2026-27 Pre-Budget Submission

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Foreword

Australia's healthcare system is built on a foundation of responsibility, collaboration, and a deep commitment to patient wellbeing[1] – but it also stands at a crossroads, facing both longstanding strengths and emerging challenges. What's clear is that real progress relies on shared accountability across a many number of stakeholders including government, patients and carers, healthcare professionals, the private sector, pharmacists and wholesalers. At AbbVie, we are committed to advancing innovation through partnership, ensuring that timely access to the latest therapies is possible for all Australians.

The legacy of the Pharmaceutical Benefits Scheme has made Australia a leader in providing affordable medicines. Yet, in a changing global environment, we now face distinct challenges in ensuring timely access to the advances that modern medicine can offer. While Australia's current approach rooted in cost containment has delivered benefits, it risks limiting access to life-changing treatments and slowing the introduction of the next wave of therapies. We see the impact in numbers and in the lived experiences of patients and families who wait far too long for effective care. This has real consequences for patients and carers, affecting their quality of life and ability to live fully. Over time, these delays impact not only individuals but also the vitality and productivity of our wider economy.

We know that Australians value secure access to new medicines. The task before us is to strengthen systems that underpin that commitment, making them more transparent, more responsive, more accountable, and ready to support future innovations. Through this submission, we share practical proposals for reform, centred on better transparency, fit-for-purpose policies, and greater recognition of the full value of innovation. Our recommendations are not just about medicines, but about improving outcomes, supporting public trust, and building a resilient framework for years to come.

AbbVie remains dedicated to being part of this progress. We stand ready to work with government and stakeholders – openly, constructively, and with a shared sense of purpose. By taking these steps together, we can uphold Australia's reputation as a leader in healthcare and ensure that patients, now and in the future, receive the benefits of innovation without compromise.

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[1] https://www.health.gov.au/sites/default/files/2022-12/national_medicines_policy_2022_-_plain_language.pdf

About AbbVie

AbbVie is a research-based biopharmaceutical company with the mission to discover and deliver innovative medicines and solutions that solve serious health issues today and address the medical challenges of tomorrow. Each year, AbbVie products help approximately 60 million people in more than 175 countries, treating over 60 conditions worldwide. In Australia, more than 125,000 patients currently benefit from our medicines, with over 2.25 million PBS prescriptions written for AbbVie products in the 2024-25 financial year. In 2025, over 3,000 Australians received compassionate access to our medicines and in 2024 we invested $30.3 million in clinical research across Australia. As a member of Medicines Australia, AbbVie actively contributes to ensuring Australians have access to sustainable innovative medicines.

Our therapeutic focus areas include immunology, oncology and neuroscience – and products and services in our Allergan Aesthetics portfolio. Within our areas of focus, we build on a deep understanding of biology and unmet patient needs to pursue world-class medicines and solutions for a number of diseases and conditions. AbbVie is proud to have played a central role in the discovery, development, and clinical trials of venetoclax—a cancer therapy jointly developed with Australian research institutions and global partners—which stands as a significant Australian innovation story and showcases the impact of ongoing collaboration between industry, scientists, and government.

Through partnerships and local investment, AbbVie continues to contribute to Australia's reputation as a global leader in biomedical research and the advancement of patient outcomes.

Background

Australia's PBS has a legacy of providing affordable access to essential medicines and is recognised as a cornerstone of the national healthcare system. However, recent trends show Australia is falling behind global benchmarks for patient access and pharmaceutical innovation. Over the past decade, Australia's net PBS expenditure has declined to just 12% of spending on health,[2] placing us 25th out of 33 countries in medicine spending—behind peers such as Japan, Germany, Canada, and Korea.[3] Notably, Australia ranks among the top five wealthiest countries in the world, per capita,[4] yet our investment in medicines is among the lowest of advanced economies.

The Australian public overwhelmingly supports increased investment in medicines, with 9 out of 10 Australians being supportive of greater government investment into the PBS.[5] Our comparatively low investment has tangible consequences: only 12% of new medicines are PBS listed within one year of global launch,[6] and Australian patients wait an average of 726 days for PBS access to a new medicine following ARTG registration,[7] showing delays are trending upwards from the previous average of 466 days.[8] Australia also ranks 16th out of 20 OECD countries for reimbursed access to new medicines,[9] highlighting a significant gap in timely patient access compared to other advanced nations.

To address these challenges, meaningful reform is urgently needed. We call on the Government to implement the recommendations outlined below in order to enhance investment and better recognise the value of innovative medicines, while supporting greater system capacity through increased resourcing and achieving efficiencies through innovative digital capabilities.

[2] AbbVie Data on File – PBS Spending Trends. June 2025. CLA-AU-250016
[3] OECD https://bit.ly/46Y4yzV
[4] Borger, E, 2025, Global Wealth Report 2025, UBS, Zurich https://www.ubs.com/gwr, p18.
[5] AbbVie Data on File – Future Medicines Access Survey Data. May 2025. CLA-AU-250014
[6] PhRMA https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report
[7] Amgen Australia Australian Patient Access Gap January 2021 – April 2025 https://www.amgen.com.au/responsibility/-/media/Themes/CorporateAffairs/Redesign/Amgen-com-au/Amgen-com-au/Documents/Amgen-Patient-Access-Gap-Tracker-and-Infographic-July-2025-APPROVED.pdf
[8] Medicines Australia Medicines Matter: Australia's Access to Medicines 2016 – 2021.
[9] Medicines Australia Medicines Matter Report 2022. https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/04/Medicines-Matter-2022-FINAL.pdf

Recommendations

1. Increase transparency around Commonwealth expenditure on medicines to enhance general public literacy and support PBS investment uplift
2. Implement Clause 7.2 of the Strategic Agreement (2022-27) between Medicines Australia and the Commonwealth (**Strategic Agreement**) by establishing a policy for Risk Share Arrangements (**RSA**) that supports commercial viability of new and existing listings.
3. Incorporate second-order benefits in the economic evaluation of medicines to recognise the full value of innovative medicines.
4. Implement reforms to Australia's HTA policies and processes:
    a. Address long-standing issues relating to comparator selection through legislative change to the National Health Act (1953) Sections 101(3A) and (3B).
    b. Increase resourcing capacity within Health Technology Assessment (**HTA**) evaluator groups and the Department of Health, Disability and Ageing (**DoHDA**) to support implementation of HTA reforms, build overall system capacity, and uphold good business practices.

1. Enhanced transparency and public visibility of expenditure on medicines to support PBS investment uplift

To achieve transparency and enhance public understanding, PBS expenditure figures in Budget documents must be presented net of funding recovered from sponsors, and clearly delineate what proportion of the expenditure is recouped through sponsor rebates, and how much is paid by the Government to wholesalers and pharmacists as part of the medicines supply chain. This level of transparency is essential to provide the public with an accurate understanding of the Commonwealth's investment in medicines as well as highlight the shared accountability and implications across all stakeholders in the health system.

Currently, Budget papers present PBS expenditure as a single aggregate figure, making it difficult to distinguish how much funding is allocated directly to medicines relative to other components mentioned above. Transparency through disaggregated figures in the Budget presents a starting point to understand stakeholders involved and related complexities, which support shared accountability. Despite PBS expenditure reports publishing disaggregated figures since 2024,[10] rebates paid back to the Government by sponsors are not explicitly reported or easily accessible to the general public, as they do not feature prominently in Budget papers. In 2024-25, rebate revenue offset approximately one third of topline government PBS spend, at $6.7 billion out of $19.3 billion, increasing to almost half of topline expenditure once pharmacy and wholesaler costs are excluded,[11] yet this information is not separately identified in Budget papers and therefore overrepresents the

[10] https://www.pbs.gov.au/info/statistics/expenditure-prescriptions/expenditure-prescriptions-report-1-july-2023-30-june-2024

[11] https://www.pbs.gov.au/statistics/expenditure-prescriptions/2024-2025/Expenditure-prescriptions-report-tables-2024-25.PDF

true level of investment in medicines. This lack of transparency can distort the public's understanding of PBS investment, including key metrics such as spend as a proportion of total health expenditure and GDP.

AbbVie therefore recommends that future Budget papers provide a clear view of Australia's direct investment in medicines, separately identifying the different PBS components and net of sponsor rebates, consistent with commitments outlined in Clause 4.3 and Appendix 3 of the Strategic Agreement. To further support public understanding and the Government's commitment to delivering cheaper medicines and lowering the co-payment, the Government could go a step further by making the value of overall patient contributions more publicly accessible. These recommendations should not require additional funding as they can be implemented through adjustments to current reporting practices.

Enhanced transparency would help the general public understand how PBS funding is allocated and enable better stewardship of public funds by fostering shared accountability and trust across stakeholders. Critically, it would support evidence-based policymaking and budget planning, and ensure informed debate on Australia's investment in medicines, particularly innovative medicines. For Australia to keep pace with global advancements, investment in innovative medicines must increase to levels comparable to other wealthy nations.[12] Achieving this can be facilitated, in part, by addressing the following proposed reforms related to risk-share arrangements (RSAs) and comparator selection.

2. Establishing a Risk Share Arrangement policy that supports timely access and commercial viability over the product lifecycle

AbbVie urges the Government to prioritise its commitment to co-develop a policy for RSAs as specifically set out under Clause 7.2 of the Strategic Agreement before the current term ends[13] and consistent with the reformative intent of addressing current issues that undermine the commercial viability of both new and existing PBS listings. A fit-for-purpose policy should ensure RSAs are not a barrier to listing, and embed a fair and balanced approach to the sharing of risk between the Commonwealth and industry. Doing so will deliver greater process clarity, accountability, predictability, and most importantly safeguard access to innovative medicines for Australians.

While RSAs were initially intended as a tool to manage residual uncertainty when reimbursing new medicines, there is evidence to suggest that they are more frequently utilised as a mechanism to manage government expenditure. A recent analysis shows that 92% of RSAs recommended between 2019 and 2025 were primarily to manage uncertainty

[12] https://cdn.aglty.io/phrma/Attachments/NewItems/Report%20-%20High-Income%20Country%20Spending%20on%20Innovative%20Medicines%20-%20June%202025_20250716125138.pdf

[13] https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf

in financial estimates[14], with a much smaller proportion used to manage uncertainty in clinical or cost effectiveness. With approximately 70% of new PBS medicines in recent years having been subject to a RSA,[15] their use is widespread.

As RSA terms have become increasingly unviable for industry, negotiations have grown more protracted, with some medicines ultimately unable to be listed on the PBS. A long-standing example is in treatments for severe atopic dermatitis (eczema), where the requirements to enter a commercially unviable RSA resulted in two innovative medicines not proceeding to PBS listing.[16,17] Another example is in migraine treatments, where challenging RSA and pricing terms have been raised by impacted Sponsors, and in certain cases preventing the listing of an innovative medicine.[18,19] Such cases significantly and directly impact patients through delayed or lack of access to innovative therapies, also creating uncertainty for industry and undermining Australia's reputation as a favourable country for new medicine launches.

Despite their increased prevalence and complexity, and potential to significantly impact patient access, there is still no comprehensive policy to guide the appropriate implementation or ongoing management of RSAs. Too often, even if the original uncertainty justifying an RSA is not realised or is addressed, or appropriate use in the eligible patient population is established, these arrangements remain in place longer than necessary, extending beyond their intended purpose and term, creating further challenges for sponsors. There must therefore be a pragmatic approach and efficient pathway for the renegotiation of RSA terms based on available evidence, including for their dissolution when no longer justified.

3. Patients, Productivity, and Prosperity: Recognising the full value of innovative medicines

Recognising the full value of innovative medicines is essential for Australia to achieve the best outcomes for individuals and the nation. When people receive timely access to effective therapies that address their individual clinical needs and preferences, their health and quality of life are enhanced, which can have a direct and measurable impact on the healthcare system and the broader economy. These medicines reduce unnecessary hospital admissions and help alleviate pressure on other healthcare resources[20] and programs such as the National Disability Insurance Scheme (NDIS) by reducing demand for allied health

[14] Wonder Drug Consulting, Sept 2025, Analysis of PBAC risk sharing arrangements (2019-2025). Analysis based on publicly available sources, including PBAC Public Summary Documents, therefore limitations exist due to limited disclosure of RSA terms and redactions.
[15] Survey of Medicines Australia Members, conducted 2023
[16] https://www.dermatologyrepublic.com.au/eli-lilly-pulls-pbs-application-for-eczema-drug
[17] https://www.puffnstuff.com.au/unsustainable-pfizer-pulls-out-of-jaki-pbs-application
[18] https://www.migraine.org.au/pbs_listing_for_popular_cgrp_not_proceeding_at_this_time
[19] https://mednews.com.au/novartis-says-no-to-dud-pbac-deal/
[20] Lichtenberg FR. Number of drugs provided by the Pharmaceutical Benefits Scheme and mortality and hospital utilization in Australia, 2002-2019. SSM Popul Health. 2023 Sep 12;24:101514.

services and support. Healthier people and their carers are able to fully participate in the workforce, driving national productivity[21] and economic growth.

The full value of innovation needs to be recognised through incorporation of broader second-order benefits, beyond just clinical outcomes, in the assessment of base-case economic evaluation of new treatments. Ultimately, failing to fully value the benefits of innovative medicines can impact Australians' access to life-changing treatments, and risks Australia falling behind global standards of care. This is already happening, with treatment access gaps in inflammatory bowel disease (IBD) and ovarian cancer; two disease areas where effective treatment can lead to considerable improvements in patient well-being and ability to participate fully in society[22,23]. This reflects a broader systemic challenge with respect to value recognition, anchored in a prevailing cost-containment approach that can ultimately limit access to innovative medicines and risks leaving Australians without access to life-changing therapies.

Countries such as the United Kingdom, Germany, and Canada, routinely consider second-order benefits such as productivity, caregiver burden, and wider societal impacts, when valuing new medicines[24]. In contrast, Australia's HTA processes permits the inclusion of only direct healthcare costs within the economic model, which puts us behind international standards in recognising value. It is therefore critical that government policy and HTA processes evolve to consistently recognise the full value innovative medicines bring, by incorporating broader second-order benefits in the economic evaluation of medicines.

4. Implementing reforms to Australia's HTA policies and processes

As a research-based pharmaceutical company, AbbVie supports Medicines Australia's asks in relation to specific proposed reforms to Australia's HTA policies and processes, including recommendations resulting from the HTA Policy and Methods Review.

a) **Meaningful change to comparator selection and the use of lowest-cost comparator**: Amending Section 101(3A) and (3B) of the National Health Act to reflect current PBAC guidelines, such that new medicines are assessed against therapies most likely to be replaced in clinical practice, rather than the lowest cost alternative.[25] While HTA Review recommendation #40 outlines updating PBAC guidelines, such changes alone are unlikely to result in effective reform given the disconnect with current legislation. Current legislation requires the PBAC to prioritise the lowest cost comparator,[26] even if clinical practice indicates otherwise. As a

[21] https://www.pc.gov.au/research/completed/measuring-healthcare-productivity/measuring-healthcare-productivity.pdf
[22] https://crohnsandcolitis.org.au/wp-content/uploads/2025/05/CCA_State-of-the-Nation-in-IBD-1.pdf
[23] https://www.abbvie.com.au/content/dam/abbvie-com2/au/docs/the-value-of-hope-addressing-the-burden-of-ovarian-cancer-in-australia-report.pdf
[24] https://www.health.gov.au/sites/default/files/2024-07/hta-policy-and-methods-review-hta-methods-economic-evaluation.pdf, pp 18
[25] https://pbac.pbs.gov.au/section-1/1-1-clinical-issue-addressed_by-the-submission.html
[26] https://www8.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/nha1953147/s101.html

result, new medicines—even those offering meaningful improvements—are often recommended and linked to the price of outdated multi-branded F2 medicines with significantly eroded prices.

This accelerates price erosion across linked therapies through the application of reference price cuts, ultimately disincentivising innovation over time. This issue is particularly prevalent when it comes to treatments for Crohn's disease and ulcerative colitis. When incremental innovation is not recognised, patients' choice is reduced, they wait longer for new treatments, and Australia risks losing its attractiveness as a launch market for medicines available globally. Any changes to guidelines relating to comparator selection must be accompanied by legislative change to ensure policy alignment and meaningful reform.

b) **Investment in HTA and Department resourcing to improve overall system capacity**: Increasing investment in and expanding the capacity of the HTA workforce within DoHDA is essential to ensure ongoing sustainability of Australia's HTA system amid growing submission volumes and complexity. The 2024 deferral of 17 PBAC submissions to an additional meeting in 2025 due to resourcing constraints highlights this urgent need.[27] To address this, AbbVie supports recommendations 49 and 50 of the HTA Review[28] to attract, retain, and optimise the HTA workforce, and bolster resource within DoHDA to support the HTA process. AbbVie supports targeted funding and strategic initiatives to increase the HTA evaluator workforce, including defined career pathways, opportunities for secondments across different organisations, relaxation of constraints relating to engagement with Industry for research purposes, and recognition of evaluator contributions as research outputs for career progression.

In 2025, administrative errors and the processing of $1.5 billion uncertified pharmacist claims further exposed Department resourcing issues and resulted in extended delays in regular invoices being issued to sponsors. In any business context, such delays are considered unacceptable as they may potentially pose significant compliance and audit risks to companies. Our public health system, entrusted by Australians, must adhere to the same standards of good business practices expected elsewhere, and timely action towards addressing these issues will enable greater predictability and certainty for sponsors, and help fortify the PBS for future innovations. Addressing Departmental resourcing deficits will be a significant step towards this end.

Increasing and strengthening the workforce will ultimately deliver more timely and equitable access to innovative therapies for patients. Delivering the recommended

[27] https://www.pbs.gov.au/info/news/2024/11/update-on-the-march-2025-meeting
[28] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf; pp 210

reforms and improving ongoing operational efficiency will require the Government to allocate greater resources to improve overall system capacity.[29] In addition, leveraging innovative data and digital technologies aligns with the Government's expectations to improve uptake of digital capabilities.[30] These will support the necessary consultation, co-design, and implementation steps as part of HTA reform, and importantly build long term system capacity.

Conclusion

Australia stands at a pivotal moment for medicines policy reform. By acting on the recommendations outlined above, the Government can unlock faster access to innovative therapies, strengthen system capacity, and realise greater value for patients, productivity, and the nation's prosperity. Enhanced transparency, progress on a reformative RSA policy, recognition of the true value of innovation, and legislative and workforce strengthening are critical steps to maintain Australia's global competitiveness and support improved health outcomes. AbbVie remains committed to working constructively with Government, Medicines Australia, and all stakeholders to deliver meaningful change. By embracing this opportunity together, we can build a PBS and HTA system that are future-ready and truly deliver for Australian patients, families, and the broader community.

[29] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf; pp 211

[30] https://www.health.gov.au/sites/default/files/2026-01/statement-of-expectations-soe-18-december-2025.pdf