



01. An Introduction to Medicines Australia



Medicines
Australia

Better health
through research
and innovation

About Medicines Australia

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.

The Australian medicines industry faces an increasingly competitive international investment environment and mounting compliance and regulatory guidelines whilst continuing to invest in the research and development of new and innovative products and ensuring the viability of commercialisation. Despite these challenges, Medicines Australia member companies have continued to grow their investment in Australia.

The Strategic Agreement Provides Business Certainty

The Strategic Agreement between the innovative medicines industry and the Australian Government is the key to ensuring business certainty. When pharmaceutical and medicines companies have clarity on their business environment

they can invest in local manufacturing and research and development. Serving as a predictive financial tool for companies and Government alike, the Strategic Agreement is a source of significant cost savings on the price of breakthrough medicines. A critical aspect to this Agreement is the mutual commitment to a prosperous partnership – working together to ensure all Australians enjoy longer, healthier lives.

The Impact Of Reform

The Pharmaceutical Benefits Scheme (PBS) has been substantially reformed in recent years to create efficiencies and deliver enduring savings mechanisms for the Australian Government. This provides capacity to list new innovative medicines and enables predictable, sustainable expenditure forecasts. Consequently, a sustained period of policy stability and predictability is needed to bolster business confidence in the innovative medicines sector.

Investment In The PBS Is Essential

- Between 2009-10 and 2017-18 PBS expenditure (less rebates) as a proportion of GDP has fallen from 0.74% to 0.58%.
- In addition, in May 2015 the Australian Government announced \$6.6 billion additional savings (\$3.7 billion net) as part of the 6th Community Pharmacy Agreement and PBS Access and Sustainability Package (PASP).
- Growth in PBS expenditure has been flat for at least the last 6 years, and this is well below growth in other health programs. Between 2011-12 and 2017-18 expenditure in the overall health budget per year was 3.5%, 3.6% for medical services, 5.6% for hospitals, but only 1.2% for PBS once rebates are accounted for. In real terms this is annual growth of only 0.5%.

Commitment To Listing Is Critical

Medicines Australia supports the Government's commitment to ensuring that Australians have access to affordable medicines through the listing on the PBS of every drug recommended by the independent experts, the Pharmaceutical Benefits Advisory Committee.

We continue to work with the Government on implementing their Affordable Medicines Guarantee as a critical industry partner. Medicines Australia has acknowledged the fiscal challenges facing Government and seeks to continue partnering with the Australian Government to find solutions to list PBAC recommended medicines in a timely fashion for Australian patients.





| Access

Our goal is timely and universal access to innovative, high-quality medicines for all Australians and our members work closely with Government to overcome barriers to support and improve patient access.



| The Value Of Medicines

Far beyond the health outcomes that our member companies' treatments deliver for individual patients, medicines have a positive impact on the community and the economy. The medicines industry works with the Australian Government to ensure optimal patient outcomes through access to new and emerging medicines and vaccines, and our members contribute to a healthy, productive and diverse economy where innovation, investment and jobs are created.

This depends on timely medicines access through regulatory and reimbursement processes and a stable and predictable business operating environment to encourage investment. Working with the Australian Government on iterative Strategic Agreements should create an environment that delivers health outcomes and generates broader economic value to the Government through health and well-being and through second round effects of improving productivity, increasing GDP, generating government revenue through income tax collection and reducing expenditure on welfare benefits, as well as spillover effects in jobs and knowledge creation.



| Clinical Trials

Investing in Australia's clinical trials ensures a robust workforce, better health outcomes for patients and an increased body of scientific knowledge and medical innovation. Clinical trials provide opportunities for Australian scientists and medical researchers to be at the forefront of solving the major health challenges of our time. Medicines Australia has strongly encouraged successive Australian Governments to implement reforms that will further enhance Australia's attractiveness as an investment destination for clinical trials.



| Intellectual Property

Australia's patent system, administered through IP Australia, aims to encourage research and development that delivers value to the economy and the community. The promotion and protection of IP spurs further economic growth; creates new jobs and industries; and enhances quality of life.

Medicines Australia strongly supports the Australian Government in the implementation of IP measures that enforce these objectives and recommends attention is placed on building commercialisation capability by encouraging investment in, and innovation by, the pharmaceutical industry.



| Introduction To The PBS

Since 1948 the Pharmaceutical Benefits Scheme (PBS) has provided Australian patients with access to affordable and high-quality, safe and effective medicines when they need them. The PBS has evolved from basic access to antibiotics and painkillers, to a sophisticated system that has had to contend with changing burdens of disease and evolving innovations in treatments.

A key purpose of a national, publicly funded, universal healthcare system is to ensure timely availability to the most appropriate innovations in medicines and vaccines. Medicines Australia members bring the latest medicines for consideration by the PBAC and work closely with the Government to ensure medicines are made available to patients as early as possible.



| Transparency

Medicines Australia established the Code of Conduct for its members in 1960 and has continued to revise and develop it ever since. The current Code is Edition 18, with Edition 19 under consideration for introduction in 2020. The Code of Conduct can be found on the Medicines Australia website: <https://medicinesaustralia.com.au/code-of-conduct/code-of-conduct-current-edition/>



| Advocacy

For a medicine to be supplied and subsidised to treat a medical condition in Australia, two key processes, both at a Federal Government level, are required:

- Registration – an evaluation of the efficacy, safety and quality aspects of the medicine in the proposed population (12-18 months).
- Reimbursement - an economic evaluation comparing the new medicine with the most commonly used treatment(s) in Australia for the medical condition focusing on clinical need, health benefits, adverse events and costs. The potential impact on the health budget is also a consideration.



| Investment

Foreign investment is a key driver of economic growth and prosperity in Australia. Recent analysis by PWC shows that Medicines Australia members contributed approximately \$9 billion to the Australian economy in 2016-17, which supported the (direct and indirect) employment of 24,000 Australians.

The strength of the innovative medicines industry depends on the talent of the people within it and their skills and knowledge. Investing in the capabilities of Australia's innovative medicines industry will deliver more jobs and new medicines that can save lives.

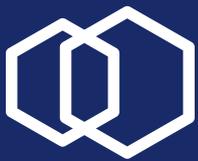
There are exciting opportunities for Australia to grow its share of the pharmaceutical trade, with global demand for medicines forecast to increase at 3-6% compound annual growth rates to 2023. Making the most of this opportunity will help drive economic growth, deliver more high-skill jobs, and provide Australians with improved access to medicines.



| Workforce Development

Australia's future prosperity will rely on science, technology, engineering and mathematics (STEM) – disciplines that are at the core of innovation. STEM qualified employees are the core drivers of innovation and are fundamental for businesses which rely on STEM graduates to remain competitive and their expertise will continue to facilitate and sustain economic growth.

The medicines industry employs around 24,000 Australians, many of which are highly skilled jobs, with above average incomes. Australia's medicines industry is one of Australia's major innovative industries, and consists of research, manufacturing, marketing and sales arms. It is an integral part of our knowledge intensive economy. The jobs the medicines industry creates require a workforce with diverse skills and educational levels.



**Medicines
Australia**

Better health
through research
and innovation

www.medaus.com.au

