (SLE), also known as lupus, is a disease of the immune system where the antibodies produced by the immune system in lupus cause inflammation, tissue damage and pain.[1]
- SLE is characterised by flare ups and periods of improvement (remissions) and can affect almost any organ or system of the body. In most people only the skin and joints are affected. However, in some people SLE can also affect the kidneys, lungs, heart, blood vessels and/or brain.[2]
- Around 90% of people with lupus are women and the majority develop the condition between 15 and 45 years.[3]
- It is estimated to affect more than 20,000 people in Australia and New Zealand.[4] Lupus is more common and severe in Indigenous Australians, Polynesians and those with ancestry from South East Asia.[5]
- In 2019, Benlysta received TGA approval.[6]
- In 2020, Benlysta was rejected by the PBAC noting that the evidence provided did not provide a substantial enough benefit or certainty of benefit to patients.[7]

1.-5. Australasian society of clinical immunology and allergy (ASCIA) 2019, Information for patients, consumers and carers: Systemic Lupus Erythematosus (SLE), ASCIA https://www.allergy.org.au/images/pcc/ASCIA_PCC_Systemic_Lupus_Erythematosus_2019.pdf

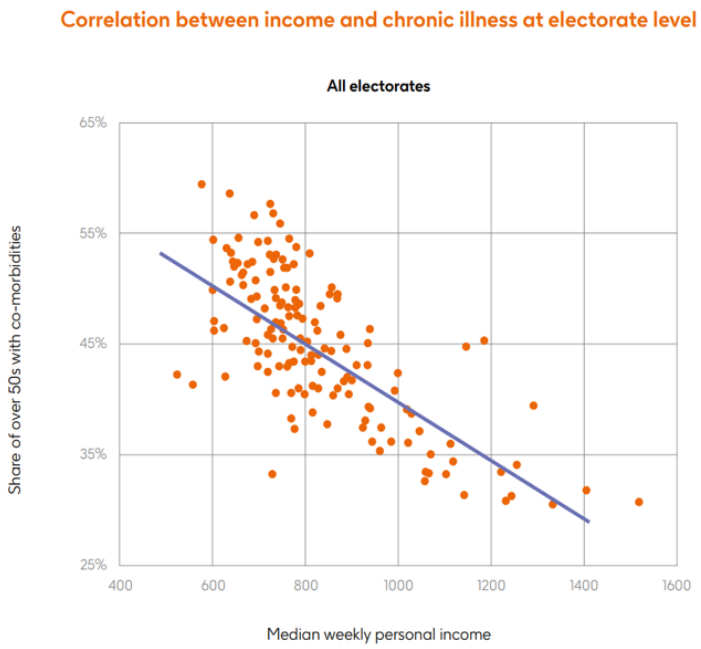
6. Therapeutic goods Administration, 2019, BENLYSTA belimumab 200 mg/mL solution for injection in a pre-filled pen (314922), Australian Government, Department of Health and Aged Care https://www.tga.gov.au/resources/artg/314922

7. Department of health. "Public Summary Documents: BELIMUMAB, Injection 200 mg in 1 mL pre-filled pen, Benlysta® GlaxoSmithKline Australia Pty Ltd, ." Pharmaceutical Benefits Advisory Committee, July 2020 https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2020-07/files/belimumab-psd-july-2020.pdf

The consequences of undervaluing medicines and vaccines

Delays in listing and reimbursement have meant that some vaccines and medicines are only available on the private market and as a result only those who can afford them have access.

For example, GSK Australia's 'Risk to resilience: a roadmap to vaccine access for older Australians' report outlined current inequity in access among older Australians due to income, location, education and ethnic/cultural diversity. The report found there was a correlation between a person's average income, state/territory of residence and proximity to metro areas, level of education attained, cultural background (particularly for Aboriginal or Torres Strait Islanders) and health outcomes.[30]



GSK Australia. (2023). Risk to resilience: a roadmap to vaccine access for older Australians. GlaxoSmithKline Australia, p9

Those with higher average incomes had less presence of co-morbidities and better overall health outcomes than those with lower average incomes. The report concluded that this gap exacerbated the impact of those with a higher income being able to access and afford better health interventions and services.[31]

For example, Shingrix is expected to be listed on the NIP late in 2023, at least 5 years after it was first submitted to the PBAC. Even at that time, it will only be available to non-Indigenous adults aged 70 years, Aboriginal and Torres Strait Islanders over 50 years and highly immunocompromised patients.[32] This has meant that people have only been able to access it if they have the financial means, and this will continue to be the case for many.

Bexsero is also currently only funded on the NIP for small sub-populations, despite being recommended for broad use in infants and adolescents by Australian Technical Advisory Group on Immunisation (ATAGI) in 2014.[33] This has led to the South Australian state government funding their own program for the vaccine for all children and adolescents that the Commonwealth government does not fund since 2018.[34]

In the most recent submission for Bexsero to the NIP, the PBAC concluded that "the rarity of invasive meningococcal B disease compared to the large number of vaccinations that are required was the primary driver of the unfavourable incremental cost-effectiveness ratio, and that … given the clinical uncertainties of a population wide prevention, there was high financial risk to the government and reduced opportunity to fund other interventions which are acceptably cost-effective."[35]

The fact that parents are willing to pay to prevent a rare but serious illness for their children if they can so afford, and that a state government has stepped in to cover its citizens, suggests that the PBAC's 'value for money' hurdle is inappropriately high.

Patient Centeredness

GSK Australia supports amplifying the consumer voice and patient involvement in HTA processes. The benefits of incorporating a patient or consumer view are well recognised within the medicines sector and within established policy frameworks. This includes the Medicines Australia Strategic Agreement 2022-2027[36] and Australia's Long Term Health National Health Plan.[37] GSK acknowledges that considerable progress has been made to engage patients and patient groups in HTA frameworks. However, gaps remain in how involvement is supported, including facilitating involvement, clarity on roles, two-way flow of information, and methods for enhancing communication between patients and the PBAC and Medical Services Advisory Committee (MSAC).[38]

The Enhanced Consumer Engagement Process aims to capture consumer and patient perspectives earlier in HTA processes to allow enough time for consumer representatives to gather feedback and influence outcomes.[39] However, the frameworks for assessing the value of medicines and vaccines such as cost-per-QALY and health system perspective are narrow, meaning that many areas of input from patients on issues that matter to them (e.g. being able to work, reduced dependence on carers and improved convenience) rarely influence decision-making.

For example, the future benefits seen from vaccines such as Bexsero and Shingrix are not fully realised using the process as a result of the discount rate, healthcare perspective and ICER thresholds. As such, patient responses discussing these benefits are unlikely to influence decisions. Patients often feel that their input is not valued and this may literally be the case given the value frameworks used. Facilitating greater input from patients will not be satisfactory for any stakeholder if the HTA system is unable to attribute value to the aspects that matter to patients.

As stated in GSK Australia's National Medicines Policy submission[40] and The Australian Cancer Plan 2022-2023 submission,[41] current regulations limit interactions between the medicines sector and consumers. This governance, while designed to protect consumers may go too far in restricting interactions. There should be an ability for medicines companies to share locally-relevant, scientifically-accurate and balanced information on the medicines with patient groups. This would better equip patient groups to educate and support their stakeholders – the consumer community.

> *"Consumers will assume a 'new power'. They will command convenience and access to high value, modern, personalised services that meet their needs. They will expect to have choice and control over the services they pay for. They will be activated more than ever with access to burgeoning information and innovations that will assist them to stay well."*[7]
>
> Tony Lawson (Chair) and Leanne Wells (Chief Executive Officer), Consumer Health Forum.
>
> Consumers Health Forum of Australia. (2018). Shifting Gears – Consumers Transforming Health. pp 1. https://chf.org.au/sites/default/files/181125_shifting_gears_-_consumers_transforming_health.pdf

GSK Australia Submission
Health Technology Assessment Methods and Policy review
June 2023

Conclusion

GSK recognises the importance of the Health Technology Assessment Methods and Policy review and is aligned with its aim of reviewing processes to improve early and equitable access for Australian patients.

The COVID-19 pandemic demonstrated the need for Australia's HTA system to be strengthened to consider future and broader socioeconomic benefits innovative medicines and vaccines can have, as well as the importance of early and equitable access.

HTA should support other Government policies such as the NMP, National Prevention Strategy and National Immunisation Strategy, and recognise the value of investing in medicines and vaccines. It must have consumers at its centre, and encourage innovation, collaboration and accountability. We support Medicines Australia's recommendations to develop a framework for a sustainable health system with the ability to keep pace with the latest medical advancements, translating them into improved health outcomes for Australian consumers such as a lower discount rate, lower ICER and broader healthcare perspective.

GSK looks forward to continuing to partner with government, industry, health professional, research and community in developing an HTA system that delivers for Australian patients.

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 by 2030 and a net positive impact on nature by 2030.

For further information please visit au.gsk.com.

References

1. Australian Government Department of Health and Aged Care. (2022). National Medicines Policy 2022. national-medicines-policy.pdf (health.gov.au)
2. Medicines Australia. (2019). Comparison of Access and Reimbursement Environments (COMPARE) Edition 5
3. *Ibid*
4. *Ibid*
   GSK Australia. (2023). Risk to resilience: a roadmap to vaccine access for older Australians. GlaxoSmithKline Australia. au.gsk.com/media/6823/2003219_gsk-vaccineaccessreport-web-version.pdf
5. Medicines Australia. (2022). Consumer Engagement. https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/11/HTA-DP-Consumer-Engagement-.pdf
6. GSK Australia. (2022). The Australian Cancer Plan 2022-2033. GlaxoSmithKline Australia. https://au.gsk.com/media/6472/20220303_submission_gsk_au_australiancancerplan.pdf
7. Australian Government Department of Health. (2021). National Preventative Health Strategy 2021-2030. National Preventive Health Strategy 2021-2030 (health.gov.au).
8. Australian Government Department of Health. (2019). National Immunisation Strategy for Australia 2019-2024. The National Immunisation Strategy for Australia 2019–24 (health.gov.au).
9. Australian Government Department of Health and Aged Care. (2022). National Medicines Policy 2022. national-medicines-policy.pdf (health.gov.au).
10. Angelis, A., Lange, A. & Kanavos, P. (2018). Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries. https://link.springer.com/article/10.1007/s10198-017-0871-0
11. AIHW. (2022). Australia's Health 2022: In Brief. https://www.aihw.gov.au/reports-data/australias-health, p13
12. Medicines Australia. (2022). Submission to the PBAC on the Base Case Discount Rate https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/02/Medicines-Australia-submission-to-PBACDiscount-Rate-Submission-January-2022.pdf
13. *Ibid*
14. GSK Australia. (2022). GSK Australia Submission: Review of the Discount Rate in PBAC Guidelines. GlaxoSmithKline Australia https://au.gsk.com/media/6796/gsk-australia-submission-review-of-the-discount-rate-in-the-pbac-guidelines.pdf
15. Australian Government Department of Health. (2021). National Preventative Health Strategy 2021-2030. National Preventive Health Strategy 2021-2030.
16. Pharmaceutical Benefits Advisory Committee, (2022). Public summary document: Review of the base-case discount rate in the PBAC Guidelines. Australian Government Department of Health and Aged Care https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-07/files/review-of-discount-rate-psd-july-2022.pdf
17. Hanley, R. Manton, A. and Trace-MacLaren, K. (2019). The Value of Vaccines Ensuring Australia keeps pace with community values and international practice. GlaxoSmithKline Australia
18. Paris, V. & Belloni, A. (2014). Value in Pharmaceutical Pricing, Country Profile: Australia. OECD. https://www.oecd.org/health/Value-in-Pharmaceutical-Pricing-Australia.pdf,
19. Mauskopf, J. (2012). Relationship Between Financial Impact and Coverage of Drugs in Australia. International Journal of Technology Assessment in Health Care. https://www.cambridge.org/core/journals/international-journal-of-technologyassessment-in-health-care/article/relationship-between-financial-impact-and-coverage-of-drugs-in-australia/FED609AC0B3FDADEF45FE6EDC2D20ED8
20. Pharmaceutical Benefits Advisory Committee. (2018). ZOSTER VIRUS VACCINE, Injection [1 vial] & adjuvant substance diluent [0.5 mL vial], Shingrix®. Pharmaceutical Benefits Scheme. https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2018-11/files/varicella-zoster-virus-recombinant-vaccinepsd-november-2018.pdf
21. Hanley, R. Manton, A. and Trace-MacLaren, K. (2019). The Value of Vaccines Ensuring Australia keeps pace with community values and international practice. GlaxoSmithKline Australia
22. Department of health. "Public Summary Documents: DOSTARLIMAB Solution concentrate for I.V. infusion 500 mg in 10 mL, Jemperli®, GlaxoSmithKline Australia Pty Ltd." Pharmaceutical Benefits Advisory Committee, November 2022 https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-11/files/dostarlimab-psd-11-2022.pdf
23. Medicines Australia. 2019. Comparison of Access and Reimbursement Environments (COMPARE) Edition 5
24. Department of health. "Public Summary Documents: DOSTARLIMAB Solution concentrate for I.V. infusion 500 mg in 10 mL, Jemperli®, GlaxoSmithKline Australia Pty Ltd." Pharmaceutical Benefits Advisory Committee, November 2022 https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2022-11/files/dostarlimab-psd-11-2022.pdf
25. *Ibid*

26. Department of health. “Public Summary Documents: BELIMUMAB, Injection 200 mg in 1 mL pre-filled pen, Benlysta® GlaxoSmithKline Australia Pty Ltd, .” Pharmaceutical Benefits Advisory Committee, July 2020 https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2020-07/files/belimumab-psd-july-2020.pdf
27. *Ibid*
28. *Ibid*
29. GSK Australia. (2023). Risk to resilience: a roadmap to vaccine access for older Australians. GlaxoSmithKline Australia. au.gsk.com/media/6823/2003219_gsk-vaccineaccessreport-web-version.pdf
30. *Ibid*
31. ZOSTER VIRUS VACCINE, Injection [1 vial] & adjuvant substance diluent [0.5 mL vial], Shingrix®”, Pharmaceutical Benefits Advisory Committee, November 2018, https:// www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2018-11/files/varicella-zoster-virus-recombinant-vaccinepsd-november-2018.pdf
32. ATAGI. (2014). Advice for immunisation providers regarding the use of Bexsero® – a recombinant multicomponent meningococcal B vaccine (4CMenB). Australian Government Department of Health. ATAGI Advice to Immunisation Providers on Use of Bexsero® – (health.gov.au)
33. SA Health. (2020). National Immunisation Program: South Australian Schedule, South Australia State Government.https://www.sahealth.sa.gov.au/wps/wcm/connect/867a5f004dda2d17a7dcff6d722e1562/20063.1+National+Immunisation+ScheduleFINAL.pdf, accessed 31/5/2021.
34. PBAC. (2019). MULTICOMPONENT MENINGOCOCCAL GROUP B VACCINE, Injection 0.5 mL, Bexsero®, Pharmaceutical Benefits Scheme. https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2019-11/files/multicomponent-meningococcal-b-vaccine-psd-november-2019.pdf
35. Australian Government Department of Health. (2021). Strategic Agreement in relation to reimbursement, health technology assessment and other matters. https://www.medicinesaustralia.com.au/wp-content/uploads/2021/09/Medicines-Australia-Strategic-Agreement-2022-2027.pdf.
36. Australian Government Department of Health. (2019). Australia’s Long Term National Health Plan To Build The World’s Best Health System. https://www.health.gov.au/sites/de fault/files/australia-s-long-term-national-health-plan_0.pdf
37. Scott, A.M., Wale, J.L. & On behalf of the HTA Patient and Citizen Involvement in HTA Interest Group, Patient Involvement and Education Working Group. Patient advocate perspectives on involvement in HTA: an international snapshot. Res Involv Engagem 3, 2 (2017). https://doi.org/10.1186/s40900-016-0052-9
38. Medicines Australia. (2022). Consumer Engagement. https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/11/HTA-DP-Consumer-Engagement-.pdf
39. GSK Australia 2021 ‘National Medicines Policy, GlaxoSmithKline Australia, https://au.gsk.com/media/6462/20210810_gsk_au-submission-the-review-of-the-national-medicines-policy.pdf
40. GSK Australia 2022, ‘The Australian Cancer Plan, GlaxoSmithKline Australia, https://au.gsk.com/media/6472/20220303_submission_gsk_au_australiancancerplan.pdf

Contact

Penelope Kaltzis
Government Affairs and Policy Manager
GSK Australia
Level 4, 436 Johnston Street, Abbotsford, Victoria, 3067
PO Box 18095, Melbourne, Victoria, 8003.
Email penelope.j.kaltzis@gsk.com
Mobile +61 (0) 403 106 516