03. Access to New and Innovative Medicines

Medicines Australia

Better health through research and innovation

Access

> Medicines Australia represents the discovery-driven pharmaceutical industry in Australia.

Our member companies invent, discover, develop, manufacture and supply innovative medicines, biotherapeutics and vaccines to the Australian community. These treatments keep Australians out of hospital, prevent disease and play a pivotal role in ensuring a productive and healthy community.

Medicines Australia supports timely and equitable access to innovative, high-quality medicines for all Australians. To support and improve patient access, Medicines Australia has the following priority asks for the Australian Government:

- A multi-stakeholder review of the National Medicines Policy to ensure breakthrough medicines and therapies can be effectively accommodated and choice maintained for Australian patients.
- Commitment to the continued practice and delivery of outcomes of a mutually beneficial Strategic Agreement every 5 years.
- Commitment to list all positive PBAC recommendations of a new medicine within 6 months from agreement on pricing including by improving processes.
- Harmonisation of clinical trial governance across the Federation.
- Commitment to retain the R&D tax incentive in a form that supports clinical trials and removes the requirement for an intensity threshold.

Medicines Australia acknowledges that much of the above has been committed to by the Government and we and our members look forward to actively contributing to these initiatives as they are delivered.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise to provide Australians with Timely Access to Medicines, that meet appropriate standards of Quality, Safety and Efficacy.	Prioritise key measures to expedite regulatory efficiency in the TGA to bring new quality, safe and effective medicines and emerging transformational therapies to the market sooner and deliver on timely access.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise of timely access to medicines at a cost the individual and the community can afford through improved processes for evaluation and subsidisation of innovative medicines and transformational therapies.	Implement appropriate, fit for purpose processes that are reliable, predictable and efficient to enable prompt availability and subsidisation of the new medicines patients need, when they are deemed cost-effective and value for money.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise of Quality Use of Medicines.	Government and Industry continue to partner to ensure the development and provision of accurate and appropriate medicines information and education.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise for a sustainable, responsible, and thriving medicines industry in Australia, which in turn encourages investment and bringing new medicines to Australia.	Government and Industry continue to partner to provide a stable and predictable Medicines policy environment to support access to and investment in new and emerging therapies for Australians.

Key Facts:

The use of medicines is the most common health intervention used to combat illness, disease and promote good health and wellness. Of the more than 148.7 million non-referred general practitioner (GP) attendances that were claimed through Medicare in 2016–17, 127.5 million (86 percent) of these services were bulk-billed.

The Australian Institute of Health and Welfare reports that in 2017-18 there were 148.3 million GP visits. More than 293 million prescriptions were dispensed on the PBS and RPBS (excluding private and below co-pay and dispensing) and 52 percent of GP visits had one or more medications prescribed.[1]

The PBS covers more than 5,000 lifesaving and life-changing medicines products across a broad range of conditions, from asthma and arthritis to diabetes and cancer. The Government's subsidy of PBS medicines reduces their cost by 89 percent on average.

Australia's National Medicines Policy (NMP) has been in place for two decades and aims to promote better health outcomes for all Australians.

It focuses on people's access to, and the safe and wise use of, medicines.[2]
The four central interlinked and co-dependent objectives of the NMP are:

01

Timely access to the medicines that Australians need, at a cost that individuals and the community can afford;

02

Medicines meeting appropriate standards of quality, safety and efficacy;

03

Quality use of medicines (QUM); and

04

Maintaining a responsible and viable medicines industry.

There are two main pieces of legislation that underpin the NMP: the *Therapeutic Goods Act (1989)* and the *National Health Act (1953).* The *Therapeutic Goods Act* ensures medicines *meet appropriate standards of quality, safety and efficacy* for marketing in Australia, through the evaluation and registration of medicines on the Australian Register of Therapeutic Goods (ARTG). The *National Health Act* relates to the provision of benefits and services, including the listing of medicines on the Pharmaceutical Benefits Scheme (PBS). This enables subsidised universal medicines access to patients *at a cost that individuals and the community can afford.*

The innovative medicines industry invents, discovers, researches, develops and manufactures new medicines and partners with government and stakeholders to make these available to patients, in a timely and affordable way, by seeking registration on the ARTG and listing on the PBS. The NMP further reinforces the importance of the industry's role in Australia by outlining that "a locally based industry maximises the opportunities for reliable and cost-effective supply of medicines in Australia."[3]

The NMP provides the key policy framework for a government and industry partnership to deliver quality, safe and effective medicines that Australian patients need, when they need them. Commentators have recently questioned whether the NMP can deliver on the promise held in the four pillars, as medicines policy has incrementally evolved.[4] Whether the NMP is meeting the needs and expectations of more empowered consumers; facilitating access to emerging technological breakthroughs; and encouraging industry investment and growth, have all been queried. Medicines Australia concludes that a review of the NMP is a timely opportunity to address these concerns.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise to provide Australians with Timely Access to Medicines, that meet appropriate standards of Quality, Safety and Efficacy.	Prioritise key measures to expedite regulatory efficiency in the TGA to bring new quality, safe and effective medicines and emerging transformational therapies to the market sooner and deliver on timely access.

Key Facts:

The average time from submission of a regulatory dossier to the TGA to approval and registration on the Australian Register of Therapeutic Goods (ARTG) is eleven (11) months.[5]

Between 2012 and 2017, Australia's average time to reimbursement from registration was 420 days. This is in contrast to the 20 OECD countries average of 331 days.[6]

> **The NMP acknowledges that nationally standardised regulation of medicines should have transparent criteria and processes.**

Furthermore that access processes need to be made as simple and streamlined as possible, so that subsidisation of medicines is timely, mechanisms are understood, and unnecessary administrative barriers and expenses are avoided.

In Australia, there is a systematic evaluation process of the quality, safety and efficacy of medicines, undertaken by the responsible regulatory body the Therapeutic Goods Administration (TGA) to approve and register medicines for marketing in Australia.

For a number of years, Medicines Australia and medicines companies have worked with Government to maximise efficiencies in the processes for TGA evaluation. Medicines Australia strongly supported the recommendations arising from the Review of Medicines and Medical Devices Regulation (the MMDR Review). This has resulted in the introduction of priority and provisional approval processes designed to expedite the registration of new medicines.

Medicines Australia welcomes the Australian Government's continued response to the Medicines and Medical Devices Regulation review. It should see the cost and administrative burdens for industry reduced, while maintaining the standards of evaluation of quality, safety, and efficacy of medicines and medical devices.

According to the TGA Business Plan 2018-19 (updated annually), the TGA will continue to implement regulatory reforms, including those associated with the Government Response to the MMDR Review. The TGA note that better use of the data provided by stakeholders and improved data analytics will shape their approach. Implementation of the Government's response to the MMDR Review began in 2016-17, with changes to legislation and regulation enabling a significant number of reforms to be put in place in 2017-18.

In 2018-19, the TGA wrote that: "we will increase our engagement with patients, consumers and health professionals by strengthening relationship with representative peak bodies."

Medicines Australia supports the TGA's key priorities for 2018-19 that are outlined in its Business Plan and will continue to work with the TGA to implement regulation that protects the health and safety of Australians, whilst minimising unnecessary regulatory barriers. Medicines Australia will work with the Government to continue to monitor the implementation of the measures resulting from the MMDR to ensure they deliver the expected efficiencies, namely:

1. Optimising work sharing activities with overseas regulatory agencies to increase efficiency, including the ability to adopt international decisions from trusted regulators where appropriate; and ensuring Australia upholds public health and safety through sovereign decision making;
2. Assessing and further developing multiple approval pathways including fast-tracked, priority registrations, breakthrough medicines and re-establishing flexibility;
3. Delivering on long-promised information technology capabilities including eCTD, communication portals between the TGA and sponsors, and a robust system of application tracking to ensure optimal operational efficiencies for both government and industry; and
4. Eliminating unnecessary red tape in the registration system related to unnecessary data requirements for pre-submission and unwarranted duplication in Australian specific requirements and duplication in state and territory poisons legislation.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise of timely access to medicines at a cost the individual and the community can afford through improved processes for evaluation and subsidisation of innovative medicines and transformational therapies.	**Implement appropriate, fit for purpose processes that are reliable, predictable and efficient to enable prompt availability and subsidisation of the new medicines' patients need, when they are deemed cost-effective and value for money.**

The Australian Government's commitment to improve registration timelines through the TGA is a welcome step.

Subsidisation is determined by a separate cost effectiveness evaluation undertaken by the independent, statutory, Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC must positively recommend a medicine before it can be added to the PBS. The Government has acknowledged that to fully realise the objective of providing timely and universal access to medicines for Australians, improvements are necessary to improve PBS subsidy timelines. We therefore also welcome the Government's commitment, through our Strategic Agreement, to improve reimbursement processes and times to PBS listing.

The evaluation, recommendation and listing process for subsidy on the PBS can range from six months to several years. The entire process will therefore take many months to years before a proven medicine becomes universally accessible to patients.

Australia's ageing population, and growing burden of chronic diseases reinforces the importance of continued investment in the PBS and quality use of medicines. Research released by the McKell Institute last year showed that early retirement due to ill health poses a significant economic cost - almost 4.5 times government expenditure on the Pharmaceutical Benefits Scheme in 2016–2017.[7] It follows that the ageing population presents significant challenges from a health perspective; early retirement due to ill health places even greater pressure on this inevitable dynamic.

The OECD estimates the number of individuals aged 65 years or older, relative to those of prime working age (20–64 year olds), is projected to increase from 24 percent in 2005 to 52 percent in 2050. Findings show that implementing effective health strategies for those at risk of early retirement due to ill health, including medicines, has the potential to recover $1.9 billion in super and return $3.9 billion to the economy.

Accordingly, quality use of medicines has been shown to be a good investment in health, productivity and economic prosperity. Every medicine recommended for PBS listing has undergone a thorough assessment through the independent, statutory, expert committee, the PBAC. The PBAC independently assesses medicines and only recommends those that are a cost-effective investment of government expenditure.

Medicines Australia's recent report compared how Australian patients fare when compared to 19 other OECD countries with comparable GDP and health expenditure.

Australia ranks 16th out of 20 OECD countries for new medicine market access – an improvement on the previous rank of 17th. Australia lists around 53% of all possible first in class medicines on the PBS – ranking 13th out of the 20 comparable OECD nations.

Australia is about three to four months behind the OECD average time to reimbursement. Our average is longer than the world leading countries such as Japan, Germany, Austria and Switzerland.

The percentage of new medicines reimbursed by the government is lower than the OECD average.[8]

There are several options available to the Australian Government that could help ensure that Australians continue to receive timely access to medicines. Many solutions have already been identified, including those arising from the Senate Community Affairs References Committee inquiry: Availability of new, innovative and specialist cancer drugs in Australia (2015).[9] The Committee examined the key issues facing cancer patients in accessing innovative cancer medicines. The inquiry received over 200 submissions from individuals and groups overwhelmingly in favour of action and reform.

The Australian Government's commitment to improve registration timelines through the TGA is a welcome step.

- enhancing engagement with sponsors and other stakeholders to better tailor their applications to the requirements of the PBAC, including consideration of pre-application planning meetings;
- applying tiered assessment processes as a means of matching resources to the complexity of applications;
- encouraging greater cooperation between the PBAC, the TGA and the Medical Services Advisory Committee (MSAC), including examination of options for enhancing the operation of parallel processing arrangements;
- ensuring greater transparency throughout the assessment process; and
- enhancing and formalising mechanisms for consumers and clinicians to play a more central and substantial role in the evaluation of new medicines and new indications for already listed medicines.

Medicines Australia suggests that to further improve the efficiency of PBS listing processes and times, these recommendations can continue to be progressed through established forums such as the Access to Medicines Working Group (AMWG). Oversighted by the Minister for Health this would deliver tangible improvements and efficiencies in the processes.

The AMWG is an ongoing joint working group of the Department of Health and Medicines Australia.

The AMWG is an ongoing joint working group of the Department of Health and Medicines Australia and is currently co-chaired by the Deputy Secretary of the Department of Health and the Medicines Australia Chair.

The AMWG was established by the Minister for Health to provide strategic oversight of joint activities undertaken by the Department and Medicines Australia to enhance the PBS processes and other matter related to the operation of the PBS, particularly those agreed through the Strategic Agreement 2017.

As the medicines industry invents, discovers and develops medicines, vaccines and biotherapeutics they also develop key materials to assist consumers and medical professionals to fully understand and use these medicines wisely. This information is provided as product information (PI) for health professionals and consumer medicines information (CMI) for patients and carers. These materials are reviewed and approved or overseen by the TGA before being made available and are regularly updated as new information is developed.

Quality Use of Medicines relies on the ability of the patient and the health professional to access accurate and up to date information in a timely and appropriate way and for prescribers, in consultation with their patients to retain choice in the selection of the medicines they need when they need them.

Medicines Australia has partnered with government and other stakeholders to improve the format, readability and usefulness of consumer medicines information to meet contemporary digital standards and increasing needs of consumers. Medication misadventure is still a major concern and accounts for as many as 250,000 hospitalisations per year and at a total estimated cost of $1.4 billion. In addition, as many as 400,000 additional presentations to emergency departments are likely to be due to medication-related problems.[10]

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise of Quality Use of Medicines.	**Government and Industry continue to partner to ensure the development and provision of accurate and appropriate medicines information and education.**

Medicines Australia and the medicines industry play a critical role in ensuring that information is accurate and up to date. It is equally critical that government policies further enhance quality use of medicines and do not inadvertently add to confusion.

Medicines Australia will work with government to ensure that active ingredient prescribing does not deny prescriber and patient choice and does not inadvertently lead to unintended difficulty in accurately selecting the medicines a patient needs, when they need them.

Furthermore, medication safety is enhanced with robust and reliable policies to monitor and track medicines and ensure a robust system of pharmacovigilance. Medicines Australia supports a system that enables pharmacovigilance and improve product identification in the event of adverse events. Medicines Australia will continue to work with the government to ensure Australia's pharmacovigilance follows world's best practice. This includes consideration of regulatory frameworks, such as serialisation, to strengthen supply chain monitoring and product management.

Challenge	Solution
To ensure the National Medicines Policy delivers on its promise for a sustainable, responsible, and thriving medicines industry in Australia, which in turn encourages investment and bringing new medicines to Australia.	Government and Industry continue to partner to provide a stable and predictable Medicines policy environment to support access to and investment in new and emerging therapies for Australians.

The industry acknowledges the ongoing fiscal challenges facing the Government, particularly in the health care system, and has sought to partner with government to address these over recent years. As a result, the PBS policy environment and architecture has undergone significant reform to meet these challenges.

Iterative reforms in 2007, 2010, 2013, 2016 and 2018 have implemented enduring policies that have ensured expenditure on the PBS remains sustainable and that the government receives frequent and anticipated savings, particularly through competition. The most recent reform agreed through the Strategic Agreement signed between Medicines Australia and the Commonwealth Government in 2017, delivering further savings and proposing improved processes for listing new medicines, demonstrates the collaborative partnership envisioned in the National Medicines Policy.[11]

However, these reforms have impacted on the business operating environment for the medicines industry and policy stability is required to ensure a thriving environment for ongoing medicines access.

Expenditure on the PBS is the most cost-effective of all the health system.

Expenditure on the PBS is the most cost-effective of all the health system. Funding decisions are considered by the independent expert body and only clinically and cost-effective treatments are recommended for subsidisation by government. Moreover, ongoing savings are provided through enduring policy mechanisms during the life of a medicine.

Other areas of the health system do not have such scrutiny, nor have they undertaken the significant reform required to provide long term systematic sustainability for the health system.

The key objectives of the National Medicines Policy require the continued existence of a responsible and thriving medicines industry in Australia. To this end, the medicines industry requests;

- Reaffirmation of the commitment to a stable and predictable PBS policy environment to ensure the industry's sustainability and encourage investment.
- Reaffirmation of the longstanding bipartisan commitment to architecture of the PBS.
- Discussion on better considering and measuring the long-term benefits of listing medicines on the PBS; in terms of life years saved, improved productivity and the savings provided outside of the PBS.[12]
- Better coordination between industry policy and health policy to provide a consistent and supportive environment for the industry, and appropriate returns for the research and development, manufacture, and supply of medicines.

A stable policy and business environment encourage manufacturers to undertake long-term innovative medicines research and development in Australia to further enhance prevention, treatment and cure of illness and disease.

1 AIHW Health report 2018: *https://www.aihw.gov.au/getmedia/7c42913d-295f-4bc9-9c24-4e44eff4a04a/aihw-aus-221.pdf.aspx?inline=true*

2 The Australian Government, Department of Health, National Medicines Policy, available at: *www.health.gov.au/nationalmedicinespolicy*

3 3 The Australian Government, Department of Health, National Medicines Policy, available at: *http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029EEAC8CA257BF0001BAF3F/$File/NMP2000.pdf*

4 In 2018, PBAC Chair Professor Andrew Wilson said he maintained a strong backing for a review of the National Medicines Policy. According to Professor Wilson, sector-specific and individual company interest has driven a piecemeal approach to the PBS that has the potential to undermine the wider strategic objectives of the NMP.

5 The Pharmaceutical Benefits Scheme in Australia, February 2018; available at: *https://au.gsk.com/en-au/behind-the-science/how-we-do-business/pulling-back-the-curtain-on-the-pbs/*

6 Medicines Australia, COMPARE 4, available at: *https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/10/MA_Compare-final.pdf*

7 McKell Institute (2018), "Our Health Our Wealth: The Impact of Ill Health on Retirement Savings in Australia" accessed via *https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/09/Our-Health-Our-Wealth-full-report.pdf*

8 Medicines Australia, COMPARE 4, available at: *https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2018/10/MA_Compare-final.pdf*

9 Senate Standing Committee on Community Affairs, Report on Availability of new, innovative and specialist cancer drugs in Australia, September 2015. Available at: *http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/Cancer_Drugs*

10 Pharmaceutical Society of Australia; Medicine Safety, Take Care. Available at; *https://www.psa.org.au/wp-content/uploads/2019/01/PSA-Medicine-Safety-Report.pdf*

11 The Australian Government, Department of Health, Landmark compact with Medicines Australia, *https://www1.health.gov.au/internet/main/publishing.nsf/Content/landmark-compact-Medicines-Aust*

12 Innovative, single brand, medicines are listed on a value-based assessment in the F1 formulary (F1) and commoditised, multi-brand, generic medicines are listed in the F2 formulary (F2). Competition and price disclosure in F2 provide an enduring savings mechanism. Regular staged price reduction policies in F1 provide further anticipated savings. Alongside other savings measures, this provides headroom for listing new medicines.

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