Medicines Australia | Better health through research and innovation

30 January 2026

Treasury
Langton Cres
Parkes ACT 2600
Via email: PreBudgetSubmissions@treasury.gov.au

Dear Budget Policy Division,

RE: Medicines Australia 2026-27 Pre-Budget Submission

Thank you for the opportunity to urge the Government to use this Budget to increase investment in innovative medicines through the Pharmaceutical Benefits Scheme (PBS) and implement reforms to Australia's Health Technology Assessment (HTA) system.

The PBS, a cornerstone of Australia's health system, intends to provide affordable and equitable access to essential medicines for millions of Australians while supporting better health outcomes nationwide. However, without investment and reform, Australian patients will continue to miss out on medicines that are already improving and saving lives overseas—waiting years or never receiving affordable access at all. This is not an abstract policy issue; it affects people living with cancer, rare diseases, chronic illness and preventable conditions who are running out of time and options. Increased geopolitical pressure from international reference pricing policies is having impact now on Australia's launch status for innovative medicines. Reforming Australia's HTA system and appropriately valuing medicines is a domestic policy solution to alleviate this pressure.

Clinical trials, real world data and independent expert research and analysis, demonstrate that innovative medicines substantially improve the lifespan, quality of life and productivity of Australians. Yet net expenditure on medicines and supply chain services in the PBS has declined relative to the health budget: from 13.5 per cent in 2014 down to only 9.5 per cent in 2025. In this period our access to innovative medicines started slow and decelerated further. From 2014-2019, there was, on average, a delay of 391 days between the TGA deeming a new medicine as safe and effective and Australians receiving subsidised access to it. From 2016-2021, this delay increased by 19 per cent, jumping up to 466 days. In addition, only around 27 percent of globally supplied innovative medicines are made available to Australians via the PBS.

This Budget represents a once-in-a-generation opportunity to arrest this deterioration and fix a system that is falling behind, so the PBS can once again deliver on its promise of timely, equitable and affordable access to medicines for all Australians:

1. The comprehensive, once-in-a generation review of Australia's HTA policies and methods was completed in 2024 and a roadmap to better policy was delivered to Government in 2025.
2. Patients, clinicians and industry are united in their call for reform via this roadmap.
3. Implementing this roadmap is the best opportunity to deliver the investment increase that is required to ensure timely and equitable access to innovative medicines for Australian patients.
4. Geopolitical pressures are rising, driven by "Most Favored Nation" (MFN) reference pricing policies from the United States. Lack of action on implementing domestic reform may result in further deterioration of our access to medicines.

Recommendations to improve access to innovative medicines in this budget

REC #1: Increase investment in innovative medicines and implement HTA reform

Medicines Australia recommends the Government substantially increases investment for innovative medicines in the PBS and undertakes a once-in-a generation reform of the Heath Technology Assessment (HTA) System that governs this spending. Medicines Australia recommends this reform follows the Implementation Advisory Group (IAG) Roadmap for implementing recommendations from the HTA Review. These reforms are designed to reduce the delay between TGA registration and PBS listing to 6 months, for 90 per cent of products demonstrating superiority (where parallel processes are used). In vaccines and ultra-rare diseases, where the current delay in close to 4 years, the recommendations are designed to reduce the delay to weeks (20 weeks and 4 weeks, respectively). A commitment to these reforms is required in the 2026-27 Federal Budget.

REC #2: Focus on reforming lowest cost comparator and discount rate applied to appropriately value innovative medicines

Medicines Australia recommends immediate implementation of a revised guideline for comparator selection and the discount rate used by the Pharmaceutical Benefits Advisory Committee. This is consistent with Minister Butler's commitment in September 2025 to make these issues an early focus, for which stakeholders are yet to see progress. These reforms are most likely to reduce the delay in patient access to some medicines. Medicines Australia recommends The National Health Act includes an additional clause to clarify that, in subsections 101(3A) and (3B), in having regard to the alternative therapy or therapies for the relevant patient population and any sub-populations, the Committee must consider the therapy or therapies most likely to be replaced in clinical practice. A new bridging fund as recommended by the HTA Review would also reduce patient delay for specific medicines.

A healthy innovative medicines sector underpins the delivery of the medicines that Australians need, and brings highly skilled jobs, strengthens national security and supply chains, investment in R&D and commercial partnerships and clinical trials. Commitments that are important drivers for this ecosystem are below.

REC #3: Continue to drive NOSS to boost research ecosystem for innovative medicines

As committed in the 2025-26 Budget, and progressed in October 2025, continued progression on the National One Stop Shop (NOSS) for clinical trials is critical. The NOSS is a digital platform designed to streamline approval and reporting processes for research across Australia. It will underpin improved productivity in our clinical trials sector, encourage greater investment, enhance domestic capabilities in addition to supporting the development of essential new medicines.

Industry-sponsored clinical trials contributed $1.3 billion to Australia's economy and R&D sector in 2023 and given barriers to accessing innovative medicines, clinical trials provide some Australians with access to medicines they would not otherwise be able to receive.

REC #4: Establish a national life sciences council

Medicines Australia supports continued calls for the Australian Government to establish an Australian Life Sciences Council under the auspice of the Prime Minister, and to invest $3.6 million over four years for the establishment and operation of the Council. The rationale for establishing a Council is clear – it

will create the conditions to realise the full potential of Australia's life sciences industry, and maximise its contribution to national health, wealth and security goals. A Council, properly constituted with the right stakeholders could oversee and ensure delivery of the NHMRS and the SERD.

Five reasons why these recommendations matter

Reason	Proof point
Investment in innovative medicines to date has been highly effective	The Productivity Commission shows the quality of our health is growing relative to the cost of our healthcare by around 3 per cent per year, concluding: "*more timely approval processes for pharmaceuticals and other medical technologies would help ensure that the diffusion of new treatments remains a positive contributor to productivity growth."* This is precisely what HTA reform will achieve.
Missing medicines	Australians receive access to a fraction of globally supplied innovative medicines, after a long delay. Selected examples are detailed below.
Australia is under-investing	Australia invests only 0.26 per cent of GDP in innovative medicines, compared to: 0.78 per cent in the USA, 0.4 per cent in Japan and 0.34 per cent in the EU.
Innovative medicines create productivity benefits that offset some of their costs	Early retirement due to poor health is estimated to reduce Australia's economy by 2.5 per cent; programs including medicines can reduce this cost by up to 20 per cent. Had PBS medicines not increased between 1994 and 2011, our hospital expenditure would have been an estimated $6 billion per year higher in 2019. The roll-out of COVID vaccines added an estimated $180 billion to the economy in 2021-2023 (relative to a scenario where the vaccines were not rolled out). The government invested $18 billion in these vaccines. Clinical trials (in disease areas that cover around 23 per cent of the PBS) find innovative medicines create significant productivity improvements for patients of between 18 per cent to 50 per cent. For the USA, it is estimated the economy would be $210 billion smaller per year if applicable patients (13 per cent of the workforce) did not have access to these medicines. Globally, fast tracking the roll out of antiretrovirals to treat HIV-AIDS is estimated to create $2.5 worth of productivity benefits for each $1 of cost. Expanding the treatment of Hepatitis C patients with curative Ledipasvir/Sofosbuvir is estimated to generate between £1.8-£5.4 of welfare/disability savings and tax revenue for the UK Government for each £1 of additional Government investment.
Investment in the PBS is required	The value that the Government puts on the health benefits created by innovative medicines (between $50,000 to $75,000 per QALY gained), is far below the value Australian society puts on these health benefits, as found in economic research (around $250,000 per life-year gained, expressed by the Office of Impact Analysis). Expert researcher Peter Abelson notes his view and others' view that these values should be the same. MA suggests this under-valuation by government, as a barrier to access, is (implicitly) why patients are so strong in their support for HTA reform to improve access to innovative medicines. Health authorities in comparable countries are taking steps to increase their willingness to pay for medicines (for example, the United Kingdom).

Properly account for expenditure	Headline PBS investment was $19.3 billion in 2024-25. Of this: $6.8 billion was collected back by government in rebates from innovators. From headline investment plus copays, at least $3.4 billion was payments to manufacturers of F2 (older) medicines, and at least $5.4 billion was income for wholesalers and pharmacists.

This budget is a unique opportunity to take the action required to ensure Australian patients get improved access to the medicines they need when they need them. We welcome the opportunity to discuss our recommendations further and share our relevant assumptions and modelling to provide surety of the necessary expenditure.

Yours sincerely,

Elizabeth de Somer
Chief Executive Officer

Appendix 1: detailed discussion of missing medicines

The following are summary case studies of medicines that are "missing" from the PBS (other programs). HTA reform will strengthen the PBS to improve patient access to these and other medicines. To be clear: this list is by no means comprehensive.

Missing medicines #1: Missing and delayed treatments for rare diseases

There is a substantial opportunity to improve the access to medicines for Australians living with rare diseases. In total, this is around 2 million Australians (collectively, people with individual diseases that affect less than 5 in 10,000 people).[i] Around 80 per cent of these diseases are of genetic origin,[ii,iii] and around three-quarters of these diseases impact children. There are two parts to this opportunity.

Firstly, Australia's subsidized program for accessing medicines for ultra-rare diseases, the Life Saving Drugs Program (LSDP), is arguably too small and too slow. Currently, this program lists 17 innovative medicines.[iv] Of these, only 8 were added in the decade 2016-2025. For these innovative medicines listed 2016-2025, the average delay between the TGA deeming them to be safe and effective (ARTG registration) and LSDP listing (when Australians receive subsidised access) was 1437 days. This means Australians (many of whom are infants and children) received these life-saving treatments 3 years and 11 months after the Government deems them to be safe and effective.

Secondly, Australia is slipping behind in cell and gene therapies, many of which aim to cure rare diseases. These therapies are one of the world's greatest medical achievements and are at the leading edge of advanced healthcare. They are increasingly being used in clinical practice within Australian hospitals. But arguably, progress has been slower than elsewhere in the world. The US Food and Drug Administration (FDA) have, for example, approved 48 cell and gene therapies.[v] From this list, only 7 appear to be registered on the ARTG.

Missing medicines #2: Improved access to treatments for blood cancers

An example is polatuzumab vendotin, which is recommended as first line treatment for diffuse large b-cell lymphoma (DLBCL) by multiple overseas institutions (European Society for Clinical Oncology, American Cancer Society, and British Society of Hematology). Patients in the UK have been receiving subsidised access to this drug since January 2023.

More than 2000 Australians were diagnosed with DLBCL in 2021, but they do not receive subsidised access to polatuzumab vendotin, as it is not listed on the PBS. No access to polatuzumab vendotin means that Australian patients miss out on a treatment that could prevent relapse; critical as once DLBCL relapses, it becomes much harder to treat and often requires aggressive costly later-line interventions like stem cell transplants or CAR T-cell therapy.

Missing medicines #3: System improvements so Australians can access the latest Vaccines

There has been a "concerning" decline in Australia's childhood vaccination rates (by around 3 per centage points) since 2020.[vi] Australia's adult immunisation schedule is assessed as "very limited"; expanding this schedule is judged to be a clear opportunity to improve Australia's health. [vii] In 2019 Australia had a higher rate of vaccine-preventable deaths than comparable countries. In 2019 Australia had 3.4 vaccine-preventable deaths per 100,000 population, a significantly higher rate than Canada (2.7 vaccine-preventable deaths per 100,000 people), France (2.9), Germany (2.9), Italy (1.5), South Korea (3.1) and the UK (2.4). Japan (4.2), Brazil (3.8) and Mexico (3.6) had higher rates.[viii]

HTA reform (especially adjusting the discount rate) is a key pathway to improving this situation.

1. There is a 1,375 day delay between a vaccine being deemed "safe and effective" by the TGA and Australians receiving subsidised access to it.[ix] This delay is far longer than for other medicines (for all innovative medicines, the average delay is 466 days between TGA approval and the

granting of subsidised access). This vaccine delay is similar to the delay for accessing medicines on the LSDP.

2. Research finds the health technology assessment process by which medicines are evaluated in Australia generally assumes that a quality-adjusted year of life saved by a vaccine is worth only around $15,000 - this is much lower than other types of medicines, and much lower than for other Government policy areas.

A good example is our (limited) access to a Meningococcal B Vaccine. In 2002, there were 210 confirmed cases of Meningococcal B and 162 confirmed cases of Meningococcal C in Australia. In 2003, the Vaccine for Meningococcal C was introduced.[x] By 2022, there were 100 confirmed cases of Meningococcal B and zero confirmed cases of Meningococcal C.[xi]

Up to 10 per cent of people with Meningococcal disease may die; around 25 per cent suffer serious long-term disabilities (including brain damage, deafness or loss of limbs). [xii] One severe case of Meningococcal B is estimated to create cost to Governments of $10 million (including: educational assistance, disability support, direct support and lost tax revenue). [xiii]

ATAGI (Australian Technical advisory Group on Immunisation) strongly recommends Meningococcal B vaccination for a significant share of the population: (1) Infants & children under 2 years, (2) Healthy adolescents aged 15-19 years, (3) Individuals aged 15-24 years living in close quarters and (4) Aboriginal and Tores Straight Islander peoples aged 2 years – 19 months.

Individuals who are able can choose to self-fund the vaccine. The governments of South Australia, Queensland and Northern Territory have delivered their own immunisation programs. Tasmania's Government has committed to a program for infants. This means access is now dependent on Australians' income and postcode.

Despite four submissions for inclusion of the National Immunisation Program (NIP), the vaccine sponsor has been unsuccessful in securing access for all Australian children to the Meningococcal B vaccine demonstrating system failure. HTA reform is required to improve access to vaccines for all Australians.

Missing medicines #4: Greater focus on prevention will deliver dividends

The Australian Institute of Health and Welfare (AIHW) finds that Australians being overweight (including obesity) is the leading risk factor that is causing preventable health loss in Australia. Australians being overweight and/or obese increases the risk of chronic disease, including an increased risk of Type 2 diabetes mellitus.

The PBS grants Australians subsidised access to Ozempic for Type II diabetes mellitus. However, it does not grant Australians access to Wegovy (essentially the same drug) for being overweight or obese. GLP-1s such as Semaglutide (Wegovy) are clinically proven to achieve significant and sustained weight loss, improve glycaemic control, and reduce risks associated with conditions such as cardiovascular disease.[xiv,xv]

Missing medicines #5: Radiopharmaceuticals

Prostate Cancer is the most commonly diagnosed cancer in Australia. In 2022, there were approximately 24,000 males diagnosed with prostate cancer in Australia.[xvi]

Radiopharmaceutical therapies are an innovative form of precision nuclear medicine, harnessing radioactive isotopes to detect and destroy cancerous cells while sparing healthy tissue. These therapies are rapidly becoming known as an essential sixth pillar of cancer care, with TGA registered therapies now available for prostate cancer (Pluvicto) and neuroendocrine tumours (Lutathera).

Pluvicto was approved for use in the various countries form 2022 onwards.[xvii] Patients can access the medicine via public reimbursement in most Canadian provinces, Japan, Germany, France Italy and Belgium.

Unfortunately, the experience in Australia has been quite different. While the sponsor was undergoing TGA assessment for Pluvicto, a process that ensures the quality, safety, and efficacy of medicines made available to Australian patients, an application was made to the Medical Services Advisory Committee (MSAC) seeking public reimbursement for a generic version therapy that had not been assessed by the TGA, and which relied upon Pluvicto's Phase III trial data, not its own. Despite intellectual property concerns and the absence of regulatory evaluation, MSAC positively recommended and the Government subsequently funded MBS item numbers to subsidise access to the entire class of therapies, including both the generic version and Pluvicto.

This creates several problems for patients who need to access these medicines:

1. Significant private costs - Patients face substantial out of pocket costs, as the reimbursement paid via the MBS is only a small part of actual costs, with patients required to make full payment up front and seek the partial rebate thereafter.
2. Geographic access barriers - Patients can only access the medicine in private clinics or in public hospitals that allow doctors to charge private costs. This adds to the out-of-pocket costs faced by patients and means patients in many areas cannot access the medicine. This is particularly problematic in States like South Australia, where public hospitals cannot charge patients out of pocket and are restricted from providing private options unless they are also available publicly.

Medicines Australia urges the Government to ensure, as a pre-requisite to reimbursement, Radiopharmaceutical therapies should be subject to TGA assessment.

Missing medicines #6: Implement reforms to incentivise Anti-Microbial Resistance investment and improve access to new treatments

The HTA Review recommended that Australia's HTA system be developed to improve incentives for antimicrobial development in Australia (for example, the adoption of subscription models trialed elsewhere). Each year hundreds of Australians are affected because of drug resistant infections. The World Health Organisation (WHO) estimates the development of resistance by infections to antibiotics (and other drugs, so-called: "antimicrobial resistance") could result in up to 10 million deaths per year by 2050.[xviii] Unfortunately, research efforts to develop new, more powerful medicines have been stalled by low return on investment to this research provided by existing reimbursement/payment systems (such as Australia's HTA system) and changing use, hence the need for reform.

Missing medicines #7 Improved access to medicines for Crohn's Diseases

It is estimated that Inflammatory Bowel Disease (IBD) had total economic costs of $7.8 billion in 2025. The disease's incidence is growing more quickly in Australia than in comparable countries. Within this, Crohn's Disease has significant economic costs and preventing disease progression through ongoing management on effective treatments has been found to create significant economic benefits. The suite of medicines to tackle Crohn's disease is lower than in comparable countries. Patient groups are calling for HTA reform to increase access to Crohn's Disease treatments.[xix]

Patient story: Harrison Kefford

Harrison Kefford's was unable to work because his Crohn's disease was so severe. He feared he would be stigmatised, because he had to go on a disability support pension. Harrison, similar to the other 180,000 Australians diagnosed with IBD are dependent on the Australian Government to provide

affordable, equitable access to innovative treatments so they can live more productive and 'normal' lives.

Source: Inflammatory bowel disease rates increasing in Australia, costing the economy billions - ABC News

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[ii] Rare Voices discussion see: Learn more about rare diseases including genetic disorders (accessed 8/1/2025)
[iii] Murdoch Children's Research Institute, see: Rare genetic disorders - Murdoch Children's Research Institute (accessed 8/1/2025)
[iv] Department of Health, see: About the Life Saving Drugs Program | Australian Government Department of Health, Disability and Ageing (accessed 8/1/2025)
[v] FDA, see: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products (accessed 8/1/2026)
[vi] NCIRS 2025, see: Annual Immunisation Coverage Report 2024.pdf (accessed 13/1/2025)
[vii] Office of Health Economics 2025, see: Analysing-Global-Immunisation-Expenditure.pdf (accessed 20/1/2026), pg. 35
[viii] Office of Health Economics 2025, see: Analysing-Global-Immunisation-Expenditure.pdf (accessed 20/1/2026)
[ix] ShawView 2021, *Valuing Vaccines,* see: 8a9719_c61751a436ac49638ceed8b75cbf62af.pdf (accessed 20/1/2026)
[x] See: Meningococcal disease | Australian Vaccination-Risks Network Inc. (accessed 6/1/2026)
[xi] Annual Reports of Australian Meningococcal Surveillance Program, Communicable Diseases Intelligence, Reports: 2002 and 2022, see: Department of Health and Aged Care | Australian Meningococcal Surveillance Program (AMSP) annual reports (accessed 20/1/2026)
[xii] GSK Meningococcal study
[xiii] GSK Meningococcal study
[xiv] Wilding, JPH, et al. (2021). Once-weekly Semaglutide in adults with overweight or obesity. The New England Journal of Medicine, 384(11), 989–1002. https://doi.org/10.1056/NEJMoa2032183
[xv] Lincoff, AM, et al. (2023). Semaglutide and cardiovascular outcomes in obesity without diabetes. The New England Journal of Medicine, 389(24), 2221–2232. https://doi.org/10.1056/NEJMoa2307563
[xvi] Cancer data in Australia, Overview of cancer in Australia, 2025 - Australian Institute of Health and Welfare
[xvii] TGA 2025, *Public Assessment Report of Pluvicto,* see: Australian Public Assessment Report for Pluvicto (accessed 16/1/2026)
[xviii] ACSCHC 2023, Its time to weigh up harm from antibiotics: new report, see: It's time to weigh up harm from antibiotics: new report | Australian Commission on Safety and Quality in Health Care
[xix] Crohn's and Colitis Australia 2025, see: https://crohnsandcolitis.org.au/wp-content/uploads/2025/05/CCA_State-of-the-Nation-in-IBD-1.pdf (accessed 6/1/2026)