MEDICINES Australia

Issues Brief
1 Access

SUPPORTING BETTER HEALTH OUTCOMES FOR AUSTRALIA

The medicines industry nurtures the talent who research and develop innovative medicines and vaccines.

Such innovation helps keep people out of hospitals, prevents disease and ensures Australia's future as a productive and healthy community.

Our goal is timely and universal access to innovative, high-quality medicines for all Australians.

OBJECTIVES BRIEF 1: ACCESS

Medicines Australia supports the Australian Government's commitments to:

Continue to work with health educators, health practitioners, consumers, the states and territories and the medicines industry to deliver on the aims of the National Medicines Policy.

Support improvements to the assessment processes and timelines for the registration of new medicines.

Make available the new medicines and vaccines Australians need at a cost they can afford through the Pharmaceutical Benefits Scheme (PBS).

Maintain stable and predictable policies for the PBS so that both patients and the medicines industry can effectively plan for the future.

Key fact:

Medicines are the most common health intervention used to combat illness, disease and promote good health and wellness.

Of the more than **137.3 million** General Practice Medicare-claimed visits in 2014–15, medicines were prescribed **86%** of the time.[1]

OVERVIEW

"A locally-based industry maximises the opportunities for reliable and cost-effective supply of medicines in Australia."[3]

Australia's National Medicines Policy (NMP) has been in place for more than a decade 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 Australia's NMP are:

1. Timely access to the medicines that Australians need, at a cost individuals and the community can afford;
2. Medicines meeting appropriate standards of quality, safety and efficacy;
3. Quality use of medicines (QUM); and
4. Maintaining a responsible and viable medicines industry.

There are two main pieces of legislation that underpin the NMP. The **Therapeutic Goods Act (1989)**, which ensures medicines **meet appropriate standards of quality, safety and efficacy** through the evaluation and registration of medicines for marketing in Australia; and the **National Health Act (1953)**, which enables the listing of medicines on the PBS to provide subsidised universal medicines access to patients at **a cost individuals and the community can afford**. See the Glossary and Appendix for more information.

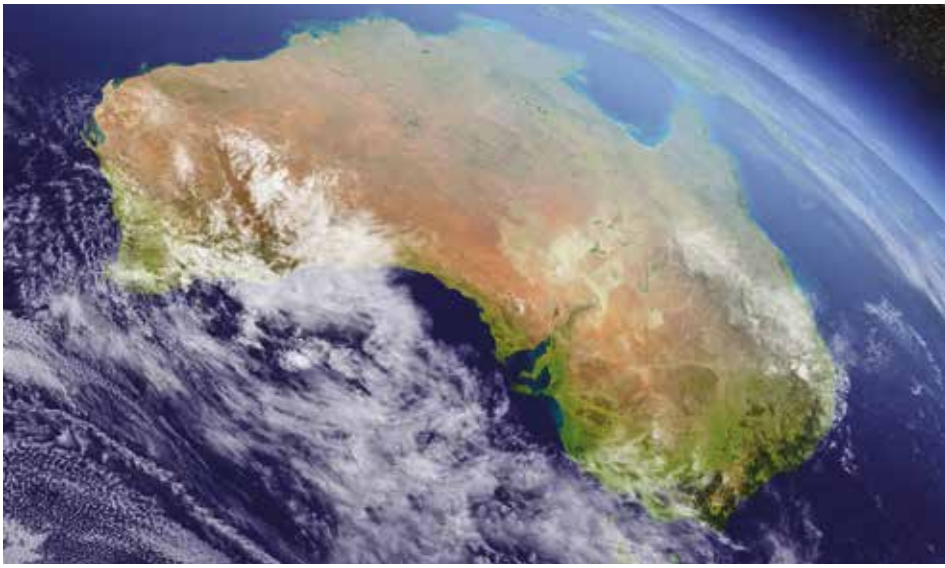
Furthermore, in partnership with the industry, the regulatory framework seeks to support quality use of medicines by ensuring that information on the medicine and its intended use is accurate and up-to-date.

The innovative medicines industry researches, develops and manufactures new medicines and seeks to make these available to patients, in a timely and affordable way, by seeking listing on the PBS so that patients receive subsidised access. The NMP further reinforces the importance of a viable industry in Australia by outlining that "a locally-based industry maximises the opportunities for reliable and cost-effective supply of medicines in Australia."[3]

1. General Practice Activity in Australia 2014-15, Family Medicine Research Centre, University of Sydney, page 37.

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

3. The Australian Government, Department of Health, National Medicines Policy. Available at pg7: http://www.health.gov.au/internet/main/publishing.nsf/Content/B2FFBF72029EEAC8CA257BF0001BAF3F/$File/NMP2000.pdf



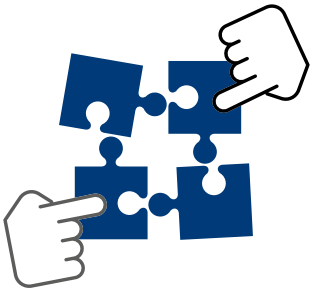
CHALLENGE: EXPEDITING REGULATORY APPROVAL TIMES TO BRING NEW MEDICINES TO THE MARKET SOONER

Key fact:
Assessment for market approval of a medicine or medical device takes a minimum of 12–15 months.

In Australia, there is a systematic evaluation process 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 process and encourage greater collaboration between the TGA and other (international) regulators. Nevertheless, approval, registration and listing times have not measurably improved.

In 2015, the Australian Government commissioned an expert panel, chaired by Emeritus Professor Lloyd Sansom AO and including Mr Will Delaat AM and Professor John Horvath AO, to review Medicines and Medical Devices Regulation (the MMDR review or TGA Review). The panel recognised that even greater efficiencies could be achieved in regulatory approval times, leading to earlier access for patients if the medicine is also subsidised. The two main recommendations from the review panel were:



Greater levels of collaboration between international agencies to help streamline approvals for products already available in other markets, such that assessments conducted by comparable overseas regulators can be adopted with minimal duplication of the assessment process.

Priority 'fast-track' approval mechanisms for certain drugs where there is a high clinical need or lifesaving therapies. Such accelerated approval mechanisms are available through both the EMA (Europe) and the FDA (United States).

The Australian Government responded to the review and committed $20.4 million from the TGA as part of the 2016/17 budget to bring life saving medicines and medical devices onto the Australian market faster, by as much as two years sooner, through streamlining of processes and regulations. Some low risk products will be considered for removal from the regulatory scheme altogether.

TABLE 1: REGULATION OF THERAPEUTIC GOODS – KEY MEASURES TO BE IMPLEMENTED

NEW AGREEMENTS	• New medicines such as cancer drugs will enter the market sooner, through new provisional approvals and making greater use of overseas assessments. ◦ Assessment times will be reduced by up to three months through utilising work carried out by comparable overseas regulators. • New medicines and medical devices will be approved faster in certain circumstances, based on criteria to be developed in consultation with consumers, health professionals and industry.
ALTERNATIVE APPROVAL PATHWAYS	• Sponsors will be able to add medicines and medical devices to the Australian Register of Therapeutic Goods through new approval pathways. The Scheduling Policy Framework will be reviewed in consultation with state and territory governments. • Pre-approval will be introduced under the Special Access Scheme (Category B) for low-risk products such as those that have specific and well-established patterns of use for patients with a non-terminal condition.
STREAMLINED ADVISORY COMMITTEES	• The Government will reduce the number of statutory advisory committees that provide independent expert advice to the TGA from 11 to seven. The new committees will advise on medical, chemical and scientific matters, market approval of new therapeutic goods, and product safety issues. • Appointment of new membership and expert advisors will be made with consideration to requirements for technical expertise and stakeholder representation. Adapted from the Australian Government's Budget 2016/17 Fact Sheet. Source: Improving the regulation of therapeutic goods in Australia, Fact Sheet, Department of Health, May 2016

SOLUTION: PRIORITISE KEY MEASURES TO IMPROVE THE REGULATION OF THERAPEUTIC GOODS

The Australian Government's commitment to improve registration timelines is a welcome first step. However, to fully realise the objective of providing timely and universal access to medicines for Australians, improvements are necessary to improve PBS subsidy timelines.

Medicines Australia has welcomed the Australian Government's 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.

Of the key measures to be implemented by the Australian Government[4] it is recommend the following be prioritised:

- **Optimising work sharing activities with overseas regulatory agencies** to increase efficiency. This includes the ability to adopt international decisions from trusted regulators where appropriate; and ensuring Australia upholds public health and safety through sovereign decision making.
- **Creating multiple approval pathways** including fast-tracked, priority registrations, breakthrough medicines and re-establishing flexibility.
- **Delivering on long-promised information technology capabilities** including the Electronic Common Technical Document (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
- **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.

The Australian Government's commitment to improve registration timelines is a welcome first step. However, to fully realise the objective of providing timely and universal access to medicines for Australians, improvements are also necessary to improve PBS subsidy timelines.

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.

4. Medicines Australia, Submission to the Expert Review of Medicines and Medical Devices Regulation, January 2015. Available at: http://www.medicinesaustralia.com.au/files/2010/02/20150109-sub-medicines-australia-submission-to-medicines-review-FINAL.pdf

CHALLENGE: ENSURING PATIENTS RECEIVE EARLIEST POSSIBLE ACCESS TO NEW AND INNOVATIVE MEDICINES

Key fact:
In Australia, patients wait an average 383 days from registration of a new medicine to reimbursed access.[5]

Despite the declining fatal burden of disease, the burden of chronic diseases and dependence on long-term management of chronic illness is growing due to Australia's ageing population. This reinforces the importance of continued investment in the PBS and quality use of medicines.

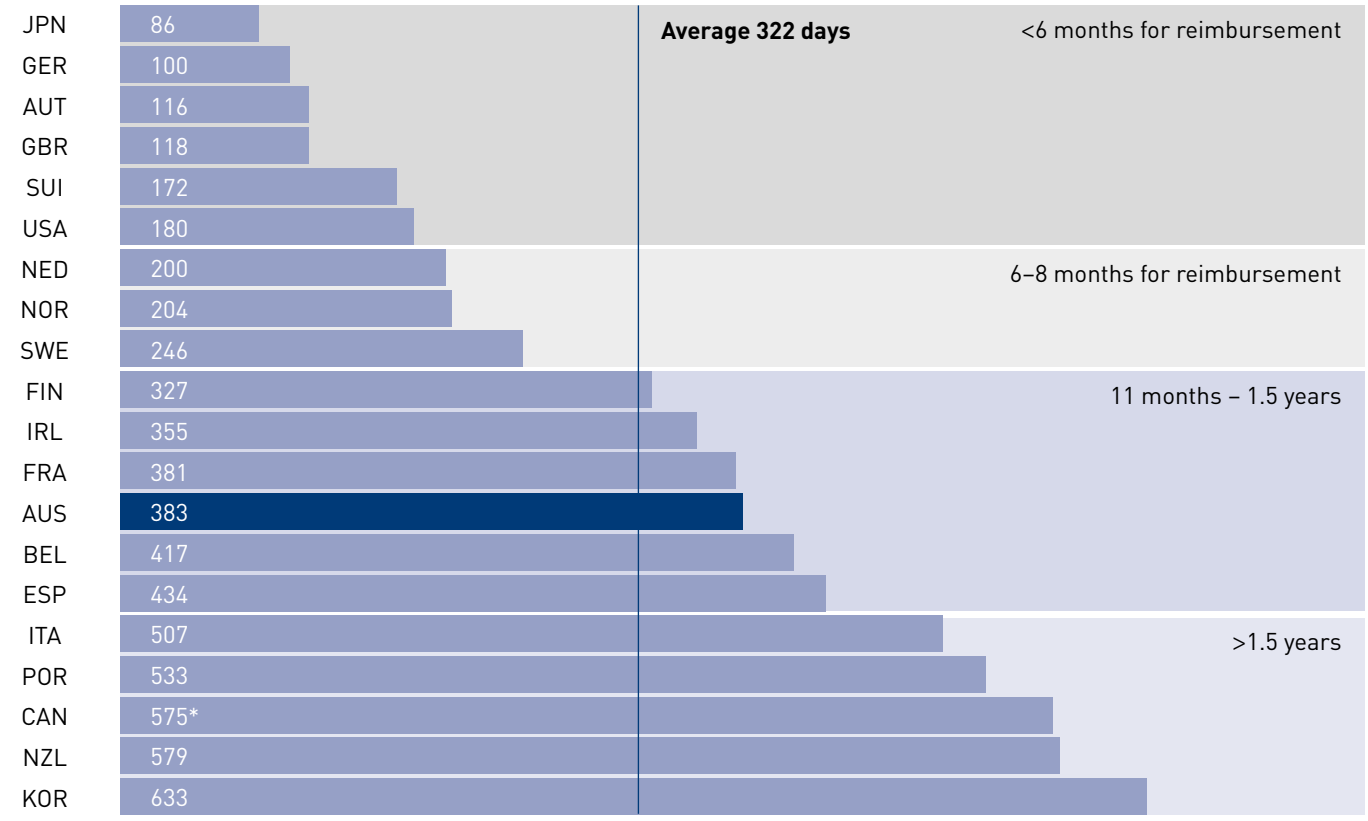
Quality use of medicines has been shown to be a good investment in health. Every medicine recommended for PBS listing has undergone a rigorous Health Technology Assessment (HTA) through an expert committee called the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC independently assesses medicines and will only recommend those that are deemed a cost-effective investment of government expenditure. However, the system is facing significant challenges.

A recent report compared access to medicines for Australian patients to those in comparable OECD countries from 2009–2014. The report found that 39% of the medicines registered in Australia gained reimbursement compared to an average of 54% across the 20 OECD countries.

The report also found that it takes an average 383 days for Australia to list a new medicine on the PBS following registration by the TGA. The average of all OECD countries in the report is 322 days (Figure 1).

5. Medicines Australia, COMPARE Report 2015. Available at: https://medicinesaustralia.com.au/wp-content/uploads/sites/52/2015/03/20150331-pub-Compare_Edition1_March2015-FINAL.pdf

FIGURE 1: COMPARE – AVERAGE TIME FROM REGISTRATION TO REIMBURSEMENT (DAYS) FOR NEW MEDICINES, 2009-2014



* The time to reimbursement for Canada varies greatly depending on methodology applied, as reimbursement is at provincial level. The average of all provinces reimbursed is used for this chart.

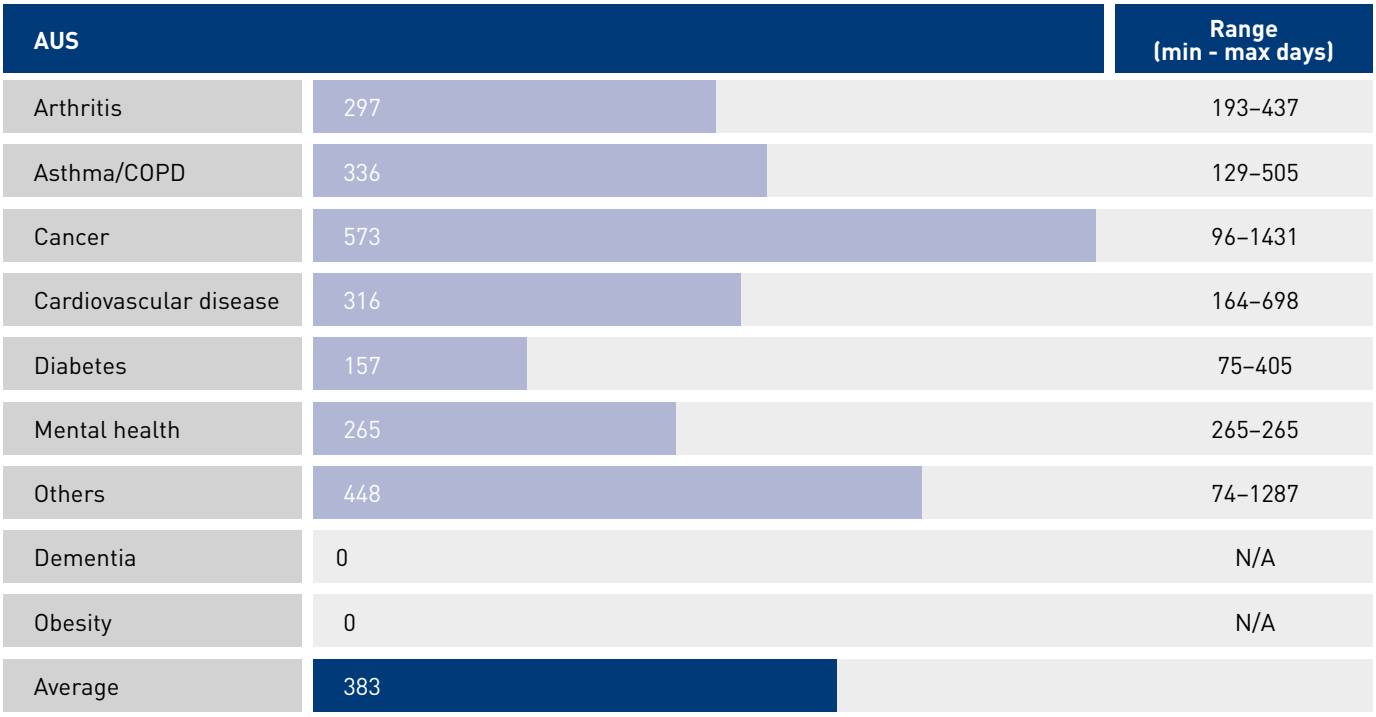
Source: Medicines Australia, COMPARE Report, 2015.

Key fact:

It takes longer for Australian cancer patients to gain subsidised access to innovative medicines than in countries such as the UK, Canada, France and Germany.

For Australian cancer patients, evidence suggests that it takes longer for them to gain subsidised access to cancer medicines compared to their counterparts in the UK, Canada, France and Germany (Figure 2).[5,6] This delay has a detrimental impact on health outcomes for the individual, their carers, and society.

FIGURE 2: AVERAGE TIME FROM REGISTRATION TO REIMBURSEMENT (DAYS) FOR NEW MEDICINES BY NATIONAL HEALTH PRIORITY, 2009-2014



Source: Medicines Australia, COMPARE Report, 2015.

The Government is in the process of implementing reforms to the TGA which should help to improve registration processes and time lines. However, if there is to be noticeable acceleration in PBS access for patients then improvements to PBAC and related approval processes are needed.

To meet this challenge there needs to be a mature debate on whether current HTA processes can keep pace with the significant evolutions in medicines. Therapies are becoming increasingly targeted and even personalised, which makes them more challenging to assess using current HTA methods.

6. Wonder Drug Consulting, February 3, 2014, "Reimbursement success rates and timelines for new medicines for cancer: an international comparison", accessed at: http://medicinesaustralia.com.au/issues-information/oncology-industry-taskforce/

SOLUTION:
MAKE AVAILABLE THE NEW MEDICINES PATIENTS NEED AT A COST THEY CAN AFFORD

Medicines Australia welcomes the commitment by the Australian Government to provide more timely access to medicines, including new treatments for cancer.[8]

There are a number of key 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 cancer patients face in accessing innovative cancer medicines. The inquiry received over 200 submissions from individuals and groups overwhelmingly in favour of action and reform.

TABLE 2: SUMMARY OF KEY RECOMMENDATIONS

- 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, including examination of options for enhancing the operation of parallel-processing arrangements.
- Ensuring greater transparency throughout the assessment process.
- 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.

Adapted from the Senate Community Affairs References Committee – Final Report.

Medicines Australia suggests these recommendations would best be progressed through established forums such as the Access to Medicines Working Group (AMWG) and oversighted by the Minister for Health to demonstrate 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 currently co-chaired by the Deputy Secretary of the Department of Health and the Medicines Australia Chairman. 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.

8. Liberal Party of Australia, Coalition response to Medicines Australia Questionaire, June 2016, unpublished.

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

CHALLENGE: POLICIES TO ENCOURAGE A SUSTAINABLE, RESPONSIBLE AND VIABLE MEDICINES INDUSTRY IN AUSTRALIA

Key fact:
A stable policy and business environment encourages manufacturers to undertake long-term innovative medicines research and development.

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. To meet these challenges, the PBS policy environment and architecture has undergone significant reform.

Iterative reforms implemented in 2007, 2010, 2013 and 2016 will ensure expenditure on the PBS remains sustainable and the Government can receive regular and anticipated savings, particularly through competition. The most recent reform though the **PBS Access and Sustainability Package** will lead to multi-billion dollar savings for Government.[10]

These reforms have impacted on the business operating environment for the medicines industry and a period of policy stability is required to adjust to these changes.

Expenditure on the PBS is the most scrutinised of all the health system. Funding decisions are considered by the independent expert body the PBAC and only clinically effective and cost-effective treatments are recommended for Government subsidy. Moreover, ongoing savings are provided through enduring mechanisms once the medicine goes off patent, as well as other mechanisms to review ongoing cost-effectiveness and utilisation.

Other areas of the health system do not have such scrutiny, nor have they undertaken the significant reform to provide long-term systematic sustainability for the health system. This is an objective fact.

10. The Australian Government, Department of Health, PBS Access and Sustainability Package including the Sixth Community Pharmacy Agreement, June 2016. Available at: http://www.pbs.gov.au/info/general/pbs-access-sustainability-package

SOLUTION: GOVERNMENT AND INDUSTRY TO CONTINUE TO PARTNER TO PROVIDE A STABLE AND PREDICTABLE PBS POLICY ENVIRONMENT

The key objectives of the National Medicines Policy require the continued existence of a responsible and viable medicines industry in Australia. To this end, the medicines industry welcomes:

- Commitment to a stable and predictable PBS policy environment to ensure the industry's viability.
- Reaffirmation of the longstanding bipartisan commitment to the architecture of the PBS broadly speaking with innovative single-brand medicines listed on a value-based assessment in the F1 formulary (F1) and commoditised multi-brand generic medicines in the F2 formulary (F2).
- 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.
- 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 encourages manufacturers to undertake long-term innovative medicines research and development in Australia to further enhance prevention, treatment and cure of illness and disease.

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EXECUTIVE SUMMARY

A COMMON GOAL

Improving health outcomes for Australian patients through access to innovative medicines

KEY CHALLENGES

- Supporting a sustainable, responsible and viable medicines industry in Australia which encourages investment and early access to innovative medicines and vaccines.
- Improving processes for listing innovative medicines on the PBS to ensure patients get subsidised access without unnecessary delay.
- Expediting regulatory approval times to bring new medicines to the market sooner – currently the assessment process takes a minimum 12–15 months, delaying the availability of innovative medicines to Australian patients.

KEY SOLUTIONS

- To accelerate TGA medicines approval times:
  - Optimise work-sharing arrangements with comparable overseas agencies
  - Create multiple approval pathways and eliminate administrative duplication
  - Utilise improved technological capabilities.
- To improve the PBS process consider:
  - Applying tiered assessment processes
  - Improving parallel processing between the TGA, PBAC and the Medical Services Advisory Committee
  - Boosting the roles of industry and consumers on the PBAC
  - Encouraging industry and policy makers to work together to ensure the PBAC Health Technology Assessment (HTA) and other related processes keep pace with the advent of more targeted and personalised medicines.
- Through ongoing Government-industry partnership, create a stable and predictable PBS policy environment to enable the medicines industry to adjust to recent policy reforms.