



Medicines
Australia

Pre-Budget Submissions

The Treasury

Langton Cres

PARKES ACT 2600

By email: prebudgetsubs@treasury.gov.au

Dear sir/madam

Medicines Australia is pleased to lodge its 2021-22 Pre-Budget Submission with you for consideration.

If you have any questions, please contact me on jsnashall@medaus.com.au or 02 6147 6500.

Yours sincerely

Jamie Snashall

Head of Government Relations

11 February 2021



Medicines
Australia

Better health through
research & innovation

Pre-Budget Submission 2021-22

Introduction

As the peak body representing the innovative, research-based medicines and vaccines industry in Australia, Medicines Australia is pleased to present its 2021-22 Pre-Budget submission. Our members invent, develop, manufacture and supply critical medicines, therapies and vaccines available on the Pharmaceutical Benefits Scheme (PBS), National Immunisation Program (NIP), Life Saving Drugs Program (LSDP) and the National Blood Authority (NBA).

Our members contributed approximately \$9 billion to the Australian economy in 2016-17; they employ (directly and indirectly) around 23 000 Australians; and invest more than \$1 billion in research & development annually to help over 33 000 Australians get early access to emerging therapies. In 2017-18, the industry exported \$1.6 billion worth of medicinal products. None of this, of course, accounts for the additional and largely unquantified benefits to the health and wellbeing of Australian patients and the significant economic spillover effects.

Medicines Australia, working with the Australian Government, wants to ensure that in 2021 and beyond, Australia's healthcare system can continue to deliver lifesaving and life-changing medicines, therapies, and vaccines to Australian patients. Access to newly invented treatments and the viable supply of existing treatments are paramount to the medicines industry. However international moves on reference pricing and the value placed on medicines and vaccines pose a real risk to patient access and the sustainability of the industry in Australia.

Summary of Recommendations for Government

Fully implement the 2020 Budget commitments including:

- > Demonstrated funding through the PBS new medicines funding guarantee.
- > Rapid PBS listing times due to removal of offset policy.
- > Finalise a strategic agreement to commence from 2022-2027.

Fully implement the 2019 election commitments including:

- > Continue its work with States and Territories to harmonise clinical trial governance to ensure Australia is seen as a top investment destination.
- > Conduct the previously promised National Medicines Policy review.

Convene a Ministerial Roundtable with industry in the first half of 2021 to discuss the challenge that international reference pricing poses to Australian patients.

The Current Environment

Throughout the COVID-19 pandemic, Medicines Australia and our members have been focussed on:



The research, development and provision of COVID-19 diagnostics, vaccines, and treatments as part of **domestic and international collaborations**.



The global supply network to ensure **continuous supply** of newly invented and existing treatments to Australians.



The **continuation of Australian clinical trials** to support job creation, medical research and early patient access, noting the reforms still required as per the Federal Government's election commitment in 2019.



Supporting continuity of care by ensuring that Australians, especially those with chronic disease, **continue to access timely healthcare** and have their health monitored.

Medicines Australia welcomed the Government's landmark policy in the 2020 Budget to introduce a guaranteed PBS new medicines funding guarantee, worth at least \$2.8 billion over 4 years, providing access for Australian patients to newly invented medicines, therapies and vaccines while ensuring ability to supply the treatments on which Australians rely. The 2020-21 Budget commitment removed the requirement for cost offsets for new medicines listings on the PBS and the industry is fully committed to helping Government deliver on this promise.

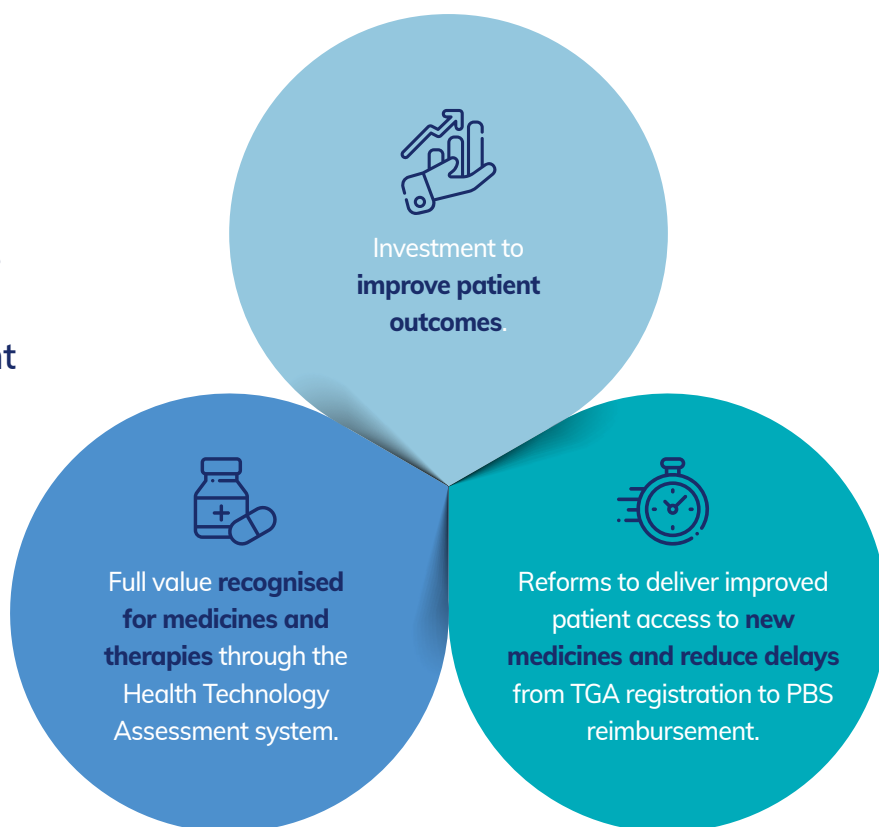
Given the (ongoing) health and economic impact of the COVID-19 pandemic, Medicines Australia is acutely aware that the Budget is in deficit and projected to be so for some time. The pandemic established beyond dispute that Australia's health and economic indicators are inextricably linked and that access to medicines and vaccines is integral to the economic recovery for the nation which places access to healthcare as a central component.

The forthcoming COVID-19 vaccine rollout is one of the biggest public health challenges in Australia in decades and several members of Medicines Australia have negotiated, or are negotiating supply deals with the Government, with the possibility of more to come. COVID vaccines will help Australia's health-led recovery and Medicines Australia continues to highlight the broader benefits of all vaccines, not only to the individual and the community, but also to the economy. Reductions in the burdens of disease, by keeping people in school, work and out of hospital will allow Australians to enjoy longer, healthier lives¹.

1. <https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Med-Aus-Lichtenberg-Report-12pg-Booklet.pdf>;
<https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/Our-Health-Our-Wealth-full-report.pdf>;
https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/20160905-rpt-FINAL-Schofield-OA_productivity-final-report.pdf

Strategic Agreement

Medicines Australia is currently negotiating a Strategic Agreement with the Government focussed on:



We look forward to a satisfactory resolution of these negotiations.

Current House of Representatives Inquiry

Medicines Australia welcomed the inquiry and provided a submission in late 2020². Our submission made 19 recommendations (covering regulatory, reimbursement, research & development, clinical trials, and the role of the consumer) and we urge the consideration and adoption of those recommendations.

2. <https://www.medicinesaustralia.com.au/wp-content/uploads/2020/11/20201103-sub-Medicines-Australia-Submission-to-HOR-Inquiry-into-approval-processes-for-new-drugs-and-novel-medical-technologies-.pdf>

Medicines Australia Recommendations

International Reference Pricing

Medicines Australia requests a Ministerial Roundtable in the first half of 2021 to address and progress the issue of International Reference Pricing and the threat to access to medicines for Australian patients.

Emerging changes in international policies have the potential to threaten patient access to medicines and vaccines in Australia. The new Biden Administration has set out a clear policy interest in reference pricing which will delay or prevent medicines and vaccines being brought to Australia or even stop them entirely. As such, it is imperative that the Government and industry work together to present a united position and create an understanding of the impact that such an approach would have on patients around the world.

Clinical Trials

Medicines Australia requests that the Government:

- > Harmonise clinical trial governance across the Federation (a 2019 election commitment).
- > Develop a national community awareness campaign for clinical trials.
- > Develop a national standard approach to the conduct of clinical tele-trials in rural, remote, and regional areas.
- > Adopt digital technologies to position Australia as a top destination for international clinical trials.

National Medicines Policy Review

Medicines Australia urges the Government to progress its 2019 election commitment to conduct a multi-stakeholder review of the National Medicines Policy to ensure innovative therapies and medicines can be accommodated and choice maintained for Australia patients. The COVID-19 pandemic has seen the review temporarily put on hold, and Medicines Australia supports this position, as there should be sufficient time and resources allocated to a comprehensive and all-encompassing review. Medicines Australia looks forward to the review recommencing in the near future and seeks a commitment that the relevant panel will be adequately equipped to fully understand industry and consumer views.

New Medicines Funding Guarantee

Medicines Australia encourages the Government to deliver its new medicines funding guarantee, as announced in the 2020 Budget. Delivery in full will significantly improve patient access to new medicines and therapies and will be demonstrated by further investment in the PBS.