Medicines Australia

Access denied

The twin threat to innovative medicines availability in Australia and the impact on patient access

May 2026

Contents

Foreword

For almost 80 years, the Pharmaceutical Benefits Scheme (PBS) has been one of Australia's greatest public policy achievements giving generations of Australians affordable access to life saving and life changing medicines. It remains central to the health of our nation, and an important contributor to our productivity and economic prosperity.

Access to innovative medicines via the PBS not only helps people live longer and healthier lives, to stay working and connected to their families and communities, medicines also reduce the long-term burden on the health system.

Yet despite its strengths, the PBS is not keeping pace with global medical innovation. Australians are now waiting 3.6 years for access to medicines already available in comparable countries. Increasingly, some medicines are not launching here at all.

This report presents a challenging picture and reinforces an urgent need to act. It shows the issue is no longer simply about delays, it's whether Australian patients will receive the latest medicines their counterparts have in other countries. The question is whether Australia will be a country that can keep up and offer the latest generation, cutting-edge medicines now and in the future.

We are now at a critical point. An interplay of local domestic issues and international dynamics is determining what future access to the latest and best medicines will look like in this country. It is significant and urgent. Discussion and reviews must become decisions and actions.

Declining Government investment in new medicines and longstanding policy mechanisms that undervalue innovation are being impacted by a profound shift in the international medicine markets. US policies are reshaping how pharmaceutical companies make decisions about investment and launch internationally.

The flow on effect will matter deeply for Australian patients. Behind every statistic in this report are people living with cancer, rare diseases, chronic illness and complex conditions, patients and families waiting for medicines they know exist overseas but cannot access here.

Medicines Australia strongly supports the PBS and the principle of equitable access to affordable medicines but it must evolve alongside science, innovation and global market realities. Other countries are already responding to protect future access to medicines for their citizens. Australia cannot afford to stand still.

Ensuring Australians continue to access the latest medicines will require partnership, political will and a shared commitment to long-term health and economic prosperity. We stand ready to work with Government to modernise the PBS and strengthen Australia's position in an increasingly competitive global environment.

The decisions we make now will shape whether Australia falls further behind or takes this opportunity to build a stronger system that equips us with the latest advances and innovation for a healthy and prosperous future.

Sue MacLeman
Chair
Medicines Australia

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Summary

The Pharmaceutical Benefits Scheme (PBS) is crucial to the health of Australian citizens and to the economic prosperity of Australia.

This is an achievement of which the Government is rightly proud and, by lowering copayments, it has moved decisively to reduce the cost of the PBS to those who rely on it.

Yet the PBS is blighted by the fact that it does not secure access to some of the most cutting-edge medicines in the world. It is ultimately patients who suffer – and face the prospect of using their squeezed household budgets to access the medicines that they need. It is an issue that now demands urgent attention.

This problem has been driven by two longstanding structural weaknesses:

- **Low and falling levels of government investment.** The Australian Government pays low prices for new medicines, is investing less in new medicines over time, is increasingly reliant on industry rebates to manage the costs of new medicines and is spending less on new medicines than other advanced economies.
- **A worsening reimbursement process for new medicines.** The time taken to secure reimbursement and for new medicines to become available on the PBS is getting longer, with no sign of improvement. Moreover, Australia is not internationally competitive – it is taking longer than other advanced economies to fund new medicines that have been deemed safe and effective.

As a result, Australian patients are missing out on access to innovative medicines that are available in other countries.

The critical need to address these issues is now being amplified by the twin threat of:

- **US policy causing an unprecedented rebalancing of global medicine pricing incentives.** It is the stated aim of the US government to aggressively push down US medicine prices whenever, and wherever they are undercut in other wealthy countries. This means that pharmaceutical companies launching medicines in Australia in the future can only do so if they accept the risk that low Australian prices might then be replicated in the far bigger US market.
- **Australian policy creating an inflexible system that undervalues new medicines.** Multiple mechanisms drive down the medicine prices that the Australian government pays for innovative medicines. These include willingness to pay thresholds, discount rates, low-cost comparators, risk sharing agreements, domestic reference pricing and Statutory Price Reductions. These mechanisms are in place pre-PBS approval and post-PBS listing, meaning that the valuation of a medicine begins low in Australia and is then systematically eroded further.

The interplay of these policies means that any pharmaceutical company accepting a low price for a medicine launched in a smaller market, such as Australia, risks damaging consequences in larger overseas markets.

The risks posed by these threats are not hypothetical. There is emerging evidence from across the world that launch plans and medicines access are being disrupted. The results of a Medicines Australia member survey also highlight a negative impact:

- 79% of respondents described their company as "very concerned" about the effects of US policies; a further 16% are "somewhat concerned"
- 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

Other countries are recognising and responding to these challenges and have adapted their health systems to protect medicines access for their citizens.

The PBS cannot stand still while the world changes around it. The reimbursement system has not kept pace with innovation. It was designed for a simpler era and is now being stretched to accommodate precision medicine, rare disease innovation, oncology advances, and cell and gene therapies.

The case for PBS reform has been long recognised, with both this government and its predecessor commissioning reviews and acknowledging structural weaknesses. US policy is exacerbating these pre-existing problems.

A proactive Australian response can be found in partnership with the pharmaceutical industry. The current Strategic Agreement between the Australian Government and Medicines Australia – which sets out medicines access and savings measures in the PBS – is due to expire in 2027. Negotiations on the next Strategic Agreement are expected to commence in 2026.

This is the opportunity to improve access to innovative medicines for Australian patients and safeguard the health and economic benefits of the PBS for Australia.

Introduction

The Pharmaceutical Benefit Scheme (PBS) is the cornerstone of Australia's health system. It provides millions of people with access to affordable, cutting-edge and life-saving medicines.

The PBS also boosts the Australian economy; researching, trialling and commercialising new medicines and driving productivity. But in addition, medicines enable people to live healthier lives, contribute productively to work, families and to broader society. As concluded by the Australian Government's Productivity Commission, the effectiveness of health treatments is intrinsically linked to the health of the economy.[1]

Put simply, Australia would be sicker and poorer without the PBS.

Yet the PBS is not without challenges and limitations. This report puts forward that the government and pharmaceutical industry must work together to address them. Only then will Australians have full access to the health and economic benefits that the PBS has the potential to provide.

Access denied

The PBS cannot claim to be world leading. Ever-greater numbers of the most innovative medicines – widely used in comparable countries – are not available on the PBS at all.

It is patients who lose out. Recent survey evidence found that:[2]

- 43% of Australians have been prescribed medicines that are not on the PBS
- 16% of those who rely upon medicines not funded by the PBS report having to choose between medicine and food
- 89% of respondents supported increasing investment in the PBS to ensure more medicines are available

There are numerous, often complex, reasons why medicines are not available on the PBS. Nevertheless, there is strong evidence that demonstrates:

- **Low and falling levels of government investment in new medicines**
- **A worsening reimbursement process for new medicines**

These longstanding problems undervalue the benefits of innovative medicines and undermine access to innovative medicines.

Until they are tackled, they mean that the Australian Government cannot realise the vision of the National Medicines Policy to, *"…achieve the worlds best health, social and economic outcomes for all Australians through a highly supportive medicines policy environment".*[3]

The twin threat

The value of a new medicine is represented by its price. The policies of the Australian government and of overseas governments interact to influence how this price is determined.

Within this context, there is a twin threat facing medicines access in Australia (see Figure One). Current US policy is driving an unprecedented rebalancing of pricing incentives in the global medicines market. At the same time, the calibration of Australian policy gives little room for manoeuvre in how medicine prices adjust. These threats interact and amplify each other.

Figure One: A twin threat to medicines access from US and Australian policy

US medicines policy

- The US Government has implemented a range of measures to force down high medicines prices.
- These benchmark the price the US pays for medicines against the price that other, comparable countries pay, to choose the most favourable (lowest) price.
- It is an attempt to get other countries to pay a "fairer share", changing how pharmaceutical companies around the world are selling innovative medicines.
- This means that the price paid for a medicine in Australia can impact the price paid in the US – and elsewhere.

Australian medicines policy

- The Australian Government has a suite of cost containment measures that affect price.
- It is less willing to pay for innovative medicines than most comparable countries.
- It inappropriately and unpredictably references the price of new medicines against low-cost, inferior older medicines.
- It imposes more stringent rebates on new medicines.
- It requires price reductions on PBS medicines at regular intervals.

Whatever the context, there is established evidence on how price control policies affect medicines access:

- **Reduced investment in medicines Research & Development (R&D).** The elasticity of innovation – how investment in innovation changes in response to revenue expectations – is positive, i.e. lower revenues lead to lower R&D.[4]
- **Reduced new medicines launches.** A 2019 analysis of medicines pricing found that the US had access to 89% of novel medicines launched between 2011 and 2018, but other developed countries with price controls only had access to 47% of these medicines on average.[5]

Emerging evidence – set out later in this report – highlights that these consequences for medicines access are playing out increasingly seriously in Australia.

Governments around the world are facing similar questions around how domestic policy should respond to the changed global context and are aware of the consequences. Many have already responded by increasing investment in innovative medicines, both now and into the future – moving fast to protect access for their citizens.

The opportunity to act

In April 2026, the Australian Prime Minister rightly warned of the dangers of, *"…standing still while the world changes around us".* He went on to argue that economic reform to drive growth, boost productivity and lift living standards is *"always necessary".*[6]

Rarely has this been truer than with the emerging twin threat to innovative medicines access.

The next Strategic Agreement – the multi-year deal between the government and the pharmaceutical industry that underpins innovative medicines availability in Australia – is an opportunity to take the action required.

Negotiations on the agreement are due to start in the second half of 2026.

Collaborative working between government and industry is a necessary condition to get the agreement right, and to deliver better reimbursement processes, higher investment, improved medicines access and greater economic activity.

The pharmaceutical industry is committed to this process, but political will is critical to guarantee success. The 50 recommendations in the 2024 Health Technology Assessment (HTA) review showed promising recognition from the government for how to improve medicines access. But at the time of this report's publication, none of the 50 recommendations have been implemented and further reviews have been initiated.

The rest of this report

The following sections outline a clear rationale for immediate action to increase investment and improve reimbursement processes for Australians to access innovative medicines:

- Key problems with PBS performance
- US policy and the "chilling effect" on medicines access
- Australian policy undervaluing new medicines
- A call to action

Ahead of a Strategic Agreement between the Australian Government and the Australian pharmaceutical industry, this document is a vital guide to the changed commercial realities facing companies and the unique risks this poses for Australian patients, unless the government takes decisive action to protect the PBS.

Key problems with PBS performance

The problems described below have arisen through government policy choices. They deter medicines innovation and are barriers to medicines access. As a result, Australian patients are missing out.

This is happening in already difficult business conditions that see the costs of production, transport and distribution increasing for pharmaceutical companies. When these high-value add companies experience challenges, it has knock-on impacts for the Australian economy.

Low and falling levels of government investment

It is recognised that countries that pay lower prices for new medicines tend to get access to those medicines more slowly than countries that pay higher prices (if they get access at all).[7]

Australia pays lower prices for innovative medicines than many comparable countries when looking at list prices. There is limited evidence on comparisons of confidential net prices (because they are confidential), but it is reasonable to assume that a relatively low list price starting point will likely translate into a relatively low net price.

31%

LOWER PRICES

The amount Australia's list prices are below Canadian[i] list prices when comparing 470 patented medicines (based upon company reporting).

Australia pays lower prices for innovative medicines than many comparable countries.

Paying low prices is reflected in the amount that the Australian government spends on innovative medicines overall.

0.26%

BELOW AVERAGE OF OTHER COUNTRIES

Australia spends a lower share of its income on innovative medicines (0.26% of GDP per capita)[ii] than the average across other high-income countries (0.31%) and lower than the European Union average (0.34%).[9]

i This is one example of price differentials across the world – Canada was included here because it is an advanced economy.

ii Note that this is spending on innovative medicines and is framed in terms of GDP per capita. PBS spend, taking rebates into account, was referenced by the Health Minister as being 0.5% of GDP, https://www.health.gov.au/ministers/the-hon-mark-butler-mp/media/speech-from-minister-butler-afr-healthcare-summit-30-march-2026

As well as being comparably low, spending on innovative medicines in Australia is also falling. Despite the 2022–27 Strategic Agreement stating an expectation of increased, "*…real expenditure on new medicines*",[10] net spend on innovative medicines has fallen in real terms in recent years.

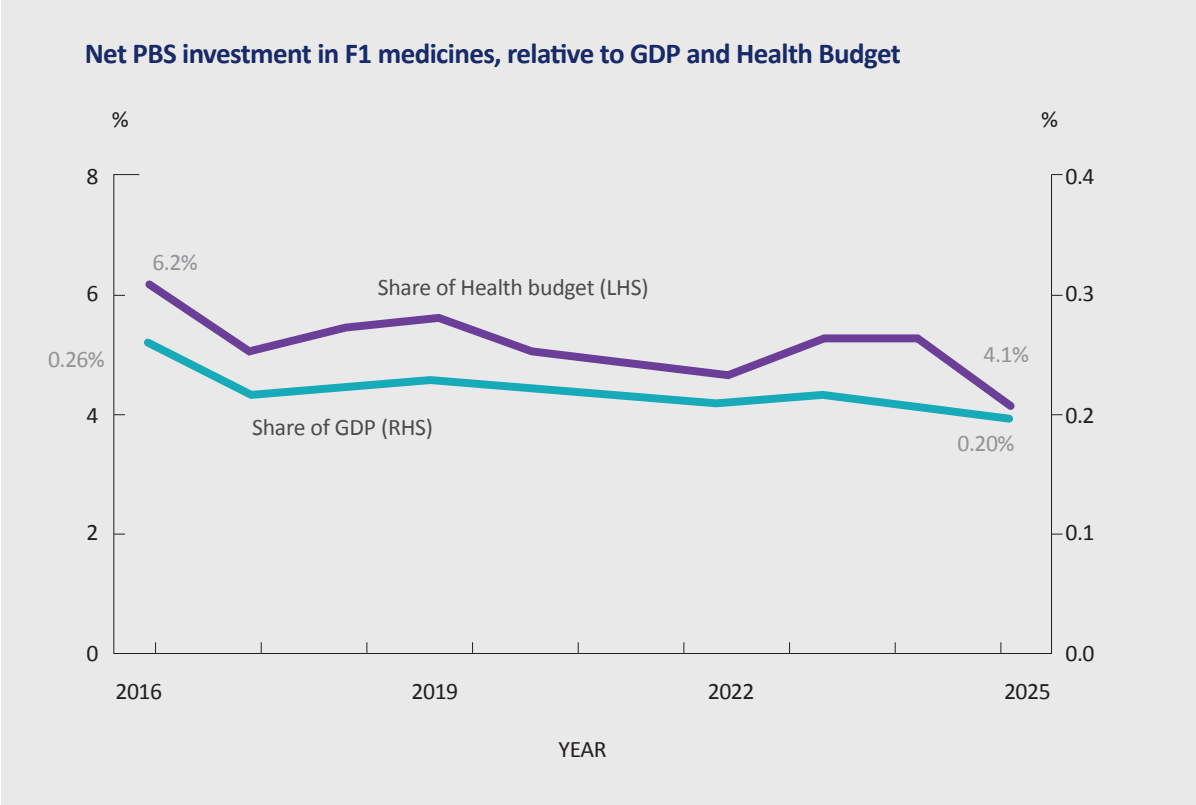
-3%

The decline in real terms after accounting for net investment in innovative (F1) medicines from 2021–22 to 2024–25.[11]

Further to government investment in innovative medicines spend decreasing, net investment in innovative medicines has declined as a share of GDP, from 0.26 per cent in 2015–16 to 0.20 per cent in 2024–25, and as a share of the health budget from 6.2 per cent to 4.1 per cent (over the same timeframe). See Chart One.

This is despite the innovative pharmaceutical industry paying ever-increasing amounts in rebates to the Australian Government, money which is not transparently ringfenced for reinvestment to support medicines access but goes back into consolidated revenue.[iii]

Chart One: Net spend on innovative (F1) medicines medicines as a share of the health budget and share of GDP; breakdown of PBS investment in medicines



Source: Department of Health; MA estimates; years are FY

iii The New Medicines Funding Guarantee was supposedly the mechanism within Consolidated Revenue to deliver new funding each year for listing new medicines, and all savings from the agreement was to be reinvested in the PBS.

iv The research defines "regulatory submission" as the "Date of submission at the first regulatory agency"

35% The proportion of total PBS expenditure that was paid to the Australian Government by pharmaceutical companies in the form of rebates from negotiated agreements in 2024–25, up from 20% in 2017–18.

Weak and worsening reimbursement processes

Significant challenges in the reimbursement process mean that getting a medicine listed on the PBS is taking up increasing amounts of resources.

This is driven by a failure to recognise the investment required to develop new medicines and, therefore, a failure to recognise the value of new medicines.

This ultimately affects the attractiveness of Australia as an early launch market.

There are different numbers in the public dialogue that capture the time from when a medicine is deemed safe and effective by the TGA to reaching a conclusion on reimbursement. But whichever the number, the delay is too long for patients to wait.

639 days The Department of Health's briefing to the new government on the median time to PBS listing after a medicine's registration.[12]

534 days The average time between regulatory submission[iv] and HTA recommendation in Australia in 2024, up from 428 days in 2020.[13]

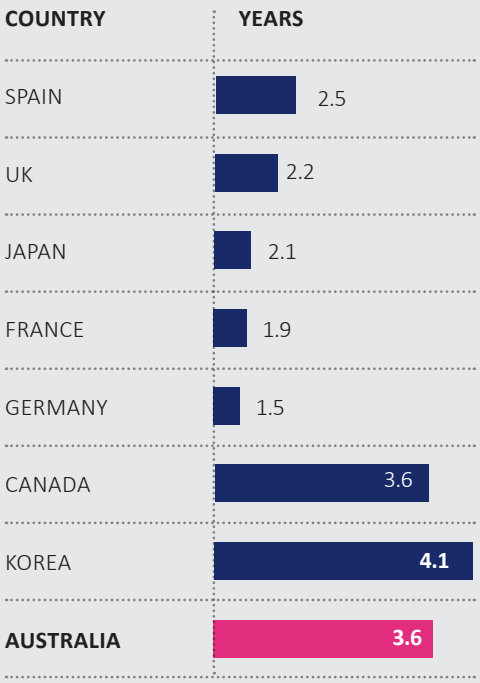
466 days Medicines Australia has calculated an average time of 466 days from registration to reimbursement, 82 days above the OECD average.[14]

This performance looks even weaker when looking at the average time difference between global registration of first in class medicines and countries providing reimbursed access to that medicine. Australia is taking longer than Spain, the UK, Japan and Germany.

Average wait for reimbursed access to first in class medicines

3.6 years

This was based on an assessment of 179 medicines that had been registered by the US Food and Drug Administration (FDA) between 2015–2024. In Spain, the average wait was 2.5 years, the UK 2.2, Japan 2.1, France 1.9 and Germany 1.5 years. Australia had comparable times to Korea (4.1 years) and Canada (3.6 years).[15]



There are also the medicines that are simply not funded. The above study also identified that of the 179 first in class medicines it looked at, 124 had not been PBS funded in Australia. Put another way, only around 30% of these medicines were available to patients on the PBS.

There is clear and consistent evidence that Australia simply does not fund as many new medicines as many comparable countries.

Medicines Australia analysed the registration of 472 New Molecular Entities (NMEs) – which are considered innovative medicines – in 20 Organisation for Economic Co-operation and Development (OECD) countries between 2016–2021.

It found that Australia launched 91 NMEs in this period, 26.4% less than the average of 123.6 across the other 19 OECD nations.[16]

-26%

LESS NMEs THAN THE AVERAGE ACROSS OTHER NATIONS

A separate study analysed 302 innovative medicines supplied globally and found that only 81 (27% of the total) were listed on the PBS.[17]

US policy and a "chilling effect" on medicines access

- **It is the stated aim of US medicines pricing policy to rebalance global spend on medicines.**
- **The policy aggressively pushes down US medicines prices to incentivise higher prices in other countries and has uncovered structural issues in the recognition of medicines value around the world.**
- **Specifically, the Most Favoured Nation (MFN) policies require pharmaceutical companies to offer their medicines in the US at prices that are towards the bottom of those offered in comparable countries overseas.**
- **This means that pharmaceutical companies launching medicines in Australia in future will only do so if they accept the risk that low prices such as in Australia might be referenced in the far bigger US market.**
- **In Australia, a structural undervaluation of innovative medicines (see next section of the report) is leaving it more exposed to the pressures created by the global medicines market.**

Background

The US is by far the largest pharmaceuticals market in the world. Changes to US medicines pricing rules can cause massive disruption in overseas pharmaceutical markets and supply chains.

This is exactly what is happening now. The Most Favoured Nation (MFN) policy is a seismic shift and will influence the global medicines market, with consequences for global medicines development and patient access for years to come.

US pharmaceuticals market generated around

$800bn

CHINA HAS THE SECOND LARGEST MARKET, ONLY GENERATING AROUND $110BN IN SALES[18]

The rationale for the MFN policy was set out in President Trump's first term (2017–2021). It was argued that:[19]

- America's "broken system" means much higher medicines prices in the US than in other countries.
- By paying these prices, Americans are subsidising the R&D costs of medicines innovation.
- High US prices are driven by foreign governments paying "unreasonably" low prices – through policy that undervalues innovation.

But regardless of the original rationale and which administration introduced it, the MFN policy is here to stay.

The policy and its consequences

Today's MFN and MFN-related policy effectively caps US medicines prices to levels benchmarked in comparable nations.[v]

The response to the policy in other nations is creating a new global paradigm. The rules of the game have changed and with it, so has the global medicines market:

- **Fewer launches and more withdrawals in Europe.** Analysis from market research company GlobalData found that European launches of new medicines have fallen by 35% in the 10 months following US policy change. While multiple factors contribute to this effect, it is consistent with the expected consequences of MFN.[20]
- **Price increases outside the US.** A survey of members of European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) found 60% of respondents were likely to increase their non-US prices in the next 1–3 years in response to MFN, with 70% likely to increase prices in the long run (5–10 years).[21]

Alongside the evidence of MFN in changing the decisions of pharmaceutical companies, governments are also changing policy in recognition of MFN's impact. Table One summarises just some of the major policy shifts that have been observed.

The emerging impact in Australia

Health Minister Mark Butler has recognised this concern in a keynote address, saying that reducing US prices creates price pressure in every other market, including Australia:[22]

"We are concerned, as I think is every other country around the world, that it could have a chilling effect on pharmaceutical companies' willingness to bring new medicines to a market like ours".

This concern is also evident among Australian pharmaceutical companies. In a recent survey of Medicines Australia members (March 2026), respondents were asked how concerned they were about the effects of US domestic policies (e.g. MFN, GENEROUS, GUARD, GLOBE etc. see footnote) when it comes to the ability to launch products in Australia:

- 79% of respondents described their company as "very concerned"
- A further 16% of respondents described their company as "somewhat concerned"

Respondents were also asked about the position of Australia in their launch sequence planning:

- 84% 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.
- No members reported an improvement or expected improvement.

This reflects challenging domestic policy and underinvestment in the PBS (see next chapter) and overseas policies, including MFN.

v The MFN policy detail is not set out here, but interested readers can search for information with the policy acronyms GLOBE, GUARD and GENEROUS

Table One: Policy changes in other markets in an MFN context

Agreed Under consideration

Market	Policy changes	Status
United Kingdom[23]	**As part of the US–UK Economic Prosperity Deal the UK has agreed to a landmark pharmaceutical pricing arrangement reflecting growing global pricing pressures.**[24] The UK will double spending on new medicines as a share of GDP from 0.3% in 2026 to 0.6% by 2036, with an expected increase in the NHS budget spent on medicines from 10% in 2026 to 12% by 2036. The agreement outlines an increased cost-effectiveness threshold range, from £20,000 – £30,000 per additional Quality-Adjusted Life Year (QALY) raised to £25,000 – £35,000 and a new method for valuing health related quality of life in HTA.[25] The agreement signals expectations for earlier launch of innovative medicines in the UK and the expected adoption of more flexible pricing and access mechanisms, including outcome-based approaches, reinforcing a shift toward higher effective prices and a more negotiated, globally responsive reimbursement system.	
Republic of Ireland	**The Irish Government announced in January 2026 a Framework Agreement in principle with the Irish Pharmaceutical Healthcare Association (IPHA) and Medicines for Ireland (MFI) on Supply and Pricing of Medicines.**[26] The Agreement27 provides a range of measures to deliver faster access for patients, including a commitment to a structured process towards achieving a 180-day timeline for reimbursement decisions; strengthening security of supply and reducing risk of shortages; and streamlining access to medicines while supporting financial sustainability. The agreements sit alongside an additional €200m in spending on medicines, with €30m dedicated to access for new treatments. Ireland's reforms reflect the same global pricing pressures, with increased funding aimed at maintaining access and competitiveness for innovative medicines.	
Italy	**Italy has recently implemented a series of pharmaceutical pricing and reimbursement reforms aimed at strengthening access to innovative medicines while maintaining budget control.**[28] Italy is recalibrating its system to better support innovation, manage high-cost therapies, and remain competitive for early launches within an increasingly interconnected global pricing environment. The government has also committed to a €1.2 billion increase in the pharmaceutical budget (+7.13% compared with 2025), linked to agreed pricing reforms with industry, and reduced historical payback liabilities by approximately €535 million.	

Market	Policy changes	Status
Sweden	**In April 2026, Sweden launched a major investigation into overhauling its pharmaceutical pricing and reimbursement system, explicitly citing global pricing pressures, including MFN-type policies and geopolitical competition, as key drivers.**[29] The review will examine expanding state responsibility, strengthening incentives for cost-effectiveness, and introducing centralised management of confidential pricing, signalling a potential shift toward more flexible and strategically managed reimbursement. Concerns about delayed access and companies deprioritising the Swedish market have reinforced the need for reform.	
South Korea	**In November 2025, South Korea released a comprehensive overhaul of its reimbursement system, with a planned rollout from 2026 onward of the Pharmaceutical Pricing and Reimbursement System Reform.**[30] The reforms are widely recognised as a response to delayed launches of innovative medicines in Korea and mitigate the spillover effects of global pricing pressures. The reforms are intended to introduce greater pricing flexibility, including more flexible application of cost-effectiveness thresholds and expansion of dual pricing (public list prices alongside confidential net prices). They also propose to streamline evaluation pathways, allowing certain high-need therapies (e.g. rare or severe diseases) to be reimbursed without full economic evaluation.[31]	
Spain	**Spain is undertaking a comprehensive reform of its pharmaceutical pricing and reimbursement system, expected to be finalised in 2026, aimed at improving access to innovative medicines.**[32] While Spain's reimbursement reforms pre-date MFN, ongoing global pricing pressures are reinforcing the shift toward more flexible, negotiated access and broader definitions of value. Reforms under consideration include faster and more predictable decision timelines, conditional or provisional reimbursement pathways, expanded use of managed entry and risk-sharing agreements and exploration of broader definitions of value in pricing decisions.	

Australian policy undervaluing new medicines

- **The pre-PBS approval process undervalues new medicines by:**
  - Inappropriately comparing new medicines to older medicines – some of which are not used in clinical practice – leading to unjustifiably low prices
  - Using discount rates which undervalue the benefits of medicines that have longer-term benefits
  - Implementing a restrictive cost-effectiveness framework for funding new medicines (which is much more stringent than comparable countries; and other Australian Government programmes)
- **The post-PBS approval process undervalues new medicines by:**
  - Exposing pharmaceutical companies to high financial penalties if new medicines exceed government uptake and cost expectations
  - Automatically reducing a medicine's price on several anniversaries after it has been listed, despite medicines often exceeding the health benefits originally evaluated
  - Unexpected price reductions flowing from domestic reference pricing when a new drug is listed on the PBS through cost minimisation to a low-cost product
- **These pre-and post-PBS approval issues conspire to deny Australians access to new medicines**
- **While the issues are longstanding (and widely discussed), they remain unresolved, and are now exacerbated by US pricing policy**
- **In short, Australia undervalues new medicines and that undervaluation now has enduring and broader short, medium and long-term consequences**

Background

A recent Medicines Australia member survey highlighted the domestic policies of most concern when pharmaceutical companies are planning medicine launches.

The policies that were regarded as the most challenging when making launch decisions all relate to pre-PBS approval processes or post-PBS approval mandated price reductions (see Table Two).

The Australian government is aware of the most challenging issues at the top of Table One. Indeed, the 2024 HTA Review recognised them. At the time of writing, however, no action has been taken to address them.[33]

As set out in the previous chapter, US MFN pricing policy puts these issues in a new context, disincentivising launch in Australia due to knock on implications in the US market, ultimately making it harder to launch new medicines in Australia (see Box Six at end of the chapter).

The following sections set out the issues in greater detail, describing the policy mechanism and why they are a challenge.

Table Two: Medicines Australia survey responses to the question: "Please advise how challenging the following aspects of the Australian medicine market are for your company when making launch decisions."

Issue	Somewhat challenging (%)	Very challenging (%)	Very + Somewhat challenging (%)
PBAC implicit willingness to pay threshold	21.7	78.3	100
Risk sharing agreements	17.4	73.9	91.3
Statutory price reductions (5, 10 and 15 years)	43.5	43.5	87.0
Reference pricing between F1 and F2 medicines	13.0	73.9	87.0
First new brand price reductions	43.5	30.4	73.9
Cost of market entry (eg. TGA and HTA submission fees	39.1	21.7	60.9
Approach to intellectual property	30.4	17.4	47.8
Combination flow on price reductions	8.7	34.8	43.5
Process for agreeing special pricing arrangements	17.4	26.1	43.5
Uncertainty around impact of reductions in copay $ value	30.4	8.7	39.1
Uncertainty around impact of supply chain agreements (eg. NPSA)	26.1	4.3	30.4
Clinical trials ecosystem	17.4	0.0	17.4
Stockholding requirements for medicines	8.7	4.3	13.0
Support for pharmaceutical manufacturing	0.0	4.3	4.3

Over 50% selected 30–49% selected Less than 30% selected

Questionable comparators

When submitting a proposal to the Pharmaceutical Benefits Advisory Committee (PBAC), a pharmaceutical company must propose an existing medicine to compare against its new medicine.

This "comparator" selection underpins PBAC's assessment of the additional value that a new medicine is bringing to the market.

It has a huge influence on the economic case for a new medicine and can be decisive in granting or denying access, as well as leading to product withdrawals when a company cannot make a commercial case for launch to its global headquarters.

There is, however, established industry concern with the guidance on comparator choice.

For each new medicine proposal, PBAC reviews a pharmaceutical company's choice of comparator. If it disagrees with the choice, PBAC can make the decision to substitute the comparator for another that the committee believes to be more appropriate. This is despite what was evaluated in the clinical trials of the innovative medicines and may not always be a comparison to what is currently used in clinical practice.

This process is placing disproportionate weight on lowest cost comparators (LCC).

This practice is encouraged by ambiguity in the PBS approval system. The wording of the *National Health Act 1953* can be interpreted to make lowest cost the defining consideration for new medicines assessments, despite the 2022–2027 Strategic Agreement suggesting that this should not be the case.[34]

By using cost as a dominant factor for comparison, medicines are being inappropriately compared – it is like comparing the latest smartphone to a model that was released several years earlier and judging that they are the same.

Evohealth surveyed pharmaceutical companies on the impact of the LCC issue, finding the following:[35]

LCC-related pricing was a significant factor for **all** companies that did not proceed to price negotiations after a positive PBAC recommendation

LCC-related pricing was the only reason not to proceed to price negotiations for almost one-third (29%) of companies after a positive PBAC recommendation

80%

OF RESPONDENTS HAD EXPERIENCED COMPARATOR SUBSTITUTION BY PBAC IN THE PAST FIVE YEARS – ALL THE SUBSTITUTIONS WERE FOR THE LOWEST COST ALTERNATIVE MEDICINE

95%

OF RESPONDENTS AGREED THAT THE APPROACH TO LCC UNDERVALUES CLINICAL INNOVATION

NINE IN TEN

AGREED THAT COMPARATOR SELECTION AFFECTS THE TIMING OF LAUNCH OR INDICATION SEQUENCING IN AUSTRALIA

70%

OF RESPONDENTS AGREED THAT COMPARATOR SELECTION POLICY OFTEN LACKED TRANSPARENCY

Through inappropriate valuation of medicines at launch, the use of LCC disincentivises pharmaceutical companies from listing new medicines on the PBS, particularly in a post-MFN world where companies are now considering how to value medicines in different markets.

The implications of LCC being applied can be seen in an analysis of PBS submissions. See Box One.

Box One: LCC analysis based on MAESTrO Consulting Data[36]

Between 2016 and July 2025, almost 100 medicines had LCC applied.

Of those medicines, 63 medicines were not listed on the PBS as of July 2025.

This includes:

- Rejected submissions
- Deferred submissions
- Withdrawn submissions
- Submissions still pending as of July 2025
- Inactive listings
- Presentations and formulations that never progressed to PBS listing

The main therapeutic areas were immunology and ophthalmology.

An outdated discount rate

Discount rates are used in cost / benefit calculations to reflect the idea that people value future outcomes less than they value the same outcome if it happened today.

Hence, for treatments with longer-term or lifelong benefits the application of a discount rate means that the medicine is not valued as highly.

PBAC set its base discount rate at 5% in 1990 with reference to Canada. Since that time, this discount rate has not changed, despite other countries (including Canada), recommending lower base discount rates to support access to more preventative and curable medicines, vaccines and treatments. There are examples of how the discount rate can prevent reimbursed access to a medicine or vaccine. See Box Two.

The HTA review recognised that the application of the discount rate needed to change and proposed a reduction for some medicines. This would mean some medicines – which include gene therapies and certain vaccines – to be valued differently with a greater recognition of the accrual of long-term benefits to patients and society.

The (as yet unimplemented) recommendation was that Australia's discount rate would be 3.5% for a select group of health technologies. Medicines Australia sought its application across ALL health technologies in line with similar international practice and 1.5% for those medicines where the benefits accrue over a longer time.

Box Two: Case study on Bexsero and the Discount Rate

A vaccine against meningococcal B (MenB) is critically important because MenB is one of the leading causes of invasive meningococcal disease (IMD) in Australia — a rare but extremely serious infection that can cause meningitis, septicaemia, permanent disability, or death within hours.

While vaccination programs have reduced other strains (like C, W and Y), MenB continues to circulate and cause disease in Australia. This makes MenB vaccination a key remaining gap in protection.

Bexsero is a vaccine which can prevent meningococcal B but is currently unavailable to the vast majority of people who would benefit.

Bexsero was rejected three times by the PBAC before receiving a positive recommendation in November 2019, but only for a high-risk population of Aboriginal and Torres Strait Islander children, rather than the proposed general Australian population.

The time period between initial PBAC consideration in November 2013 and recommendation in 2019 was more than six years.

One of the key reasons why Bexsero has not been made widely available is because of the discount rate used by the PBAC, which does not properly value the long-term future health of Australia's population in the way comparable countries do.

Unwillingness to pay

PBAC evaluates the cost and health benefits of a new medicine. For example, the Government decides to list a new medicine by calculating how much they would spend on a new cancer drug and how the drug would prolong or save lives.

The number representing these calculations is called the Incremental Cost-Effectiveness Ratio (ICER). The ICER is a major consideration when PBAC makes a recommendation on whether to fund new medicines.

Essentially, this makes ICER-based PBAC decisions the threshold for what the Australian Government is "willing to pay" for a new medicine. Medicines Australia has long argued that this threshold is:[37]

- Too restrictive
- Outdated
- Lacking transparency

This ultimately affects PBAC decision-making. Box Three sets out a case study relating to PBAC guidance on weight loss drugs and how cost considerations can lead to confused conclusions.

Some countries publish ICER thresholds, but in others – including Australia – it is implicit, or not transparent.

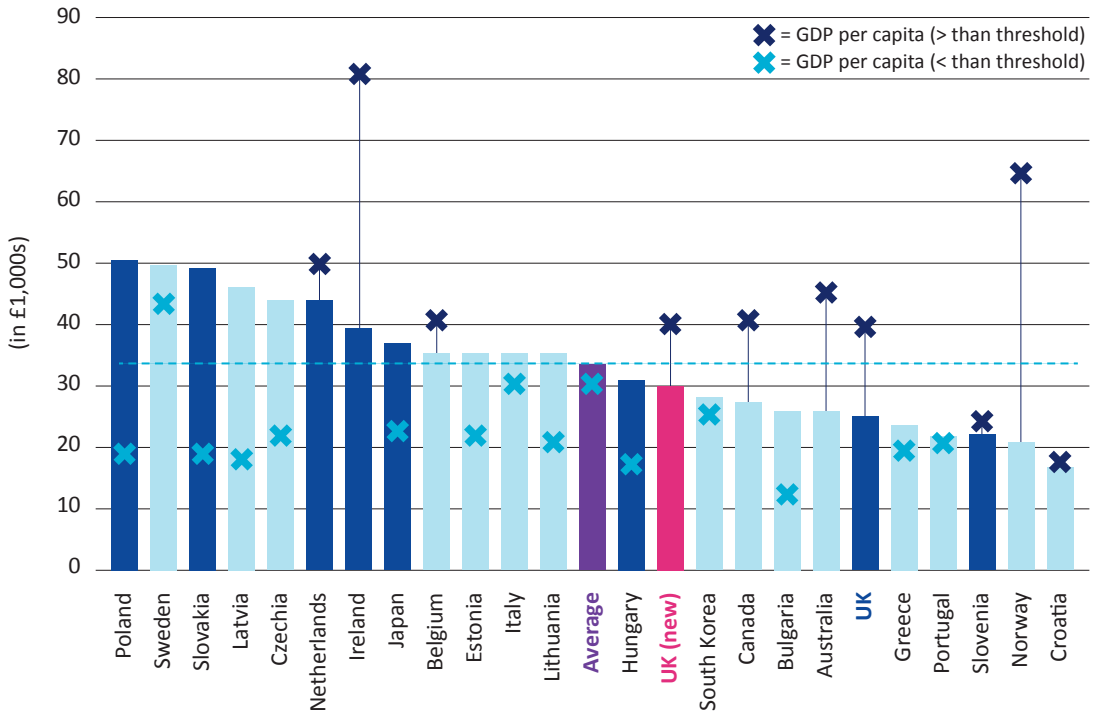
Australia's ICER threshold can be inferred from past PBAC decisions. Research suggests that this threshold sits below the international average and that Australia is willing to pay less for innovative medicines than a host of other countries, including Bulgaria, Lithuania and Hungary.[38]

In April 2026, the UK[vi] increased its cost-effectiveness range, from £20,000–£30,000 to £25,000–£35,000 (up 25% at the lower end and 17% at the upper end). This was the first increase in the threshold for over 20 years and was influenced by the effects of US MFN policy.[39]

This took the UK's ICER threshold from below Australia's to above it. See Chart Two. The data also shows that, of the countries included in the research, Australia is in the minority in having a level of GDP per capita above its ICER threshold.[40]

vi Note that the ABPI research refers to the UK, even though there is autonomy in applying cost-effectiveness thresholds in Scotland.

Chart Two: International cost per QALY threshold vs GDP per capita



Source: Association of British Pharmaceutical Industry[41]

Box Three: Case study on PBAC's conclusion on GLP-1s

GLP-1s are medicines that can be used to support weight-loss. Their effectiveness has seen an explosion in public and private global demand, with annual sales forecast to grow by 30% in the coming years.[42]

In Australia, PBAC has expressed concern that new obesity treatments that are currently being trialled (and, therefore, have not yet been submitted for review by the manufacturers) may be superior to a listed GLP-1, resulting in higher PBS costs to fund the potentially more effective treatments in the future. [43]

In short, PBAC raised concerns about listing current GLP-1s on the PBS because more effective medicines ***might be*** available in the future.

As a result, Australian patients cannot currently access approved GLP-1s for weight management on the PBS. This "wait and see" approach only acts to dampen innovation and prevent patients from realising improved health through timely access to effective new, innovative medicines.

PBAC's advice to ministers on listing GLP-1s on the PBS to address weight-management exemplifies how cost-effectiveness frameworks can ultimately limit access to new medicines when poorly calibrated or misapplied.

A rebate overreach?

After PBAC has recommended a new medicine for listing on the PBS, the price for that medicine is negotiated between the Department of Health and the pharmaceutical company.

These negotiations typically involve a "Deed of Agreement", setting out when government will receive a rebate on the cost of a medicine (essentially, the conditions under which the government pays a lower price).

There are two key elements to a Deed of Agreement:[44]

- **Special Pricing Arrangements (SPAs).** Offering access to the PBS at a lower confidential price to meet cost-effectiveness criteria (e.g. a confidential discount).
- **Risk Sharing Agreements (RSAs).** Mitigating the expenditure risks arising from uncertainties in medicine cost estimations, cost-effectiveness, usage and health outcomes.

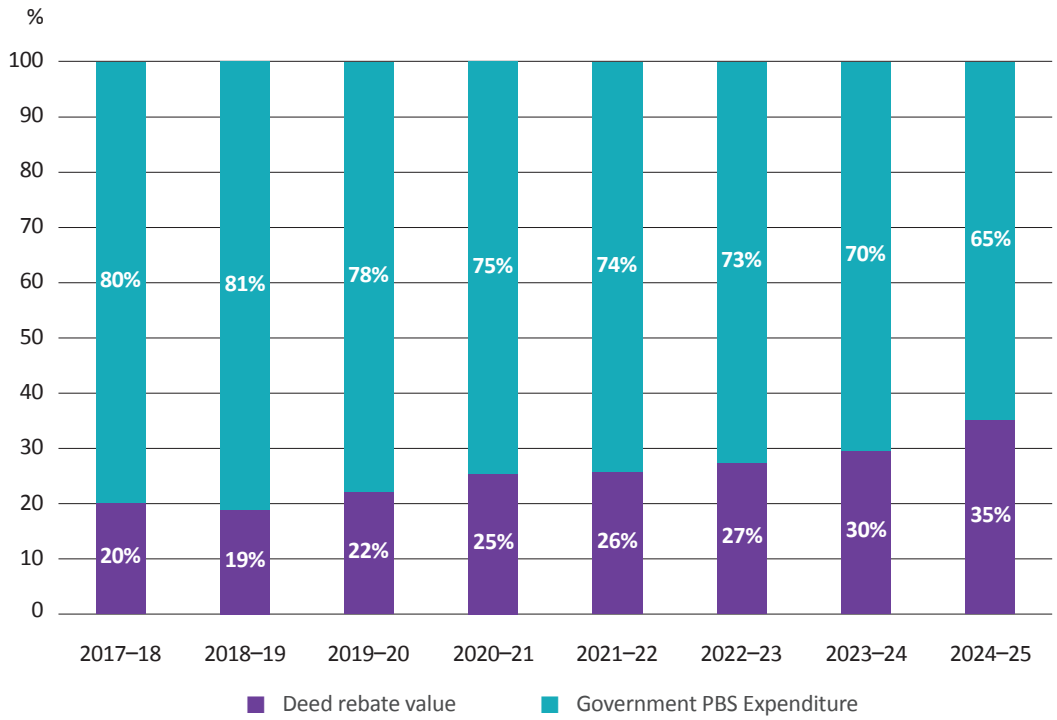
The value of Deed of Agreement rebates has significantly increased in recent years. Between 2017–18 and 2024–25, the value of industry rebates increased by $4.4bn, a greater amount than the $3.3bn increase in PBS net expenditure over the same period, i.e. the amount of money that industry pays in PBS rebates has outstripped the amount of money the government has invested in the PBS by $1.1bn over the eight years.

This means that industry rebates amounted to 35% of total PBS spend in 2024–25, up from 20% of total PBS spend in 2017–18 (see Chart Three).

Australia is not alone in increasing rebates. There is evidence that the confidential agreements that dictate the net price of a medicine have become much more common around the world.[45]

A Medicines Australia survey found that SPAs are broadly supported by the industry, although confidentiality remains critical.

Chart Three: Deed of Agreement rebate value and government PBS expenditure, 2017–18 and 2024–25



Source: PBS Expenditure and Prescription reports

The key issues raised in the survey around RSAs included that:

- Too often the entire financial risk is placed on the company irrespective of the level of risk associated with a specific RSA.
- There is limited scope for renegotiation of RSAs when the conditions for establishing an RSA have changed – a resubmission can be made to PBAC but is often unsuccessful. This means that companies are trapped in RSAs even if, for example, the original uncertainty they were designed to address is resolved, there is legitimate demand for a medicine that breaches agreed caps, or external factors affecting utilisation arise that are beyond the sponsor's control.

Given their increasing prominence and issues attached to them, reform of RSAs is urgently needed.

Mandatory price reductions

Enforced price reductions have applied to medicines listed on the PBS for over 20 years. Policymakers made two arguments for their introduction:

- **Ensuring price competition among o -patent medicines.** The first mandatory price reductions in 2005 were designed to reduce the price of existing PBS medicines when a generic competitor medicine – one with the same ingredients and strength – entered the market.[46] The government explicitly believed that high-volume discounts on generic drugs, meant to reduce prices, were instead being retained as higher profits by pharmacists rather than being passed on to consumers. As such, the policy was designed to accelerate the lowering of prices brought in by generics to deliver greater savings to consumers, rather than waiting for market adjustments.[47]
- **Supporting investment into innovative medicines.** A 5% price cut that applied five years after an innovative medicine's PBS listing was introduced in 2015. Further price reductions at the 10–year and 15–year listing anniversaries were applied in 2017. These have been justified by policymakers as a method to manage the increasing cost of innovative medicines, and enable pharmaceutical companies to contribute to *"the long-term growth of [innovative medicines'] market access"*.[48] The five-year anniversary was initially justified with the assertion that it was considered a proxy for the length of time for a pharmaceutical company to recoup the R&D costs of bringing a medicine to market.

The suite of current price reductions is codified in the 2022–2027 Strategic Agreement and *National Health Act* as Statutory Price Reductions (SPRs). Broadly speaking, there are three types:

- **Anniversary price reductions.** Taking place on the 5th, 10th and 15th anniversaries to an F1 medicine[vii] being listed (the reductions are (5%, 5% and 26.1%, respectively).[49]
- **First new brand (FNB) price reductions.** Applies when a new medicine that is bioequivalent or biosimilar and has the same manner of administration as an existing medicine is listed on the PBS. The FNB price reduction is currently set at a rate of 25% and triggers the existing medicine to change its categorisation from an F1 to an F2 medicine.[50]
- **Catch-up reductions.** These apply to medicines that have been listed on the PBS for 15 years or more but have not been subject to a price disclosure reduction.[51]

vii F1 medicines are generally patented or single-branded medicines and F2 generally contains off-patent, multi-branded or generic medicines

Box Four: Illustrative example of SPR impact on medicine prices

The table below sets out price reductions consistent with those included in the 2022–2027 Strategic Agreement. It is based on the Approved Ex-Manufacturer Price (AEMP).

	Price reduction	Resulting AEMP
AEMP of comparator at initial listing (price at which comparator was deemed cost-effective)		**$1,000.00**
5-year statutory price reduction	5%	$950
10-year statutory price reduction	5%	$903
First new brand statutory price reduction	25%*	$677.25
New benchmark for cost-effectiveness		**$677.25**

*25% up to a maximum of 60% off the earliest of 1 January 2016 or date of listing AEMP

An illustrative example of the impact of SPRs on medicines prices can be found in Box Four.

The government estimated that SPR savings would amount to $1.9bn over the 2022–2027 Strategic Agreement period and that these would be *"fully-reinvested"* in the PBS.[52] But there has been no transparency on the extent to which this has happened.

While SPRs are known and predictable in their application to medicines listed on the PBS, they signal that, in addition to low net prices at launch, Australia will seek to further erode medicine prices throughout their lifecycle, undervaluing innovation and disincentivising launch.

Taking LCC as an example, if the lowest cost alternative to a new medicine is an older medicine, it may have been subject to statutory price cuts already. If this product is selected as the comparator in the health technology assessment process, the new, innovative medicine price becomes anchored to an old technology that has already experienced price cuts, some of which were designed to apply after R&D costs had been recouped.

Flow on price reductions

Medicines can also experience unpredictable price cuts through flow on price reductions. These can be highly punitive, sometimes reducing the price of innovative medicines to match the price of an older medicine, which may already have gone through anniversary SPR price reductions.

A flow on price reduction happens when a new medicine lists on the PBS through cost minimisation.

- A cost-minimisation recommendation can be made when the PBAC considers a new medicine (Medicine B) to be of similar safety and efficacy to a currently listed medicine (Medicine A).
- The medicines could have the same or different active ingredients but would form a reference pricing group along with other medicines cost minimised to match Medicine A (e.g. Medicine B, C & D) Medicine A = $100; Medicine B = $100, Medicine C =$100, Medicine D =$100.
- A few years later, when Medicine A has moved into F2 and been subject to several SPRs, Medicine Z agrees to cost-minimise to Medicine A and is launched. Medicine A = $100 => $95 (5 yr SPR)=> $90.25 (10yr SPR) => $67.69 (F2); Medicine Z = $67.69
- The prices of Medicines B, C & D are adjusted down to the price of Medicine A & Z. Medicine B = $67.69, Medicine C =$67.69, Medicine D =$67.69

These types of price cuts undermine business predictability and certainty and are instrumental in reducing the options available for patients on the PBS. See Box 5 for a case study.

Box 5: Case study: Impact of the intersect between LCC and flow on price reductions

The voices of Australians either waiting or missing out on access to medicines can be heard through the Stronger PBS campaign. For example, Sandeep shares her story on living with ulcerative colitis (https://www.strongerpbs.com.au/voices). For Sandeep, timely access to medicines is about more than affordability — it is about dignity, independence and the ability to live a full life. 'A stronger PBS plays a tangible part of recognising a fundamental human right to safe and effective healthcare.'

Ulcerative colitis is a chronic inflammatory bowel disease characterised by continuous mucosal inflammation of the colon. The clinical course of the disease consists of periods of exacerbation (flares) and remission.

The estimated prevalence of ulcerative colitis in Australia is between 130 and 300 people per 100,000. This represents one of the highest rates in the world and contributes to an estimated total economic impact of inflammatory bowel disease (IBD) of $AUD 7.8 billion in 2025 (ref: https://onlinelibrary.wiley.com/doi/full/10.1002/jgh3.70387?msockid=237162fa4f816f47101177394e476eee.)

Eli Lilly Australia Pty Ltd applied to list a new treatment option for ulcerative colitis on the PBS. Omvoh© (mirikizumab) is an intravenous infusion and a pre-filled pen for subcutaneous injection, for the treatment of moderate to severe ulcerative colitis in adult patients who have had an inadequate response to, lost response to, or were intolerant of conventional therapy.

The addition of Omvoh© to the PBS would provide an alternative treatment option for patients, as it has a different mechanism of action compared with currently listed therapies. The value of having alternative treatment options was recognised in the HTA review final report (pg 178).

At its July 2023 meeting, the PBAC recommended Omvoh© for listing, but advised that the cost effectiveness of Omvoh © would be acceptable if it were cost minimised to the least costly alternative therapy (i.e lowest cost comparator) of 8 other comparators, some of whom had been on the market for more than 10 years , were now genericised and, as a result, their prices had been heavily eroded by up to 60%.

A decision was subsequently made not to proceed with PBS listing under these conditions, as the pricing requirements would have aligned Omvoh© with the lowest-cost comparator, including older biosimilar therapies, and would also have implications through domestic reference pricing mechanisms.

Following this outcome, two paediatric clinical trials and one adult combination trial involving Omvoh© were discontinued. It was noted that there are important ethical considerations for patients completing clinical trials where ongoing access to therapy may be uncertain (Pharma in Focus, June 16, 2025.)

These price reductions are different to combination therapy flow on price reductions, which are also problematic. Combination therapies combine two or more different medicines into a single therapy and may provide improved patient outcomes. An anniversary SPR applied to a component medicine can flow onto a combination therapy containing that medicine, leading to a price cut for the combination product ahead of the usual anniversary price reductions.

Box Six: Company views on the interaction of US MFN policy and Australian policy

Open text responses to a Medicines Australia member survey demonstrate how US MFN policy is interacting with Australian Government policy to challenge access to new medicines.

"Accepting low pricing in Australia now has a substantial impact on business sustainability because accepting low pricing in Australia means accepting low pricing in many larger markets".

"Low willingness to pay for innovation coupled with tighter global pricing corridors will inevitably delay or restrict access."

"Due to MFN, our parent company are asking us to consider the impact of risk share agreements on the net price and to include all discounts and rebates into the net price calculations. As a result, there is upward pressure on the net price to be achieved in Australia in order to launch our new innovative assets. This may result in delayed entry into the Australian market or potentially no launch at all."

"The current uncertainty regarding the impact of [MFN] policies (scope & reach) for our global counterparts forces them to take an even more conservative approach to launch sequencing and price expectations than previously with the potential result of delayed or de-prioritised launches. Equally the lack of commentary or commitment from the Australian government or policy makers is very frustrating as we are caught between divergent/opposing local & global practices."

"...reference pricing between F1 and F2 has significantly eroded the value of new medicines in Australia, creating substantial challenges for their launch and ongoing access, particularly under MFN policies"

Call to Action – improving access to innovative medicines for Australians

Australian pharmaceutical companies are caught between conflicting domestic and international policies.

This twin threat – on top of low levels of investment and weak reimbursement processes for new medicines – makes Australia an increasingly difficult place to launch medicines.

Without decisive action, these combined pressures will intensify to restrict further the number of new medicines available on the PBS.

Ultimately, it is Australian patients and their families who are missing out on the best treatments for them, and which are already available in other countries.

It is now vital that the Australian Government works with the pharmaceutical industry to navigate the new global medicines paradigm and put Australia in the strongest possible position to protect the PBS, ensuring its citizens are at the front of the queue for new medicines.

Central to this is improving the current HTA and innovative medicines access policy framework. The next Strategic Agreement presents the opportunity to make meaningful improvements by increasing investment in the PBS.

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