2025-26 Pre-Budget Submission

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About AbbVie

AbbVie is a research-based biopharmaceutical company committed to discovering, developing and delivering innovative new medicines with distinct and compelling benefits for people. Globally, approximately 57 million people are treated with AbbVie products annually across 60+ conditions and live in more than 175 countries. In Australia, more than 125,000 patients currently benefit from our medicines, with over 2.4 million PBS prescriptions written for AbbVie products in the 2023-24 financial year. In 2023, over 2,500 Australians received compassionate access to our medicines. 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, eye care, virology, and neuroscience. 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.

In this pre-budget submission, we focus on execution of the Risk Share Arrangement Clause of the Strategic Agreement between Medicines Australia and the Commonwealth (2022-27), the implementation of specific reforms identified through the now complete Health Technology Assessment Policy and Methods Review, and acceleration of the digital transformation process for authority prescriptions for medicines reimbursed through the Pharmaceutical Benefits Scheme (PBS). We also call for greater transparency around the level of investment in medicines, underpinned by including rebates in the disaggregated reporting of PBS spend for improved transparency of Australia's investment in medicines.

As a research-based pharmaceutical company, AbbVie also supports Medicines Australia's pre-budget submission that calls for 1) Implementation of the roadmap of HTA reforms in accordance with the advice of the HTA Implementation Advisory Group, and 2) Implementation of all remaining clauses of the current Strategic Agreement between Medicines Australia and Commonwealth (2022-2027).

Recommendations

1. Implement Clause 7.2 of the Strategic Agreement (2022-27) between Medicines Australia and the Commonwealth by establishing a policy for Risk Share Arrangements.

2. Implement reforms identified through the HTA Policy and Methods Review
    a. Address long-standing issues relating to comparator selection through legislative change to the National Health Act (1953) Sections 101(3A) and (3B).
    b. Implement improvements to processes and pathways by:
        - Decoupling the TGA delegate's overview from the PBAC's ability to evaluate a submission and communicate its likely advice to Sponsors
        - Improving processes for evaluation of codependent health technologies through a unified HTA pathway and committee.
    c. Grow resourcing capacity within Evaluator Groups and the Department of Health and Aged Care (DoHAC) to support implementation of HTA reforms and build overall system capacity.

3. Reduce the administrative burden for PBS prescriptions by accelerating the digital transformation process to transition all written authority applications to online.

4. Increase transparency around Commonwealth investment in medicines by including rebates paid by Sponsors in the disaggregated reporting of PBS expenditure.

Introduction

AbbVie welcomes the opportunity to provide input into the priorities for the 2025-26 Federal Budget. AbbVie has a steadfast and long-standing commitment to ensuring that Australians have timely, sustainable and equitable access to medicines that improve health outcomes. As a company that provides medicines for many thousands of Australians, we are deeply engaged in the future of Health Technology Assessment (HTA) in Australia, and the processes governing how Australians access reimbursed medicines listed on the Pharmaceutical Benefits Scheme (PBS). We are also committed to improving transparency with respect to the level of investment in medicines through the PBS through disaggregated reporting that would enable enhanced visibility and tracking of Government expenditure on reimbursed medicines.

Australia's access to new medicines needs to keep pace with the rest of the world in order to ensure the best health outcomes for all Australians. A recent analysis showed that only 24% of globally approved medicines were PBS listed in Australia from 2012-2021, and only 12% of new medicines were PBS listed in Australia within one year of global first launch.[1] Patients still wait 466 days on average for PBS access to a new medicine following ARTG registration,[2] therefore it is imperative that Australia's HTA system evolves to resolve existing issues and be fit-for-purpose to ensure patients have both timely and equitable access to all future health technologies.

Subsidising new life-saving and life-improving therapies should be viewed as the investment that it is, reaping broad societal benefits and driving economic growth and workforce productivity. The 2019 research paper *Measuring the Impact of Pharmaceutical Innovation in Australia 1998–2018*, authored by economist Professor Frank Lichtenberg,[3] demonstrated that PBS-listed pharmaceutical innovation improves patient outcomes, reduces hospital demand, and is cost-effective. While focused on cancer medicines, the findings and concepts are applicable to any treatment that generates improvements in health outcomes. Similarly, the Productivity Commission's report on Advances in Measuring Healthcare Productivity[4] concluded that advances in treatments, particularly for cancers, have been the major drivers of productivity growth, rather than across-the-board reforms to healthcare delivery. It therefore follows that it is important to assess the cost-effectiveness of potential new and existing medicines more broadly in order to identify where the greatest societal benefits are realised and therefore support funding decisions. A fundamental part of this process is to ensure that all reporting of investment in medicines is reflective of the true level of expenditure, in order to accurately quantify the level of investment in, and return on, medicines.

Implement a policy to inform the use of risk share arrangements (RSAs) between Industry and the Commonwealth

Following their initial formalisation in 2006,[5] the number of reimbursed medicines subject to a risk-sharing arrangement (RSA) has increased steadily. A survey of Medicines Australia member companies indicated that an average of 70% of medicines listed on the PBS in the five years to 2023 were subject to an RSA.[6] Despite their increasing incidence and in some cases, complexity, there remains no comprehensive policy governing the principles underpinning RSAs or guidance around the process of negotiating, implementing and administering RSAs. The effect of unviable RSA terms can be significant and have a direct impact on patients, as demonstrated by the recently negotiated RSA pertaining to medicines for the treatment of severe eczema.[7] In recognition of this, Clause 7.2 of the Strategic Agreement (2022-27) between Medicines Australia and the Commonwealth outlines the commitment to co-

[1] PhRMA https://phrma.org/en/resource-center/Topics/Access-to-Medicines/Global-Access-to-New-Medicines-Report
[2] Medicines Australia https://www.medicinesaustralia.com.au/publications/medicines-matter/
[3] 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.
[4] https://www.pc.gov.au/research/completed/measuring-healthcare-productivity/measuring-healthcare-productivity.pdf
[5] https://pbac.pbs.gov.au/content/information/archived-versions/pbac-guidelines-v4-2006.pdf
[6] Survey of Medicines Australia Members, conducted 2023
[7] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2024-07/files/dupilumab-psd-july-2024.pdf; https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/securing-cheaper-medicines-for-people-with-severe-eczema?language=en

development of a policy for RSAs.[8] Work towards this policy has commenced, however will require increased focus and commitment from all engaged parties in order to ensure agreement on RSA principles and completion within the term of the Strategic Agreement. This policy is critical in supporting the ongoing reimbursement of medicines through the PBS.

Recommendation 1

- Implement Clause 7.2 of the Strategic Agreement (2022-27) between Medicines Australia and the Commonwealth by establishing a policy for Risk Share Arrangements

Implement reforms identified through the HTA Policy and Methods Review

The HTA Policy and Methods Review (HTA Review) was one of the key commitments in the Strategic Agreement between the Commonwealth and Medicines Australia. The recommendations published within the final report, entitled "Accelerating Access to the Best Medicines for Australians Now and into the Future: A review of Australia's health technology assessment policy and methods for the Australian Government"[9] provide an opportunity to improve upon the performance of Australia's HTA system and the policies that support it through system-wide transformation. The proposed reforms are intended to ensure that Australia's HTA system evolves to keep pace with advancements in medical technologies and delivers faster access to new medicines for patients.

a. Address the issue of comparator selection

The first of the HTA Review recommendations that would serve to future-proof Australia's HTA system relates to the long-standing issue of comparator selection. Currently, the PBAC Guidelines state that the main comparator should be the therapy that prescribers would most likely replace with the proposed medicine.[10] However, Section 101(3A and 3B) of the National Health Act 1953 (NHA) states that "*where a therapy is substantially more costly than an alternative therapy or alternative therapies, the PBAC shall not recommend it unless the therapy, for some patients, provides a significant improvement in efficacy or reduction of toxicity over the alternative therapy or therapies*."[11] There is no formal or accepted definition of "comparator" or "alternative therapy" in the legislation and as such, the PBAC continues to interpret "alternative therapy" as being the lowest cost comparator (LCC).

This results in new medicines, even those which confer a small yet meaningful incremental benefit, being price-referenced to the LCC, which in most instances is a multi-branded F2 medicine that has been subject to significant price erosion through statutory price reductions and price disclosure cuts. The LCC price is then flowed onto existing price-linked medicines in F1 through reference pricing. The use of LCC does not reflect the improvements in patient outcomes associated with incremental innovation over time and leads to the persistent undervaluing of new medicines.

Recommendation 40 of the HTA Review states that this could be addressed through updates to the PBAC Guidelines,[12] however it is AbbVie's position that this is unlikely to rectify the existing issues in the long-term. The following legislative change is required: Section 101(3B) of the NHA should be repealed in its entirety to enable the selection of comparator(s) to be based on the PBAC Guidelines Section 1.1.3 i.e. *the medicine/intervention most likely to be replaced in clinical practice*. For indications where multiple therapeutic options are available, this would allow for recommendations to be made based on a derived weighted price based on utilisation.

[8] https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2023/10/ma-strategic-agreement-22-27.pdf
[9] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf
[10] https://pbac.pbs.gov.au/section-1/1-1-clinical-issue-addressed_by-the-submission.html
[11] https://www8.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/nha1953147/s101.html
[12] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf; pp 183

Recommendation 2a

- Address long-standing issues relating to comparator selection through legislative change to the National Health Act (1953) Section 101(3A) and (3B).

b. Improve Systems and Processes

Decouple the delegate's overview from PBAC advice to enable full parallel processing

Currently, the PBAC is unable to provide a recommendation to Sponsors without prior receipt of the TGA delegate's overview. This can lead to delays in the reimbursement of new medicines for two reasons: 1) The consideration of submissions may be deferred to a subsequent PBAC meeting if the delegate's overview has not been received in time, or 2) a Sponsor may time their PBAC submission to align with predicted availability of the delegate's overview, rather that submitting at the earliest possible opportunity. Updating the PBAC Guidelines to permit the PBAC to communicate its likely advice to Sponsors prior to receipt of the delegate's overview, consistent with Recommendation 8c of the HTA Review,[13] would enable true parallel processing, and reduce the number of delayed PBAC evaluations due to delegate overview availability. Importantly, this recommendation does not seek to circumvent TGA advice, but rather implement a practical approach which would streamline processes and expedite timings for the majority of submissions where PBAC advice is consistent with the Australian Register of Therapeutic Goods (ARTG) listing.

Improve the process for codependent submissions through a unified HTA pathway and committee

Currently, the HTA process for codependent technologies, i.e. medicines with a corresponding technology/diagnostic test, is recognised as slow and complex due to evaluation taking place across two discrete committees (PBAC and MSAC) and sequential, rather than parallel processes and timings. The implementation of a unified HTA advisory committee and pathway for all health technology evaluation, as per Recommendation 4 of the HTA Review,[14] would in part address the existing system inefficiencies, providing the committee is adequately resourced and review cadence sufficiently frequent to meet the increasing volume of HTA submissions; this recommendation is therefore also underpinned by recommendation 2c) of this Pre-budget Submission. The unification of HTA committees would result in an expanded scope across a broader set of funding programs and support the simplification of processes. However it is critical that this does not also involve an increase in remit whereby decision-making powers are conferred to existing or future HTA committees – this responsibility must remain with the Government/Minister of Health.

Given that a unified HTA committee and pathway should also support the realisation of process and resource efficiencies that have been subject to protracted examination by DoHAC as part of the now complete Time-and-Motion Study, there must be transparency around how any additional cost-recovery fees have been calculated and what activities are included as part of any proposed fee changes. Codependent submissions must not be subject to a duplication of fees where specific activities relating to the evaluation of the medicine and device/test are now combined.

Recommendation 2b

- Implement improvements to processes and pathways by:
  - Decoupling the TGA Delegate's Overview from the PBAC's ability to evaluate a submission and communicate its likely advice to Sponsors
  - Improving processes for evaluation of codependent health technologies through a unified HTA pathway and committee.

[13] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf; pp 64
[14] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf; pp 54

c. Increased resourcing for HTA Reform and overall system capacity

As evidenced by the deferral of 17 submissions from the March 2025 PBAC meeting due to resourcing constraints,[15] the level of external evaluator, DoHAC, and PBAC and sub-committee resource and capacity requires evaluation given the increasing number and complexity of reimbursement submissions. Increasing resourcing to build overall system capacity for the substantive review of all submissions is essential to ensure ongoing sustainability of Australia's HTA system and prevent the introduction of further inequities into the system through any form of submission prioritisation or triaging.

Therefore, as per recommendation 49 of the HTA Review,[16] funding towards growing the capacity and capability of the Australian HTA evaluator workforce, including a detailed examination of how to attract and retain evaluators through more favourable Government and institutional policies is essential. While it is essential that robust consultation with relevant groups is undertaken to inform any policy reforms, some potential changes that could be explored include: more defined career pathways with greater opportunities for secondments across different organisations, relaxation of the constraints relating to engagement with Industry for research purposes, and a consistent and pragmatic approach to the recognition of evaluator work as research outputs for the purposes of career progression.

Underpinning all recommendations resulting from the HTA Review is the need for the Australian Government to allocate adequate resources, both in terms of personnel and funding, towards the necessary consultation, co-design, and implementation of reforms as outlined in Recommendation 50.[17] While this will be guided based on the prioritisation of reforms for implementation, it will require appropriations for new activities and processes, and sufficient staffing in the short, mid and long term to ensure no disruptions or delays to HTA evaluations and PBS listing process throughout any transition period and deliver enduring system capacity.

Recommendation 2c

- Grow resourcing capacity within Evaluator Groups and DoHAC to support implementation of HTA reforms and build overall system capacity

Reduce the administrative burden for PBS prescriptions

Currently, 29.4% of medicines on the PBS require prescribers to gain authority approval from Services Australia prior to prescribing and dispensing to patients.[18] These approvals can be processed either online, over the telephone, or through a written application due to the need for certain information to be supplied as supporting evidence for the application. It is also not just the initial application that must be approved by Service Australia, but subsequent applications for continuation of therapy through the PBS must also be pre-approved by Services Australia based on a positive response to treatment as measured by set criteria.

In mid-2022, the Government announced the start of the process of Digital Transformation of Authority Required (Written) PBS listings.[19] These changes, to be introduced on a tranche basis, were to allow prescribers to apply for authority approvals using Services Australia's Online PBS Authorities (OPA) System in real time. The intent of these changes was to reduce the administrative burden for prescribers and enable patients to have faster access to their medicines by being able to leave their consultation with the prescription for their medicine. Despite initial momentum in transitioning a number of medicines to real-time, online prescribing, the process of Digital Transformation appears

[15] https://www.pbs.gov.au/info/news/2024/11/update-on-the-march-2025-meeting
[16] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf; pp 210
[17] https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf, pp 211
[18] Auditor General Report No. 19 2024-25, Administration of the Pharmaceutical Benefits Scheme, accessed here: https://www.anao.gov.au/sites/default/files/2024-12/Auditor-General_Report_2024-25_19.pdf
[19] https://www.pbs.gov.au/info/news/2022/06/digital-transformation-of-authority-required-written-pbs-listings

to have slowed substantially and a significant administrative burden for prescribers of advanced therapies, particularly within the specialties of rheumatology, gastroenterology, and dermatology remains. This is despite some incremental progress in transitioning to streamlined prescribing for some advanced therapies for patients with rheumatoid arthritis (continuation only). This lack of consistency in authority levels inherently creates additional administrative burden for the already stretched medical workforce. There is no transparency as to when remaining medicines will transition to online, real-time approvals, as no workplan or tranche schedule has been made publicly available.

To better understand the administrative burden associated with prescribing advanced therapies (specifically, biological disease-modifying anti-rheumatic drugs (bDMARDS)), AbbVie recently conducted an online survey and series of roundtables with 46 healthcare professionals to discuss, understand and validate the challenges uncovered in the survey. 80% of healthcare professionals are spending between 1 and more than three hours per week on administrative tasks relating to prescribing advanced therapies, with lack of uniformity in authority levels and requirements, as well as delays in the availability of the PBS approval number cited as main drivers of this administrative burden. Nursing staff are impacted even more acutely, with 50% of gastroenterology nurses spending 16 or more hours per week, i.e. 2 out of 5 working days, completing the administrative tasks associated with written authority applications, rather than on other critical clinical tasks, including patient care.[20] These results are consistent with the recently published results of the Australian National Audit Office's (ANAO's) Audit of the PBS, which shared stakeholder feedback on the PBS authorities system. The following were cited as creating confusion and administrative burden for prescribers: multiple authority codes for the same medicines; the Health Professional Online Services (HPOS) portal not being user friendly; poor integration of OPA with prescribing software; and the need for specialist software in order to submit authority applications. The ultimate impact of these issues is reduced contact time with patients.[21]

There is therefore a clear and urgent case for expediting the Digital Transformation process by transitioning all remaining written authority medicines to online, real-time approval as soon as possible; this includes initial, first continuation, and subsequent continuation applications. This will allow patients to leave their appointment with prescription in-hand, without the need for a subsequent journey to the clinic for collection, thereby reducing cost-of-living pressures. It will also maximise efficiencies within the healthcare system and contribute significantly to alleviating the well-recognised administrative burden faced by an already-stretched healthcare workforce

Recommendation 3

- Reduce the administrative burden for PBS prescriptions by accelerating the digital transformation process to transition all written authority applications to online.

Enhance transparency around investment in medicines

To date, the reporting of PBS spend in the budget papers and final budget outcome has been limited to a single, aggregate figure comprising the following:

- New, innovative medicines (at the list-price level) and older, genericised medicines reimbursed through Formularies 1 and 2 respectively
- Supply chain expenditure which includes pharmacy dispending fees, community service obligation, wholesaler payments, and other handling fees
- Rebates paid by Sponsors through special pricing and/or risk share arrangements, as well as other agreements.

This approach to reporting has not enabled effective measurement, analysis, or tracking of investment in medicines and distorts key measures of medicines expenditure including as a proportion of overall health spend, and relative to

[20] Survey of Healthcare Professionals, conducted by AbbVie, June-July 2024

[21] Auditor General Report No. 19 2024-25, Administration of the Pharmaceutical Benefits Scheme, accessed here: https://www.anao.gov.au/sites/default/files/2024-12/Auditor-General_Report_2024-25_19.pdf

GDP. Furthermore, it results in an underestimation of the value of health outcomes and broader benefits delivered by innovative medicines. AbbVie was pleased to see the first set of disaggregated figures published by the DoHAC in December 2024,[22] however these figures still did not include rebates paid back to the Government by Sponsors. This is an important consideration as, for example, in FY2023-24, the PBS topline spend was $18.8 billion,[22] inclusive of $5.3 billion in rebates paid by Sponsor companies.[23] Rebates alone now account for almost a quarter of total PBS spend, and over a third of PBS spend once supply chain costs are excluded. Therefore, the inclusion of rebates in the reporting of disaggregated spend is essential to providing an accurate picture of Commonwealth expenditure and delivering fully on the commitment made in Clause 4.3 and Appendix 3 of the Strategic Agreement (2022-27) to report expenditure on new medicines separately from expenditure related to other PBS components.

Recommendation 4

- Increase transparency around Commonwealth investment in medicines by including rebates paid by Sponsors in the disaggregated reporting of PBS expenditure.

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

[23] https://www.health.gov.au/sites/default/files/2024-10/department-of-health-and-aged-care-annual-report-2023-24.pdf, pp 256