AMGEN AUSTRALIA SUBMISSION TO HTA POLICY AND METHODS REVIEW CONSULTATION 2

RECOMMENDATIONS

RECOMMENDATION 1:

The Australian Government should systematically collect, collate, and publish data on Australians' access to new medicines. Amongst other metrics, this should include the time taken for equitable Pharmaceutical Benefits Scheme (PBS) listed access, from the date of entry into the Australian Register of Therapeutic Goods (ARTG) to PBS listing, as well as following registration in international jurisdictions. This is of particular importance as we transition from the HTA Review to a period of reform.

RECOMMENDATION 2:

To ensure consistency across government investment decisions, the Pharmaceutical Benefits Advisory Committee (PBAC) should align its willingness to pay with the Australian Government's advised value of life, as recommended by the Office of Impact Assessments in the Department of Prime Minister and Cabinet ($235,000 per statistical life year).

Furthermore, we encourage the Reference Committee to convey to the Australian Government that it has not struck the right balance in terms of enabling timely patient access to innovative treatments and containing the net expenditure of the PBS.

RECOMMENDATION 3:

In developing its final report for government, the Reference Committee should further reflect on the incentives that underlie Australia's place in the global pharmaceutical industry and ensure recommendations to government do not have the potential to seriously impact Australians' access to new medicines.

There are some proposed reforms in the committee's final report that are disincentives for investment in Australia for health technologies and these do not align with the vision of the National Medicines Policy.

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The Australian Government should systematically collect, collate, and publish data on Australians' access to new medicines. Amongst other metrics, this should include the time taken for equitable Pharmaceutical Benefits Scheme (PBS) listed access, from the date of entry into the Australian Register of Therapeutic Goods (ARTG) to PBS listing, as well as following registration in international jurisdictions. This is of particular importance as we transition from the HTA Review to a period of reform.

The HTA Review and the reform to follow is dedicated to enhancing access to medicines for the Australian population, aligning closely with the National Medicines Policy's goal of achieving the best health, social, and economic outcomes. These reforms present an opportunity to ensure improved, equitable access to innovative medicines through public subsidy on the PBS.

A cornerstone of ensuring these reforms meet their objectives, is the need to measure the performance of the listing process. Systematic measurement and regular publication of performance data provides the community with the necessary information to assess the efficacy of the reforms, identify unintended consequences impacting patient access, and promote transparency. Regularly sharing the system's performance will build trust among stakeholders and in the PBS more generally as a central part of Australia's public healthcare system.

The Department of Health and the HTA Review Reference Committee deserve commendation for developing the research paper *"Health Technology Assessment Policy and Methods Review Australian market authorisation, funding, and assessment pathways and timelines"*[1] (DOH Analysis).

The paper contributes to analysis undertaken by the Reference Committee by providing an understanding of the time Australians wait for access to new medicines. The report establishes a baseline for evaluating the PBS listing process moving forward, and we encourage the Reference Committee to recommend to the Australian Government that it is regularly updated and published.

Several key points from the Department of Health (DOH) analysis deserve attention:

- **Time from ARTG registration to PBS listing** is informative, as it represents a critical patient-centric milestone. The data reveal a median delay of 21 months in patient access once the TGA has approved a treatment as safe and effective for supply to Australian patients (see Figure 1 for DOH Analysis summary data).
- **Time from FDA & EMA registration to PBS listing** highlights that Australians wait a median of 37 months, or about three years, for equitable access to a new medicine compared to when they were approved by European or American regulatory authorities (see Figure 1). This delay underscores the disincentives inherent in Australia's public subsidy scheme, including de-prioritisation due to low valuations and prices, protracted negotiation for subsidy and increasingly due to international reference pricing policies.
- **New Molecular Entities (NMEs) listed in Australia**: The international comparisons included in Figure 1 provide useful insights into the listing timeframes for new molecular entities (NMEs), which are the first-time registrations of new molecules seeking public subsidy. While acknowledging the analytical challenges, the data suggest Australia ranks low in access to new molecules compared to peer countries. The DOH's Analysis also presented data from PhRMA's *Global Access to New Medicines Report 2023* that shows that over the period 2012-2021, only 24% of globally launched medicines were reimbursed in Australia (replicated in Figure 2)[2]. Also contained in the DOH Analysis Medicines Australia's data shows that in the years 2016-2021, 45% of NMEs available in the US were subsidized in

[1] HTA Policy and Methods Review – Draft paper: Australian market authorisation, funding and assessment pathways and timelines. Published 24 January 2024. Access ed at: https://www.health.gov.au/resources/publications/hta-policy-and-methods-review-draft-paper-australian-market-authorisation-funding-and-assessment-pathways-and-timelines

[2] Table 11 in HTA Policy and Methods Review – Draft paper: Australian market authorisation, funding and assessment pathways and timelines.

Australia. These figures highlight the challenges and disincentives in bringing new medicines to Australia and supports the argument for reform and lifting the willingness to pay.

Amgen supports systematic, timely, and transparent measurement of both NMEs and new indications for medicines registered in peer countries but not submitted for registration in Australia to further elucidate Australians' access to world leading new medicines.

Figure 1: Time to PBS listing – 2021–22 listings – headline figures (Source: Table 8: Health Technology Assessment Policy and Methods Review Australian market authorization, funding, and assessment pathways and timelines).

Analysis characteristics	Details			
Measures	Minimum, median, average and maximum timeframes for subsidy of medicines through the PBS from earliest application to EMA or FDA to PBS listing			
Listing type	New medicines and extension of listing for existing PBS-listed medicine to a new population Breakdown for listings where the PBAC was satisfied the medicine offered an improvement in efficacy or reduction in toxicity over alternative therapies.			
Time period	2021–2022			
Data sources	PBS Medicines Status, EMA, FDA, and TGA websites.			
New Drugs (all)	**Min**	**Median**	**Average**	**Max**
First EMA or FDA approval to PBS listing	11 months	37 months	47 months	205 months
PBAC submission to PBS listing	9 months	17 months	22 months	75 months
ARTG registration to PBS listing	2 months	21 months	25 months	84 months
Extension (all)	**Min**	**Median**	**Average**	**Max**
PBAC submission to PBS listing	9 months	12 months	15 months	45 months
ARTG registration to PBS listing	2 months	15 months	23 months	152 months
New Drugs (improvement)	**Min**	**Median**	**Average**	**Max**
First EMA or FDA approval to PBS listed	19 months	47 months	58 months	205 months
PBAC submission to PBS listing	11 months	17 months	24 months	64 months
ARTG registration to PBS listing	6 months	22 months	26 months	79 months
Extension (improvement)	**Min**	**Median**	**Average**	**Max**
PBAC submission to PBS listing	9 months	14 months	17 months	45 months
ARTG registration to PBS listing	2 months	16 months	24 months	128 months

As we navigate through the coming reform period, timely publication of data on Australians' access to new medicines and new indications for medicines is essential. Published data facilitates further reform if unintended consequences arise and ensures all stakeholders have a clear and accurate understanding of whether the reform objectives, and the broader National Medicines Policy, are being met.

Figure 2: PhRMA - Global Access to New Medicines Report 2023 data (Source: Table 11 Health Technology Assessment Policy and Methods Review Australian market authorization, funding, and assessment pathways and timelines).

Study details	Parameters		
Objective	To compare timelines for medicine launch and reimbursement globally		
Listing type	New active substances (460) launched globally		
Time period	2012–2021		
Comparison countries	G20 countries		
Measure	**Country**	**Result**	**Rank (G20)**
Average time from global first launch to public reimbursement	Australia	47 months	10th
	Canada	52 months	12th
	France	34 months	5th
	Germany	11 months	2nd
	UK	27 months	4th
	G20 average	**46 months**	
Average time from local launch to public reimbursement	Australia	26 months	16th
	Canada	34 months	20th
	France	15 months	9th
	Germany	0 months	Equal 1st
	UK	15 months	8th
	G20 average	**19 months**	
Proportion of globally launched medicines reimbursed	Australia	24%	9th
	Canada	21%	11th
	France	43%	6th
	Germany	61%	2nd
	UK	48%	4th
	G20 average	**28%**	

RECOMMENDATION 2

To ensure consistency across government investment decisions, the Pharmaceutical Benefits Advisory Committee (PBAC) should align its willingness to pay with the Australian Government's advised value of life, as recommended by the Office of Impact Assessments in the Department of Prime Minister and Cabinet ($235,000 per statistical life year).

Furthermore, we encourage the Reference Committee to convey to the Australian Government that it has not struck the right balance in terms of enabling timely patient access to innovative treatments and containing the net expenditure of the PBS.

Australia's current approach to pricing medicines and assessing their value has led to low valuations compared to other developed countries.

Australia's low pricing environment creates a disincentive for global healthcare companies to introduce new technologies to the Australian market. Consequently, Australians may not have access on the PBS to the best available treatments for their illnesses, despite living in a wealthy country where such access is expected.

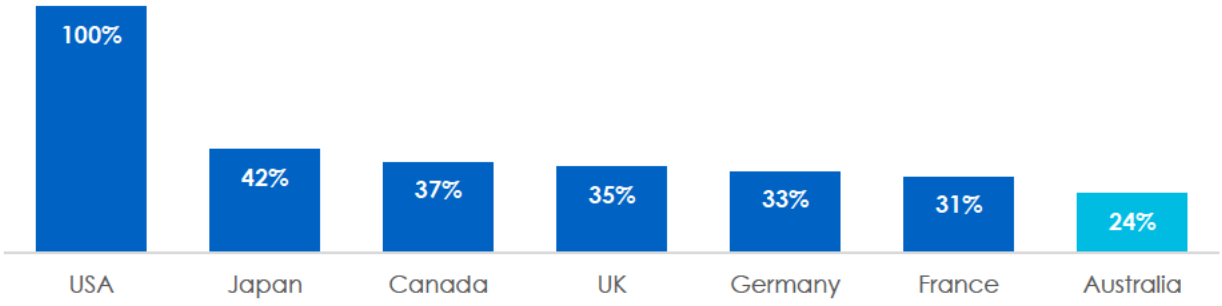
To put these low valuations into the broader context of government expenditure, it's helpful to consider the Australian Government's guidelines for valuing a statistical life. The Department of the Prime Minister and Cabinet's Office of Impact Analysis regularly updates this value, which is utilised

to inform government investment choices. In 2023, this value was established at $235,000[3], serving as a benchmark for the maximum value society attributes to a single year of life. From an economic perspective, there are net benefits to society up to the maximal valuation placed on a statistical life.

Considering that the Pharmaceutical Benefits Advisory Committee's (PBAC) range of Incremental Cost-Effectiveness Ratios (ICERs) falls between $10,000 and $100,000 (in some rare cases higher, in some cases lower)[4], it indicates that there is potential for prices to rise while still delivering value to society, particularly through patient access to innovative treatments.

Further validating this concern, PhRMA's *Analysis of Australia in U.S. International Reference Pricing Policies*[5] indicates that Australia often has the lowest prices among potential reference countries, leading to worse access to new medicines[5]. Across a basket of top-selling, single-source brand medicines and, after adjusting for GDP per capita, Australian prices were just 24% compared with the United States, and lower than our peer wealthy countries such as Japan, Canada, UK and Germany (See Figure 2).

Figure 3: Average relative prices after adjusting for GDP per capita for top-selling, single source brand drugs, biologics and biosimilars. (PhRMA analysis presented in DOH analysis)



Critically, the low pricing inherent in Australia has consequences for patient access as evidenced by the fact that only 24% of globally launched medicines between 2012-2021were subsidised in Australia[6]. Low pricing in Australia incentivises sponsors to prioritise other markets, leaving Australian patients to bear the cost.

Australia's current approach to pricing medicines and assessing their value is not conducive to ensuring timely access to affordable healthcare. To address this, there needs to be a re-evaluation of how medicines are priced and how their value is assessed, with a focus on balancing affordability with access to innovative treatments.

[3] This value has increased by $8,000 since our last submission in 2023 ($227k/LY).

[4] Provided in our Consultation 1 submission, ICERs recommended by the PBAC for four Amgen medicines (evolocumab, romosozumab, blinatumomab, and carfilzomib) provides further context. For this sample, the average valuation placed on 1 QALY is $50,100.33 (range: $25,000 - $72,782). In dollar terms, this is much lower than the VSL year (2023: $235,000) – which demonstrates that by Australian Government standards, the PBAC's valuation of improvements in health outcomes (as quantified by gaining a QALY) is low. Additionally, what these examples highlight is that the PBAC's valuation of health gains is also inconsistent across therapeutic areas, which is arguably inequitable.

[5] PhRMA Analysis of Australia in U.S. International Reference Pricing Policies submitted as part of Amgen's Supplementary Information (82.4) provided to the House of Representatives Inquiry into approval processes for new drugs and novel medical technologies in Australia. https://www.aph.gov.au/Parliamentary_Business/Committees/House/Health_Aged_Care_and_Sport/Newdrugs/Submissions

[6] Table 11 in HTA Policy and Methods Review – Draft paper: Australian market authorisation, funding and assessment pathways and timelines. Published 24 January 2024. Access ed at: https://www.health.gov.au/resources/publications/hta-policy-and-methods-review-draft-paper-australian-market-authorisation-funding-and-assessment-pathways-and-timelines

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There are some proposed reforms in the committee's final report that are disincentives for investment in Australia for health technologies and these do not align with the vision of the National Medicines Policy.

Many of the proposed options provided by the Reference Committee focus on enabling equitable patient access to innovative treatments. However, some of these options demonstrate a lack of understanding of the underlying incentives driving medicines access, particularly Australia's position in the global pharmaceutical industry.

Option 4.1, which outlines approaches to funding or purchasing new health technologies assessed as cost minimisation submissions and requiring an offer of a lower price or incentivising a lower price offer, has the potential to significantly undermine access to medicines in Australia. This goes against the intended outcomes of the reforms.

Despite Australia's already low valuations, several mechanisms are in place to manage prices effectively. These include rigorous Health Technology Assessment (HTA) processes, Risk Share Agreements (RSAs), statutory price reductions, and price disclosure for medicines after competition arises. The option proposed by the Reference Committee would be a serious disincentive for approximately 40% of technologies following the Cost Minimisation Assessment (CMA) pathway.

While the Department of Health (DOH) may view these products as providing no added efficiency or improved safety, this perspective demonstrates a poor understanding and appreciation of the diverse health benefits these products bring, as well as the importance of patient and clinical choice. It is crucial to recognise that these products are not generics or biosimilars, and they are not me-too products.

This recommendation contradicts the fundamental principle of the F1/F2 formulary split, which has delivered substantial savings to the government. It would reintroduce pricing uncertainty into the F1 formulary and could reduce the number of competitors for F2 medicines, diminishing the savings achieved through price disclosure.

These potential consequences highlight the importance of carefully considering and evaluating any changes to the current pricing mechanisms to ensure they do not inadvertently hinder patient access to medicines. Lower prices for innovative products could lead to unwillingness of companies to launch in Australia and result in pushing Australia down in the launch sequence for innovative medicines, leading to delays for Australian patients, and reducing choice for clinician treatment decisions.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing, and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Our belief—and the core of our strategy—is that innovative, highly differentiated medicines that provide large clinical benefits in addressing serious diseases are medicines that will not only help patients, but also help reduce the social and economic burden of disease in society today.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology innovator since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies and has reached millions of patients around the world.