Medicines Australia

Access unlocked

A new deal to bring the world's most innovative medicines to Australians

Contents

Summary

The Pharmaceutical Benefits Scheme (PBS) is the cornerstone of Australia's healthcare system, providing Australians with affordable, life-improving treatments.

However, the PBS is under severe pressure from a combination of chronic underinvestment in innovative medicines, and a seismic shift in the global medicines pricing environment, driven by the US policy of "Most Favoured Nation" (MFN).

This is delaying, preventing and removing innovative medicines from listing on the PBS. Without action, the impact will escalate and have increasingly serious consequences:

- **Poorer health outcomes for Australians.** There are too many case studies of Australian patients unable to access the medicines that they need because they are not listed on the PBS. These include treatments for cancer, blood disorders, mental health, heart disease, neurological conditions, rare diseases, immunological conditions, and preventable infectious diseases. Often, these medicines are widely available in other countries.
- **A two-tier health system.** Australians are increasingly being prescribed medicines that are not listed on the PBS, worsening health inequity between those who can afford to buy non-subsidised treatments and those who cannot. The financial burden on many patients and their families is substantial and forces difficult decisions between paying for a medicine, delaying treatment or opting for less effective options.
- **A less innovative and less productive economy.** Investment in medicines is investment in economic growth. Poorer health outcomes reduce workforce participation and productivity. Failure to support innovative treatments diminishes Australia's attractiveness for pharmaceutical investment, including for clinical trials and R&D.
- **Shifting costs to other parts of the health system.** Many medicines help prevent hospital admissions and consequential health issues for patients which place pressure on stretched health resources and the health workforce.

The next Strategic Agreement presents a pivotal opportunity to reset the PBS and address the growing challenges facing Australia's medicines ecosystem.

To reverse the impacts of underinvestment and withstand the consequences of MFN, incremental change will not be enough. A long-term strategy is needed, centred on three priorities:

- **Doubling investment in innovative medicines as a proportion of GDP over 10 years:** This commitment would follow the UK's lead in doubling investment and mean that Australia is no longer an international laggard in bringing innovative medicines to patients. Funding for innovative medicines in Australia has been falling as a percentage of GDP and 'increased funding' announced by the Government is primarily achieved by industry rebates and price reductions for existing products on the PBS.
- **Ambitious reform for the system both pre- and post-PBS listing:**
  - The value of innovative medicines should be recognised by modernising the methods and policies used by the Pharmaceutical Benefits Advisory Committee (PBAC)
  - There should be an equal sharing of risk around unexpected population changes, incidence or diagnosis of conditions and prescribing patterns
  - Anniversary price cuts and arbitrary and unpredictable policies that erode the price of innovative medicines should be removed
- **Strengthened accountability:** to ensure Australian patients get timely and internationally competitive levels of access to medicines.

The return on investment in delivering these priorities will be: more first-in-class and innovative medicines launched in Australia; fewer medicines withdrawn, deferred or abandoned after positive PBAC recommendation; more equitable access, reduced reliance on private payment and fundraising; and greater certainty for clinical trials and early access programmes.

Introduction

The Pharmaceutical Benefits Scheme (PBS) delivers better health outcomes for millions of Australians every year.

The PBS remains one of the nation's greatest public health achievements, granting affordable access to life-enhancing, life-prolonging and life-saving treatments.

It is, however, facing a perfect storm that threatens to profoundly weaken its impact.

A crisis brewing

Despite its undoubted success, governments have systematically underinvested in innovative medicines.

It is a problem that has been growing for several years. It means that Australia waits longer for, or misses out entirely on, medicines that offer significant social and economic benefits, and that are widely available in other countries.

Developments abroad now mean that the problem will get much worse. A seismic shift in how medicines are priced in the global market – driven by US policy – means that even fewer new medicines will be available to Australian patients through the PBS.

Without decisive action, the significant challenges caused by underinvestment will rapidly become a crisis.

A better deal for Australian patients

There is a major opportunity to reverse historic underinvestment in the PBS, counter global pricing pressures and make the PBS fit for the 21st century.

The next Strategic Agreement can be a shared commitment between government and the pharmaceutical industry to support equitable access to medicines, encourage investment in innovation, and provide a predictable environment that values new medicines.

The Government has shown appetite to strengthen the PBS with reforms that better serve patients, including reducing co-payments and implementing 60-day prescribing.

It must now go further and commit to increasing investment, implementing ambitious reform and strengthening accountability to unlock access to innovative medicines on the PBS.

Other advanced economies are acting in this way, and Australia must follow suit if it is to not be left behind.

The case for urgent action

The following chapters make the case for action in the next Strategic Agreement by setting out what must change, why investment is urgent and how Australians can unlock faster, broader access to innovative medicines. It does so in the following way:

- **A diagnosis of the problem**
- **The consequences arising from the problem**
- **The solution to the problem**

This report is the third in a series published by Medicines Australia ahead of Strategic Agreement negotiations. The other two are:

- **Access Denied: the twin threat to innovative medicines availability.** Which sets out a detailed explanation of the current policy environment related to innovative medicines access.[1]
- **Bitter Pill: How Australian patients are missing out on the latest medical breakthroughs.** Which presents case studies of innovative medicines that are not listed on the PBS, and the reason that they are not listed and what lack of access means to patients and clinicians.[2]

The problem – a twin threat to medicines access

Medicines Australia's recent report, *Access Denied*, set out how medicines access is being prevented by two interlinked threats.

Key statistics on domestic underinvestment in innovative medicines in Australia

Australia spends a lower share of its income on innovative medicines

0.26%

OF GDP PER CAPITA
LOWER THAN THE AVERAGE ACROSS OTHER HIGH-INCOME COUNTRIES **0.31%** AND LOWER THAN THE EUROPEAN UNION AVERAGE **0.34%**
*** 2023 data.**

There has been a 3% real terms decline in net investment in innovative (F1) medicines from 2021–22 to 2024–25

3%

REAL TERMS DECLINE

The proportion of total PBS expenditure that was paid to the Australian Government by pharmaceutical companies in the form of rebates from negotiated agreements was

35%

PERCENTAGE OF PBS EXPENDITURE IN 2024–25
UP FROM 20% IN 2017–18

Sources[3]

The longstanding threat is domestic. Successive governments have underinvested in innovative medicines for Australian patients. Australia spends a lower share of its GDP on innovative medicines than many comparable advanced economies. Moreover, the amount that Australia spends on innovative medicines as a share of GDP has been declining for several years.

This underinvestment happens across a medicine's life cycle. The PBS system undervalues medicines before launch, offering low prices by international standards. The system then applies staged price reductions, sometimes with additional unplanned price reductions imposed at short notice.

This situation has developed over time. Additional layers of price cuts have come in tandem with a policy of extracting ever more punitive rebates from pharmaceutical companies, all while the techniques to evaluate a medicine's benefits has not kept up with best practice. Despite government claims of huge investment in the PBS, this has disproportionately been funded by industry.

The simple fact is that the Australian government is only willing to pay for medicines at a price often far below what comparable countries pay. Pharmaceutical companies have been less likely to list their products on the PBS as a result.

The issue of domestic underinvestment is now being magnified with a new threat from overseas. The US – with the largest pharmaceuticals market in the world – has begun routinely benchmarking its medicines prices against those in other advanced economies (often referred to as the MFN policy). The US believes its citizens have been paying too much for medicines, and that other countries have not been paying their fair share towards medicine R&D. MFN is its attempt to address this.

While this new policy approach is being implemented by the current Presidency, it has broad bipartisan support in the US political system and is likely to continue under subsequent administrations.

This means that, more than ever, Australian medicines access policy has to take account of both domestic and international issues. MFN means that pharmaceutical companies that are planning new launches in Australia now must consider the very real risk that low prices paid by the Australian Government will directly influence price setting in the far larger US market.

The impact of this twin threat on medicine launches should not be underestimated, and the consequences can be seen in hard data.

Domestic underinvestment has meant Australia is a low priority for new medicines launches:

- **Poor relative performance compared to other nations.** Only around 25% of medicines launched globally over the past decade have been reimbursed in Australia. This compares to 88% in the US and 46% in the UK.[4]
- **Declining performance on access over time**. The likelihood of globally supplied new molecular entities being reimbursed in Australia within two years of the US Food and Drug Administration (FDA) registration has declined from around 20% in 2014–2018 to around 10% in recent years.

In addition, there is a growing evidence base that MFN is having a chilling effect on future launches in Australia. The results of a recent Medicines Australia member survey found:

- **Concerns about global headwinds**. 79% of respondents described their company as "very concerned" about the effects of US policies; a further 16% are "somewhat concerned."
- **Australia's worsening international competitiveness**. 84% of respondents reported that the position of Australia in their company's global launch sequence has deteriorated in the last two years, or is expected to deteriorate in the near/medium term.

It stands to reason that MFN would have a profound impact in Australia and on the patients being served by the PBS. Governments with populations and pharmaceutical markets far larger than Australia's are recognising the implications and are responding. The UK, for example, already spends 50% more on new medicines than Australia (0.3% of GDP versus 0.2% of GDP) and has just introduced a suite of new policies directly in response to MFN, including a plan to double the proportion of GDP it spends on medicines over the next decade.

Moreover, there is growing evidence that is highlighting the worldwide impacts of MFN. A study in Europe found indications of behavioural responses to the policy, including delayed launches and increased risk of product withdrawals in European markets.[5] A June 2026 survey of French pharmaceutical companies found 64% of respondents were expecting that MFN would decrease the launch of new products in the French market.[6]

At the same time as the US policy is ramping up, some large countries are considering implementing, or have implemented, their own MFN-style policies which will compound the pressure facing the PBS and access for Australians.

In short, these are not insignificant problems and policymakers should take them seriously to avert a crisis in medicines access for Australian patients.

The consequences – a weaker population, health system and economy

Delayed, restricted or denied access to innovative medicines on the PBS has a direct and material impact on people's lives, undermines the purpose and integrity of the PBS, has downstream consequences for the health system and ultimately makes the economy less productive.

A population in poorer health

Australia compares well internationally on headline measures of health outcomes. For example, Australia has higher life expectancy than the OECD average.[7] However, the headline statistics mask concerning data in specific areas. Australia has higher levels of obesity than the OECD average, a higher suicide rate than the OECD average and some of the highest rates of hospital admissions for asthma and chronic obstructive pulmonary disease in the OECD.[8]

If the latest medicines are not available on the PBS to treat the people, Australian patients will have even poorer health outcomes. There are numerous life-improving, life-prolonging and life-saving medicines that serve as case studies of this unavailability, and that can be attributed to underinvestment.

Medicines Australia regularly highlights these case studies, most recently in the report, *Bitter Pill,*[9] looking at how Australian patients are missing out on the latest medical breakthroughs. Three examples from the report are:

- **Ulcerative colitis.** An inflammatory bowel disease affecting 130–300 per 100,000 Australians. The medicine, Mirikizumab, can help patients who have had inadequate responses to conventional therapy. The PBAC recommended it for listing in July 2023 on the condition that it price matched to eight alternative PBS therapies. Some of the alternatives have been available for several years and have experienced significant mandatory price cuts. As a result, the manufacturer could not make Mirikizumab commercially viable. It has been approved in 44 countries around the world.
- **Atopic Dermatitis.** A chronic inflammatory form of eczema. A patient survey found that those with a severe form of the disease experienced four to five days per month with reduced work hours because of their condition. Lebrikizumab and Abrocitinib are new drugs that can limit the impact of the disease. Both were recommended for PBS listing, but the sponsors could not proceed because the recommended price did not appropriately value the medical innovation delivered by the treatments.
- **Stomach cancer.** Around 2,700 new stomach cancer cases are diagnosed in Australia each year. Clinical trials of new treatment, Trastuzumab deruxtecan, showed life-prolonging benefits. There is no direct comparator available in Australia to assess the benefits of the medicine. To achieve PBS listing, Trastuzumab deruxtecan must instead be compared with chemotherapy (which is an older medicine) where clinical evidence is limited. It is available via reimbursed access for patients in 16 countries including Germany, Singapore, Italy, France, Korea, Canada, Slovenia and Austria.

There are several more case studies of medicines that affect patients living with cancer, blood disorders, rare disease, mental health conditions, heart disease, and neurological conditions.

The industry is committed to working with government and PBAC to explore how medicines that are not available on the PBS can move forward to listing.

It is also the case that underinvestment can mean that medicines that are already on the PBS get delisted. At the time of writing (July 2026), government is attempting to impose a price cut of around 40% on two multiple sclerosis drugs due to a new drug coming to market.[10] The price cut is a direct result of complexity in a system that is set up to minimise cost at the expense of recognising the true value and health impact of the best medicines to patients.

Again, the industry is committed to working with government and PBAC to explain the factors contributing to delisting decisions and understand how and if they can be mitigated.

A two-tier health system

In Australia, health inequity – where differences in health status between population groups are systematic and avoidable – affects Aboriginal and Torres Strait Islander peoples, women, people with poor mental health, people with disabilities, refugees, people from culturally and linguistically diverse backgrounds, people with low socioeconomic status and people living outside major cities.[11]

Fewer PBS medicines, resulting from the combined impact of underinvestment and MFN, will only serve to worsen health inequity. This will happen specifically because of an access gap that grows between those who can afford to buy non-subsidised treatments and those who cannot.

There is evidence that this is already happening. The private non-PBS retail medicines market is becoming increasingly prominent in managing the health of Australians who can afford it. A 2025 IQVIA study highlighted:[12]

- **A high growth market**. Between 2019–24 the $ market value of the PBS prescription medicine market grew by on average 5%; in the non-PBS market $ market value increased by 20% a year.
- **A growing market share**. This growth has meant that non-PBS prescription medicines constituted 15% of the Australian prescription drug market in 2024, up from 9% in 2019.

Behind the growth in the private market are also cost concerns and worse outcomes:

- **Indicators of cost concerns**. A 2026 survey by the McKell Institute found that almost a third (30%) were not confident in their ability to pay for non-PBS medicines costing $100 a month.[13]
- **Those on low-incomes were worse affected.** A 2026 Patients Australia survey found more than a fifth (21%) of patients who had the need for a non-PBS medicine delayed the start of treatment because of cost. Low-income patients were around twice as likely to delay starting treatment or switch to a less effective medicine because of the cost of a non-PBS medicine.[14]

This evidence of worsening health inequity is emerging due to the policy choices of successive governments, which are now entrenching a two-tier health system in Australia.

A less innovative and less productive economy

Medicines access should be considered an economic policy issue as well as a health policy issue.

A healthier population provides the economy with a boost. The Australian Government's Productivity Commission highlighted the benefits of higher labour force participation, higher productivity, lower unemployment and lower absenteeism.[15] As the Health Minister has said, *"When we strengthen access to effective therapies, we strengthen the nation's productivity"*.[16]

There are evidenced examples of these types of labour market impacts:

- A study by Roche concluded that disease-related productivity losses amounted to $330 billion over the period 2017–23 across 26 European countries.[17]
- A recent report from the Australian Institute of Health and Welfare highlighted that 1.7 million Australians live with long-term migraines, making it the most prevalent neurological condition in the country. It found that the condition is more prominent in women and primarily impacts people in the prime years of their working life, between the ages of 25–55.[18]

More generally, medicines innovation has benefits in terms of Australia's global economic competitiveness:

- **The spillover benefits of clinical trials.** If Australia is perceived as a market where pricing outcomes are constrained and reimbursement is slow or uncertain, it will become less integrated into the global innovation ecosystem and attract less investment in R&D and clinical trials. Over time, this will weaken Australia's research capability and reduce investment in hospitals and trial sites.
- **The role of medicine in international trade.** The US-Australia FTA, which came into effect on January 1, 2005, has a specific chapter dealing directly with pharmaceuticals which highlighted the need to, *"…promote timely and affordable access to innovative pharmaceuticals"*.[19]

Shifting cost to other parts of the health system

The cost of the PBS should not be assessed simply as the cost paid for medicines. In many disease areas, timely access to innovative medicines can help prevent avoidable hospital admissions, slow disease progression, reduce the need for surgery or specialist care, and lessen pressure on stretched health services.

When access is delayed or restricted, those costs are often shifted to hospitals, disability services, carers, employers and households. A medicine not funded through the PBS may therefore appear as a saving in one part of government, while increasing costs and pressure across the broader health and social welfare system.

The solution – investment, reform and accountability

The PBS needs to address the negative consequences of underinvestment and MFN so that Australian patients can gain access to the most cutting-edge medicines. To do this, Australia should match the ambition shown by other nations by increasing investment, reforming the processes and increasing accountability to patients.

The PBS needs to address the negative consequences of underinvestment and MFN so that Australian patients can gain access to the most cutting-edge medicines. To do this, Australia should match the ambition shown by other nations:

- **Double investment in innovative medicines as a proportion of GDP over ten years.**[iii] This would take investment from 0.20% of GDP to 0.40% of GDP in 2036/37.[iv] It would follow the UK's lead in doubling investment and mean that Australia is no longer an international laggard in bringing innovative medicines to its citizens.[v]

Getting to 0.40% of GDP will require additional investment of $47bn over the 10 financial years from 2027–28 to 2036–37. Overall, this would mean that spending on innovative medicines would amount to 7% of the total health budget over the period.

To put the $47bn figure in further context: it is roughly the same amount that the Government expects to spend on debt interest in 2029-30 alone;[20] it is less than the $48bn that the Government estimated it spends on the National Disability Insurance Scheme in 2025–26;[21] the AUKUS nuclear submarine programme is expected to cost $370bn over 30 years.[22]

Moreover, Australia's investment in medicines is subject to a much higher degree of scrutiny than other forms of government spending, ensuring that an additional $ of medicines spend has been tested more rigorously than an additional $ spent with any other Government departments.[23]

More fundamentally, Government spending is a reflection of society's ambition as well as its values. Those that invest in innovation grow faster, with more efficient and productive economies. A study of Europe's investment in new medicines calculated that the economic and social return on investment was around six times the cost.[24]

While increased investment would make more of the world's most cutting-edge medicines available to Australian patients, the investment must be targeted and address evidenced problems in the system. Those problems exist in three phases of a medicine's lifecycle: before launch, after launch, and when competition enters the market.

The reforms required to reverse underinvestment and combat MFN are summarised at a high level in the following sections. The technical details of the policy, problem and solutions can be found in Annex I.

iii This would focus on net ex-manufacturer spend only on the F1 formulary of medicines – this is the metric determining companies' ability to bring medicines to Australia.

iv These are rounded figures – today's F1 investment in GDP is marginally lower than 0.20%. 2025/2026 data.

v This would mean Australia still trails the UK in what it spends on innovative medicines as a percentage of GDP, but would have overtaken other countries if they have not increased investment.

Industry proposals for reforming the pre-PBS listing process

Recognise the value of innovative medicines

Current PBAC Guidelines undervalue the benefits of new medicines, a problem recognised in the recent HTA Review – *"Accelerating Access to the Best Medicines for Australians Now and Into the Future"* – that evaluated how health technologies are assessed for PBS listing.

This can be addressed through policies that correct the undervaluation of medicines before they are launched:

- **Increase the Government's "willingness to pay" for new medicines.** The relative cost and benefits of a new medicine are summarised in a single number called the Incremental Cost-Effectiveness Ratio (ICER). If the ICER is too high – above a given 'ICER banding' – the Government will not pay for it (and vice versa). Australia's ICER threshold, though implicit, is known to be low by international standards. At the end of 2025, the UK increased its explicit ICER range by 25%.
- **Select the comparator most likely to be replaced in clinical practice, not simply the cheapest.** PBAC assesses new medicines against existing treatment options, but too often gives undue weight to the lowest-cost comparator rather than the treatment clinicians are most likely to replace with the new medicines.
- **Reduce the 'discount rate'.** The discount rate is the mathematical tool used by PBAC to value the benefits of long-term health gains for Australians. There is a broad consensus that the discount rate is set too high in Australia (currently at 5%, well out of line with international best practice), meaning that the value of future health gains is aggressively undervalued. A discount rate of 1.5% would better reflect how Australians value their own future wellbeing and mean medicines can be approved at prices reflective of that value.
- **Fast-track key HTA review recommendations.** Its 50 recommendations were published in September 2024, but none have been implemented (as of July 2026). The review's recommendations improve the HTA system as a package.[vi] However, implementing the following as a matter of urgency will be particularly important if Australia is to unlock access to innovative medicines:
  - ***Develop processes to identify areas of high unmet clinical need (HUCN) and health technologies with high added therapeutic value (HATV).*** This would require implementing HTA Review recommendations 44 and 45.
  - ***Adequately value incremental clinical advances.*** By establishing clear methodological principles and updated guidance on the standard of evidence required when PBAC values innovative therapies. This would require implementing HTA Review recommendations 32–36.
  - ***Develop an explicit qualitative values framework, with the addition of a pilot to account for second order effects.*** Australia's HTA system has considered a medicine's "value", but not in a way that is explicit, consistent or transparent. The framework would recognise additional dimensions of value that matter to patients, carers, society and the system. The second order effects considered in the pilot should include the benefits for carers and families, productivity, and social welfare costs in HTA. This would require implementing HTA Review recommendation 26.

vi Note that both comparator choice and discount rate were also part of the HTA review recommendations. They have been separated out here because the proposals in this report go further than what the HTA Review suggested.

Share the risk of uncertainty equally

Risk Sharing Arrangements (RSAs) are legally binding agreements between the Government and sponsors of medicines listed on the PBS. They manage uncertainties around PBS listing, e.g. the risk that the medicine's usage will exceed expectations and cost the government more than anticipated. In many instances, there are multiple factors included that are outside a company's control such as population changes, incidence or diagnosis of conditions and prescribing patterns.

In recent years, medicines sponsors have typically been expected to bear 100% of the risks associated with a PBS listing, even where utilisation and expenditure are assumptions agreed with Government. RSAs should allocate responsibility of risk fairly against those agreed assumptions, recognising that neither party fully controls real-world prescribing or uptake. In the context of US pricing reforms, one-sided risk transfer creates price and supply uncertainty and may affect revenues in overseas markets. The following reforms are necessary to rebalance risk share:

- **Limit sponsor risk liability at 50%**
- **Issue new guidance that transparently defines how to set RSA expenditure thresholds – ensuring that these are set objectively and appropriately, not as an arbitrary lever of negotiation**
- **Allow pharmaceutical companies to initiate RSA reviews at three years or in the event of major new data (e.g. on clinical effectiveness or utilisation) or new entrant**

Industry proposals for reforms post-PBS listing

After a new medicine has been launched in Australia and listed on the PBS, it is subject to repeated price erosion while it is still patent-protected. These price cuts are on top of the low prices mandated on new medicines, agreed at the time of PBS listing, and do not relate to changes in its clinical value, evidence basis, or the entry of market competition.

Protect medicines from unjustified and unpredictable price erosion

A medicine that has been listed on the PBS faces planned price cuts at years 5, 10, and 15 after initial PBS listing (called "anniversary" price reductions). There is no justification for reducing what is paid for a patent-protected product early in its lifetime, and the anticipation of price erosion impacts companies' ability to launch medicines.

What is more, the vagaries of the product linkages and flow on price reductions within therapeutic areas mean that significant price cuts can be imposed at extremely short notice.[vii]

vii Note that "flow-on" price reductions are sometimes referred to as "domestic reference pricing".

These are price deterrents to listing medicines and bake uncertainty into the system. To address these issues, the following should be implemented:

- **Remove anniversary price penalties at 5 years and 10 years.** These Statutory Price Reductions (SPRs) were introduced in 2017 and justified by policymakers as cost containment exercises.[25] Yet the costs of innovative medicines are already contained – spending has not grown in a decade in real terms, despite growth in patient numbers, morbidity, an ageing population and innovation. The impact has not been to protect taxpayers – it has been to restrict medicine availability for patients.
- **For those medicines that have already experienced 5-year or 10-year price reductions, restore the price to the originally approved level**. This should happen in the first year of the next Strategic Agreement.
- **Abolish flow-on reference pricing.** Flow-on reference pricing is an administratively applied policy that triggers price reductions for F1 innovative medicines whenever any therapeutically linked product takes a reduction, regardless of form, molecule, route of administration or clinical relevance. It operates without transparency and creates unpredictable, compounding price erosion across multiple products. This can mean that price reductions from older medicines can flow-on to newer medicines. This sometimes happens with only a couple of months' notice and can be as large as a 40% reduction – a source of instability that companies can no longer afford to risk when revenues overseas can be impacted by Australian prices.

  Similarly, existing single brands which introduce new formulations or innovation should remain on the F1 formulary, rather than being moved into the F2 formulary which houses products subject to competition.
- **Confirm that companies will receive no less than the approved ex-manufacturer price (AEMP)** by updating the Deeds of Agreement. This will ensure that any changes to co-payment or supply chain arrangements during the term of the Strategic Agreement do not further, and unpredictably, erode medicine prices.
- **Protect prices from inflation**. PBS co-payments, health insurance premiums, some hospital funding and practitioner payments are examples of part of the health system that are protected from inflation through index-linking. Yet medicines – which experience inflation in production costs – are not protected, and have their value eroded because of it. Index-linking the net prices of current and future medicines to CPI will solve this problem.

Industry proposal on reform relating to older products

The pre- and post-listing reforms set out above all support the concept of a pharmaceuticals market encouraging and attracting innovation. It means higher up-front prices and price stability while the medicine is patent-protected.

If these reforms are secured, it makes price reductions – if transparent and certain – at the end of a medicine's patent-protection more acceptable for medicines innovators.

Medicines Australia will work with Government to explore responsible options to deliver increased savings on older products, such as through reforms to price disclosure or increases to the SPR upon the entry of the First New Brand.[viii]

viii The first new brand is the first additional brand of an already listed PBS item. Its arrival triggers the shift from F1 to F2, and it sets the benchmark price for all later brands (including generics). It is the moment the PBS treats a medicine as multibrand, activating competition based price reductions through price disclosure).

Accountability to patients

The purpose of the PBS – and the point of the next Strategic Agreement – is to serve patients. If it does not deliver decisive, measurable improvements in access, it will have failed and must be revised.

This will not happen overnight. The next Agreement should have a 7-year term, to set the PBS on a safe footing for the next generation. Across this period, the following KPIs should be measured quarterly:

- **Time to listing.** The HTA Review highlighted that only around 50% of submissions were listed on the PBS within 22 months of Australian Register of Therapeutic Goods (ARTG) registration, i.e. TGA approval.[26] The minimum KPIs for the future Agreement should be the Review's recommendations in relation to this performance:
  - >90% of products demonstrating superiority should be listed on the PBS within 6 months of ARTG registration, when following the PBAC parallel processing pathway
  - >90% of products demonstrating superiority should be listed on the PBS within 12 months of ARTG registration, where parallel processing is not used
  - However, these targets should be regarded as a starting point to be met within the first two years of a new agreement. A more ambitious target should be that PBS listing occur within 60 days of ARTG registration for all submissions by the 5-year review point of the new agreement.
- **Medicines availability.** Increase the proportion of globally approved medicines that are listed on the PBS:[ix]
  - **Australia to reach the non-US average of globally approved medicines over five years and reach the average of the top three performing countries for globally approved medicines over 10 years.** To illustrate what this would mean using the latest data, Australia's current baseline figure for globally approved medicines is 25%. Reaching the non-US average over five years would mean getting to 36%. Reaching the average of the top three performing countries over 10 years would mean getting to 53% (with the top three countries currently being Germany, Japan and Spain). These baselines and targets are based upon PhRMA research on medicines access.[27]
- **Investment growth** in PBS net ex-manufacturer expenditure on innovative F1 medicines should be tracked.

Review points for the Agreement should occur after 2 years, 3.5 years and 5 years. At any of these points, should the policy reforms fail against the above KPIs, Government and industry should work together to agree corrective measures to put them on track.

If agreement cannot be met and spending growth on innovative medicines is also tracking below 10% annually, it will be clear that the Agreement is failing and either party may dissolve the Agreement in all its aspects.

ix The PhRMA report defines this as: *"New medicines refers to new active substances first launched globally during the past ten years (January 1, 2016 to December 31, 2025) and approved as safe and effective by the U.S. Food and Drug Administration (FDA), European Medicines Agency, or Japan's Pharmaceuticals and Medical Devices Agency."*

Conclusion – the case for change

The PBS remains one of the nation's greatest public health achievements, but it is facing significant challenges to medicines access that may turn into a crisis.

Persistent underinvestment in innovative medicines, combined with rapidly changing global pricing dynamics, is increasing the risk that Australian patients will wait longer for, or miss out entirely on, the latest medical advances.

The consequences are significant: poorer health outcomes, growing inequities in treatment access, diminished economic productivity and more strain on the wider health system.

Australian medicines policy stands at a crossroads. Maintain the status quo so that patients have fewer effective treatments. Or use the next Strategic Agreement as a rare opportunity to take action to address the challenges facing the PBS.

Taking the opportunity would mean:

- A firm commitment to increase investment by doubling spend on innovative medicines as a percentage of GDP will signal to the world that Australia wants the best health technologies
- Ambitious reform across a medicine's lifecycle will tear down barriers to medicines getting listed on the PBS
- Transparent performance measures will enable the Australian public to have an accurate picture of the PBS and how it performs

With bold policy choices in each of these areas, rather than incremental change, Australian patients will have access to more of the world's most innovative medicines.

Annex I – detailed reform package

Pre-PBS listing reforms

Underinvestment in innovative medicines exists at every stage of the PBS listing process. A key driver of underinvestment is the selection of inappropriate comparators within the current HTA framework, which can bias assessments towards the lowest-cost alternative instead of the treatment that would realistically be displaced. The current PBAC guidelines undervalue a new medicine's benefits (due to discount rate policy), evidence generation and assessment techniques are outdated and there is limited capacity and capability for PBAC to assess rapidly advancing health technologies (due to inertia in implementing HTA review recommendations). Once a PBAC assessment is completed, a medicine's value has to sit below the threshold at which the Government is willing to pay for new health technologies, with that threshold being low by international standards (due to ICER policy). Should a medicine get approval for listing, sponsors of that medicine are often asked to take all of the financial risk if the usage of that medicine – and therefore the cost of that medicine – exceeds expectations (due to RSA policy).

Underinvestment equates to fewer launches of new medicines. The below table describes the current policies referenced above, why the policy disincentivises PBS-listing of new medicines, and the proposed solution to underinvestment.

Current policy	Disincentive to list	Proposed solution
The Incremental Cost-Effectiveness Ratio (ICER) threshold	**A low willingness to pay for new medicines**	**Increase the Australian ICER**
The ICER calculation represents PBAC's evaluation of the costs and benefits of listing a new medicine. PBAC does not use an explicit ICER threshold to determine the cost-effectiveness of a new medicine. It instead uses a broader set of criteria within a decision-making framework. But the ICER is nevertheless a critical factor in medicines funding decisions. And where PBAC decisions are ICER-based, ICER outcomes effectively become the threshold for what the Australian Government is "willing to pay" for the benefits provided by a new medicine.	Research suggests that Australia's ICER threshold sits below the international average, implying that Australia is less willing to pay for innovative medicines than a host of other high-income nations.[x] Note that this cannot be said with absolute certainty because Australia's approach to ICERs lacks transparency.[xi] The issue of low ICER thresholds –and the impact on launches – is being recognised around the world. In December 2025, the UK announced a 25% increase in its ICER threshold. It was the first increase in over two decades. The change is expected to enable an additional 3-5 medicines or indications to be approved for use each year, at an estimated additional cost of £1.5 billion over three years.	Specifically, the Australian Government should direct PBAC to increase ICERs, with median ICER across all appraisals increasing to at least A$80,000 from 2027/28 and equivalent rises for median ICERs within each major therapy category. This is, in effect, the Australian equivalent of the UK threshold reform, expressed as a directional commitment on median accepted ICERs rather than a hard ceiling shift. This investment would represent an increase in Australia's willingness to pay for new medicines.

x ABPI, February 2026, Benchmarking the UK's cost-effectiveness threshold: findings from international comparison, https://www.abpi.org.uk/publications/benchmarking-the-uk-s-cost-effectiveness-threshold-findings-from-international-comparison/

xi Medicines Australia, October 2022, Funding Innovative Medicines, https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/11/HTA-DP-Funding-Innovative-Medicines-.pdf

Current policy	Disincentive to list	Proposed solution
Comparator choices in PBAC submissions	**Inappropriate focus on lowest cost**	**Remove the link between comparator choice and cost**
A new medicine is compared to an existing medicine or therapy when PBAC assesses the added value that the new medicine will bring. The assessed value of a new medicine affects what price the Government will pay for it. Hence, the choice of "comparator" can be decisive in PBAC and/or company decisions to list on the PBS.	PBAC often selects the Lowest Cost Comparator (LCC) when making comparisons between new medicines and existing medicines or therapies. Older PBAC Guidelines stated that the main comparator should be the therapy that prescribers would most likely replace with the new medicine. However, since 2016 the Guidelines have effectively been interpreted as requiring the main comparator to be the least costly (the current Strategic Agreement weakened this link, but improper use of LCC remains widespread). A recent survey found that LCC-related pricing was a significant factor for all companies that did not proceed to price negotiations after a positive PBAC recommendation.[xii] Moreover, this comparator choice can also create problems post-launch through linked pricing arrangements (see next section).	PBAC submissions should choose comparators using the following rules: • **Comparators must be F1, on label and for the same indication.** This ensures that comparators are also innovative medicines, that they are TGA approved ("on label") and that they are making comparisons with treatments for the same health issue ("same indication"). • **Where the clinical comparator is in F2, a shadow price should be applied (at the price when the medicine first entered F1 / was first listed on PBS).** This ensures that a comparator cannot take the price of a medicine that has already experienced significant price erosion. Taken together, these measures remove any link to cost in comparator choice. The mechanism for change is either legislative change or a changed interpretation of the current legislation.
The discount rate that values new medicines	**A medicine's benefits are discounted too heavily**	**Reduce the discount rate**
Discount rates determine how future health benefits and costs are valued in HTA. Australia currently applies a fixed 5% discount rate, established by PBAC in 1990 and embedded in PBAC Guidelines. The discount rate materially influences the valuation and price of new medicines and, therefore, PBS listing decisions. There has been a debate around reform of the discount rate. Both the HTA Review and Medicines Australia have made different cases for a reduced discount rate,[xiii] and the DoDHA is consulting on reform (July 2026).	The current 5% discount rate creates a disadvantage for medicines with long-term benefits. These medicines include preventative interventions, cell and gene therapies, and personalised medicines. They incur high upfront costs but deliver benefits over many years. Under the 5% discount rate, those long-term gains are heavily discounted while upfront costs are not, thereby producing a "*double-whammy*" that reduces estimates of a medicine's cost-effectiveness.	Specifically, the following should apply: • **Discount both costs and outcomes at a uniform, annual (compounding) rate of 1.5% per year for all costs and health outcomes that occur or extend beyond one year in the base case.** • **Present sensitivity analyses using fixed discount rates of 3.5% and 0% per year (applied to both costs and outcomes) where relevant.** These measures will ensure that medicines with longer term benefits will not be disadvantaged in assessment of their cost effectiveness. Moreover, there is provision for broader analysis of cost effectiveness with the use of sensitivity analysis.

xii Evohealth, March 2026, The cost of comparison: when the benchmark becomes the barrier, https://www.evohealth.com.au/wp-content/uploads/2026/03/The.cost_.of_.comparison-Evohealth-Report.pdf

xiii HTA Review recommendation was to reduce the discount rate from 5% to 3.5% for the minority of new medicines that have long-term benefits. Medicines Australia argued that the Review recommendation did not go far enough, advocating a discount rate of 3.5% for all medicines and 1.5% for medicines with high up-front costs and longer-term benefits.

Current policy	Disincentive to list	Proposed solution
Implementing HTA Review recommendations	**Recommendations have not been implemented**	**Implement recommendations in the three areas (with some additions)**
The HTA Review evaluated how health technologies are assessed for public funding. Its 50 recommendations were published in September 2024. All of the review's recommendations make improvements to the HTA system. However, three subject areas covered by the review are particularly important to innovative medicine access: • Australia's HTA system is under growing pressure to evaluate an increasing volume of health technologies – many with smaller or non-traditional evidence bases – while operating within a constrained healthcare environment. This is particularly relevant in areas of high unmet clinical need (HUCN) and health technologies with high added therapeutic value (HATV). • How incremental clinical benefit is recognised within the current HTA framework – the current system uses valuation techniques that are based upon outdated concepts of evidence generation. • The development of an explicit qualitative values framework.	To date (July 2026), none of the HTA Review's recommendations have been implemented.	For each of the suggested areas: • **HUCN/HATV.** HTA review recommendations 44 and 45 called for processes to identify HUCN and HATV health technologies. In support of these recommendations: – The broadest possible definitions of HATV and HUCN should be used to maximize the number of innovative therapies that can access the expedited pathway. – A binding commitment to expand the expedited pathway to all cost-effectiveness submissions as soon as practicable, contingent on the outcomes of a 12-month HATV/HUCN pilot. • **Cost-minimisation differentiation.** HTA review recommendations 34–36 establish clear overarching methodological principles and updated guidance on the standard of evidence generation that, taken together, would materially improve the ability of PBAC to assess the true clinical value of innovative therapies. HTA review recommendations 32 & 33 complement this by addressing how evidence is framed and whose perspectives are captured at the front end of the process. • **Values Framework.** Australia's HTA system has considered a medicine's "value", but not in a way that is explicit, consistent or transparent. The framework would recognise additional dimensions of value that matter to patients, carers, society and the system. The second order effects considered in the pilot should include the benefits for carers and families, productivity, and social welfare costs in HTA. This would require implementing HTA Review recommendation 26.

Current policy	Disincentive to list	Proposed solution
The application of Risk-sharing arrangements (RSAs)	**Pharmaceutical companies bear all risk**	**Improved guidance, mandatory reviews and risk share caps**
RSAs are legally binding agreements between the Commonwealth and a pharmaceutical sponsor used to manage cost-effectiveness, utilisation and budget uncertainty at the time of PBS listing. RSAs have been a feature of the Australian reimbursement system since 2006 and are now standard for high-cost medicines.	RSAs predominantly shift financial risk onto sponsors, with rebates up to and including 100% above any agreed expenditure caps.	Having the following three elements: • New robust and transparent guidance governing the setting of expenditure thresholds • Company may initiate review at 3 years or in event of major new data or new entrant; reviews for RSAs already older than 3years to be phased in over 3 years from July 2027 • 50% cap on industry liability above expenditure thresholds (future RSAs, including all post-review RSAs)

Post-PBS listing reforms

Current policy	Disincentive to list	Proposed solution
Statutory Price Reductions	**SPRs do not reflect commercial reality**	**Remove 5yr and 10yr SPRs and apply "catch-ups" to realign prices that have experienced cuts**
Under the current Statutory Agreement, SPRs take place on the 5th, 10th and 15th anniversaries after an F1 medicine has been listed on the PBS. The reductions are 5%, 5% and 26.1%, respectively. The original justification for the introduction of the 5-year SPR was to manage the cost of investment in new PBS listings, and it was applied at 5 years as an estimate of the amount of time that it took pharmaceutical companies to recoup R&D costs.[28] A 10-year SPR was subsequently added.	SPRs apply regardless of any context to the medicine. The economics of a medicine's cost-effectiveness calculation could not change at all and still have a price reduction applied.	This would mean no mandatory price cuts at 5 years and 10 years, and the F1 medicines that had already experienced a mandatory price cut at 5 years and 10 years would have these price reductions restored to the originally approved level.
No recognition of increased prices	**Manufacturing and supply costs are not inflation-proof**	**Index link net prices to CPI – current and future medicines**
Once the price of a medicine has been decided, there is no mechanism to adjust for inflation.	This means the cost of producing a medicine is likely to increase over time, while the price of that medicine will remain static. This inflation-linked price erosion gradually makes a medicine less commercially viable. A lack of Australian medicines manufacturers compounds problems around increased production costs and complex logistics.[29]	This will ensure that medicines prices are adjusted to account for some of the eroding impact of inflation.
Flow-on reference pricing	**The policy creates uncertainty and lacks transparency**	**Remove flow-on reference pricing**
When a medicine that is therapeutically linked to other medicines takes a price reduction, the Department requests equivalent reductions across all medicines that are therapeutically linked. This happens irrespective of the medicine's form, molecule or administration route.	The policy can create large price cuts – sometimes over 40% – at short notice and across F1 and F2 boundaries. It has no legislative basis and operates without a defined process.	Flow-on reference pricing should not be applied under any circumstance.

Current policy	Disincentive to list	Proposed solution
Automatic price adjustments	**Price uncertainty / inconsistency**	**Protection from automatic adjustments**
Medicines prices can change due to automatic adjustments in PBS parameters.	Reimbursement has changed in response to changes in other parts of the PBS system before in previous schemes, to companies' disbenefit, bringing unjustified instability. Medicines subject to First New Brand price reductions which are designed for the introduction of post-patent competition.	Insert clause in Deeds of Agreements to confirm that companies will be reimbursed for AEMP and no less (so reimbursement will not be impacted by any changes to co-payment or supply chain arrangements). Enable existing single brands which introduce new formulation or innovation to remain in F1.

References

1. Medicines Australia, May 2026, Access Denied: The twin threat facing medicines access in Australia, https://www.medicinesaustralia.com.au/media-release/new-report-waitlist-for-life-saving-medicines-extends-to-years-for-australian-consumers-and-patients/
2. Medicines Australia, July 2026, Bitter Pill: How Australian patients are missing out on the latest medical breakthroughs https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2026/07/03826-MA-BitterPill-Report_Accessible_Final.pdf
3. EYPhRMA, June 2025, High-Income Country Spending on Innovative Medicines, https://www.phrma.org/resources/high-income-country-spending-on-innovative-medicines; Medicines Australia analysis of the PBS using Department for Health data; PBS Expenditure and Prescription Reports

   Department of Health data, available upon request
4. Phrma, May 2026, Access to new medicines in the US vs. other high-income countries, https://cdn.aglty.io/phrma/PhRMA_OnePager_AccessToNewMedicinesReport_8.5x11_v3.2_Print%20(2)_20260513104421.pdf
5. ISPOR, 2026, Spillover Effects of US MFN policy on European drug markets, https://www.ispor.org/heor-resources/presentations-database/presentation-cti/ispor-2026/poster-session-3-3/spillover-effects-of-us-mfn-policy-on-european-drug-access
6. Strategy&, June 2026, 360 degree barometer of France's Attractiveness for the Pharmaceutical Industry, https://www.leem.org/sites/default/files/2026-06/360_Barometer_of_France_Attractiveness_Press_conference_2026_vfinal.pdf
7. OECD, November 2025, Health at a Glance 2025: Australia, https://www.oecd.org/en/publications/health-at-a-glance-2025_15a55280-en/australia_7cad4f74-en.html
8. OECD, November 2023, Health at a Glance 2023, https://www.oecd.org/en/publications/health-at-a-glance-2023_7a7afb35-en/full-report/avoidable-hospital-admissions_836e2826.html#figure-d1e26305-d6e302da5c
9. Medicines Australia, July 2026, Bitter Pill: How Australian patients are missing out on the latest medical breakthroughs https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2026/07/03826-MA-BitterPill-Report_Accessible_Final.pdf
10. The Australian, July 2026, MS drugs price fight sparks fear
11. NHMRC website, "Equity" accessed July 2026, https://www.nhmrc.gov.au/guidelinesforguidelines/plan/equity
12. IQVIA, 2025, Evolving Beyond the PBS: Exploring Australia's Private Medicines Market, https://www.iqvia.com/-/media/iqvia/pdfs/australia-and-new-zealand/white-papers/iqvia-anz-evolving-beyond-the-pbs-whitepaper.pdf
13. The McKell Institute, April 2026, Still Out of Pocket, https://mckellinstitute.org.au/wp-content/uploads/2026/04/McKell-Stil-out-of-pocket-2026.pdf
14. Patients Australia / Sandoz, July 2026, Australian Perspectives on Medicines Access, https://www.patients.org.au/_files/ugd/f3091a_7fa1520733f2462ba5f9a6768d42a41d.pdf
15. Australian Government Productivity Commission, December 2025, Delivering quality care more efficiently, https://assets.pc.gov.au/2025-12/quality-care.pdf?VersionId=7nAzvnmusPpI7NQ9bGjXennWOs37z2C3
16. Minister Butler Speech, March 2026, AFR Healthcare Summit, https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/speech-from-minister-butler-afr-healthcare-summit-30-march-2026?language=en

17. Roche CEO, LinkedIn, https://www.linkedin.com/posts/teresagrahamrochepharmaceo_societal-value-of-innovation-ugcPost-7478321543219929088-dYkm/?utm_source=share&utm_medium=member_ios&rcm=ACoAABfnMwwBcebKOsJvcy-kBJeO6GXsysiv4kI

18. Australian Government, December 2025, Migraines and headaches in Australia, https://www.aihw.gov.au/reports/neurological-conditions/migraine-and-headache-disorders?__cf_chl_f_tk=nf4b_1rnAkdxZ.qzuJqNDsQhUZGS35C5VuroqREv8j8-1783439552-1.0.1.1-9hDZWLBAmjEkDmIOil1m1NcuzeF6Ll8emnelzIMHXUs

19. US and Australia Trade Deal, Annex 2-C, https://ustr.gov/archive/assets/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/asset_upload_file659_5145.pdf

20. Budget 2026-27, May 2026, Budget Strategy and Outlook Budget Paper No. 1, https://budget.gov.au/content/bp1/download/bp1_2026-27.pdf

21. Department of Finance, October 2025, National Disability Insurance Scheme, https://www.finance.gov.au/sites/default/files/foi-25-26-146-document-01.pdf

22. Parliamentary Budget Office, April 2023, Request for budget analysis, https://www.pbo.gov.au/sites/default/files/2023-05/The%20cost%20of%20nuclear%20submarines%20PDF.pdf

23. Frontiers, May 2026, Evidence asymmetry in Australian public spending: why health alone cannot bear a higher burden of proof, https://www.frontiersin.org/journals/public-health/articles/10.3389/fpubh.2026.1843884/full

24. European Federation of Pharmaceutical Industries and Associations, June 2026, How innovation drives health and growth in Europe: Assessing the Return on investment of innovative medicines, https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/every-1-invested-in-new-medicines-returns-567-to-europe/

25. Senate Community Affairs Legislative Committee, June 2015, INQUIRY INTO THE NATIONAL HEALTH AMENDMENT (PHARMACEUTICAL BENEFITS) BILL 2015

26. HTA Review, https://www.health.gov.au/sites/default/files/2024-09/health-technology-assessment-policy-and-methods-review-final-report_0.pdf

27. PhRMA, May 2026, Access to New Medicines in the United States vs. Other high-income countries, https://cdn.aglty.io/phrma/Attachments/NewItems/PhRMA_OnePager_AccessToNewMedicinesReport_8.5x11_v3.2_Print%20(2)_20260512113247.pdf

28. Senate Community Affairs Legislation Committee, Inquiry into the National Health Amendment (Pharmaceutical benefits) bill 2015,

29. Australian Government, April 2024, Understanding the impact of medicine shortages in Australia, https://www.tga.gov.au/sites/default/files/2024-11/market-research-understanding-impact-medicine-shortages-australia.pdf