

Pfizer Australia is one of the nation's leading providers of prescription medicines. We manufacture medicines and vaccines that millions of Australians use every day to live longer, healthier and more productive lives.

Every day our people work with the sole purpose of ensuring that Australians can access new and innovative medicines that are being used to treat some of the most feared conditions of our time. Now, in the grips of a global pandemic, Pfizer is at the forefront of the search for a vaccine or treatment that will address the threat of COVID-19.

Our goal is to be a key contributor to the industry that will develop breakthrough medicines and vaccines to protect humankind from this escalating pandemic, and to work with government to ensure Australia is better prepared for future global health crises.

That is why we wanted to take this opportunity to update our pre-Budget submission.

This Budget, and the Budgets that follow, will attempt to address the immediate deficit created by the pandemic and introduce bold, long-term reform that will reset our economy and set it on the long road to recovery.

The medicines sector can play a pivotal role in this. Every innovative medicine made available in Australia has the potential to generate a significant return on investment – to the patient, the community, the economy and the Government.

We are united in our goal of ending this pandemic, of ensuring Australia's long-term health security and getting people back to work, living healthier, and more productive lives.

Pfizer Australia's pre-Budget submission includes recommendations relevant to COVID-19 and the immediate economic recovery including:

- The critical importance of vaccines to Australia's long-term health security
- Review pricing of low-cost, high-volume medicines to ensure sustainable access
- A comprehensive review and new multi-year investment to reinforce the National Medical Stockpile
- Return skilled migration to previous quotas once COVID-19 allows and invest in bridging programs to address skills shortages
- Make clinical trial harmonisation a priority consideration of National Cabinet in 2021

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia. Pfizer Australia was involved in the preparation of MA's detailed response to this consultation, and we fully support their recommendations to Government.

If we prioritise investment in health, we not only manage the impact of COVID-19 more effectively, but we will also provide a strong foundation for the economic recovery of Australia. The removal of the cost offset policy is an important step that could deliver measured growth to the PBS in the years to come.

## 2020-21 Pre-Budget Submission

### Introduction

In the past nine months Australia has had to contend with the national bushfire crisis and COVID-19, the greatest challenge to the health of our nation in living memory. The combined impact of these issues has reset the focus of our economy, from stability, to survival, and now, recovery.

Pfizer would like to take this opportunity to commend the Federal Government, the Chief Medical Officer, the Department of Health and the National Cabinet not only for the prompt action taken to ensure that essential services continued to be delivered across the nation, most critically the supply of medicines to hospitals, GP clinics, community pharmacies and the patients who need them but also the interventionist Budgetary measures, and the decisive action to brace our economy at this challenging time.

When we look back on the impact of COVID-19 in years to come, it will be a story of great human and economic loss and suffering, but also a story of resilience, of innovation, and of hope. Nowhere is this more evident than across the healthcare sector. The collective effort of frontline health workers to support people in need, the work of our research sector to inform decision-makers on the disease and how it behaves, and the medicines industry coming together to accelerate efforts to find a vaccine - research that would ordinarily take years, but could actually deliver viable options in a fraction of that time - have demonstrated compassion and firm resolve.

This extraordinary effort, in combination with the prompt action from Government, has placed the nation in a sound position, and although the road back will be long, we remain hopeful that the medicines industry will play a critical role in leading the fight against COVID-19 and the reinvigoration of the national economy.

### The critical importance of vaccines to Australia's long-term health security

The health and well-being of our community will form the basis of our economic recovery. Prioritising preventative health measures, such as immunisation, will be key to this recovery. The long-term economic health of the country will require the long-term health of our people and we encourage the government to invest in programs targeting prevention, protection and health promotion even if there are acute needs for investment elsewhere. Pfizer recommends specific attention to adult vaccination, including targets and a plan for achieving those targets, within the National Immunisation Strategy.

There have been reports from The Royal Australian and New Zealand Colleges of General Practitioners<sup>i</sup>, the Australasian College for Emergency Medicine, Cancer Council Australia<sup>ii</sup> and others, that routine attendance for medical appointments has declined during the COVID-19 period. Investment in public health campaigns may be required to keep people actively engaged in both the prevention and treatment they should be receiving.

Prevention is an essential component of an effective health system. Whether targeted at individuals or populations, interventions aim to enhance health status and maintain a state of low risk for diseases, disorders or conditions. That is, to prevent their occurrence through programs of information, immunisation, screening or monitoring.

Yet only a small fraction of health spending is spent on prevention activities. OECD countries allocate less than 3% of health spending on average to public health and prevention activities. Most countries fall within a band of 2-4%, which has remained stable over the long-term.<sup>iii</sup>

Australia sits at just 1.34% according to the report *Preventive health: How much does Australia spend and is it enough?*<sup>iv</sup>. This level of under-investment needs to be redressed to help drive Australia's economic recovery.

## 2020-21 Updated Pre-Budget Submission

Australia has a strong National Immunisation Program providing a broad range of free vaccines from birth through to adulthood. As a result of the NIP, diseases such as rubella, tetanus, diphtheria, Hib and measles are extremely rare in Australia.

Maintaining and expanding our investment in immunisation will ensure broad protection of population health. This should include maximising the uptake of vaccines for which funded access is already established and expanding the community's access to funded vaccines.

While Australia has very high coverage rates for children, the rates are much lower for adolescents and adults.<sup>v</sup> In the current COVID-19 context, maximising uptake for vaccine-preventable respiratory diseases can help to mitigate the annual burden of disease (increased mortality and morbidity and healthcare costs) from flu and pneumococcal disease, particularly in populations at greater risk of infection, such as those who are older and those with chronic diseases.<sup>vi</sup>

The Australian Government's National Immunisation Strategy sets ambitious targets of 95% coverage for our children. There are currently no targets in the Immunisation Strategy for adolescents and adults. Targets for adolescents and adults would be a first step in lifting the lagging coverage rates for these groups.<sup>vii</sup>

In addition, expanding access to funded vaccines through the NIP would further improve the health and wellbeing of Australians. In the current context, expanding access to pneumococcal immunisation could prove important in reducing the overall burden of disease. Pneumococcal immunisation is currently recommended but unfunded for a number of vulnerable groups including adults with chronic respiratory disease such as COPD or severe asthma, chronic cardiac disease, diabetes and cancer undergoing chemotherapy or radiotherapy. These groups are also vulnerable to poorer outcomes from COVID-19, so preventative measures such as immunisation may help minimise the impact of this pandemic.<sup>viii</sup>

We urge investment in health system infrastructure and a greater focus on prevention policy that supports immunisation for all ages, including expanded vaccines budgets, as well as a focus on improving the infrastructure, support and education for adult vaccines.

### Potential COVID Vaccine

*"What is important to understand with any of these vaccines is it does protect you, it does protect your family, but it also protects the community". Prime Minister Scott Morrison (19/8/20)*

It is clear that vaccines are the only long-term solution for ending the COVID-19 pandemic. As part of Pfizer's Five-Point Plan for fighting COVID-19, we are committed to bring our deep heritage in vaccine development, remarkable reach and scale, and capital resources to serve the millions of people around the world impacted by this devastating illness.

The Australian Government will need to commit substantial resources to ensure that any potential vaccine is able to be made available to the Australian public as soon as possible. This will include both the pandemic and post-pandemic phases. A program will also need to incorporate a comprehensive campaign to maximise vaccine uptake rates and develop infrastructure to roll out delivery widely. We acknowledge the Commonwealth Government's COVID-19 Vaccine and Treatment Strategic Approach, noting that the substantive detail has not been made available at this time.

We urge the Government to invest in improving vaccination rates for a wide range of preventable diseases, while developing a strategy for COVID-19 vaccination. Ensuring broad coverage for other vaccine-preventable diseases will be important in minimising the burden on Australians, the health system and the risk to our economy.

## 2020-21 Pre-Budget Submission

### Review pricing of low-cost, high-volume medicines to ensure sustainable access

While reform is required to enable our healthcare system to cater for the growing number of precision medicines coming in the years ahead, there is also a very clear need to ensure that the system is appropriately valuing high volume, low cost medicines. These are often older medicines, which are critical life-saving medicines used in the hospital setting.

The continued supply of these critical medicines has been a key focal point throughout Pfizer's pandemic response. The importance of our portfolio in the hospital setting cannot be underestimated. The TGA recently developed a list of medicines used for Intensive Care patients during COVID-19 which contained 78 medicines. Pfizer supplies 53 of these medicines, and for many we are the sole supplier.

Sustainable access to these medicines is not a new issue. For some time, Simplified Price Disclosure has placed downward pressure on the price of a number of these medicines. Hospital procurement practices have also continued to drive down prices, particularly for older, established medicines.

Manufacturing anti-infective medicines is also a complex process and it can take as long as six to 12 months, or even longer to meet increased market demands. This complexity is exacerbated by the dynamic cost of manufacturing these products. In some circumstances, a supplier may be unable to continue supply or may choose to exit the Australian market for one or more medicines. This places increased pressure on the remaining suppliers, as they work to address the ensuing market shortfall. This is particularly difficult because supply issues typically emerge at very short notice.

A prime example of this was a critical shortage of several important anti-infective medicines such as Vancomycin, Metronidazole and Acyclovir in November 2016. Shortages of this magnitude can have a ripple effect through the supply chain and can, in turn, lead to protocol changes to more novel antibiotics as their supply is more consistent. This increases the risk of anti-microbial resistance within these hospitals and, depending on the significance of the market shortage, can lead to an increased risk to patients across the country.<sup>ix</sup>

Pfizer has first-hand experience of this through our anti-infectives portfolio of medicines, but the issue also affects critical oncology and mental health medicines. In considering reform to the PBS for innovative medicines, Pfizer proposes that there also needs to be urgent consideration of how these medicines are priced on the PBS to recognise these complexities and ensure sustainable supply.

### A comprehensive review and a new multi-year investment to reinforce the National Medical Stockpile:

In assessing Australia's response to the pandemic there has been an increased focus on the National Medicine Stockpile, specifically what is kept in stock at these facilities and how it is distributed to areas of need. Much of this focus has been on stockpiles of respirators, masks and personal protective equipment given the critical need for this equipment across the country. However, there has been little focus on the medicine and vaccines reserves in the Stockpile and the demand for access to these reserves.

The 2017-18 Federal Budget included an investment of \$85 million (over three years). This was the first multi-year commitment to reinforcing the National Medical Stockpile. As this funding commitment is set to expire, and with Australia and the world responding to COVID-19, it is an ideal time to review the Stockpile and whether it is fit for purpose now, and in the future.<sup>x</sup>

## 2020-21 Updated Pre-Budget Submission

Pfizer is the largest hospital supplier of sterile injectable products in the country, and a major supplier of Pharmaceutical Benefits Scheme, National Immunisation Program and National Blood Authority listed products. A key focus of our efforts during COVID-19 has been to maintain a strong and sustainable supply of crucial medicines, vaccines, blood products and other medical therapies via our global supply chain. Shortages or failure to supply some of these critical medicines during this period could have had a catastrophic impact on the healthcare system.

During the early stages of COVID-19 it was clear that we were seeing an extraordinary increase in demand for certain products across our portfolio, in some cases demand for therapies increased six-fold as some purchasers were racing to secure stock. A collaborative effort among industry, the Medicines Shortages Working Group, and state hospital purchasers successfully prevented stockpiling behaviour and led to the temporary suspension of hospital tendering processes which, along with other initiatives, served to maintain the consistent supply of globally sourced medicines for Australians.

The situation could have been much worse. What COVID-19 has laid bare is that Australia's island geography can serve as an advantage by using our borders to quarantine infected arrivals and protect the local population. But it also presents a significant threat with intense pressure on supply chains into and out of the country in times of crisis.

Knowing what we know now, it is not unreasonable to expect that a future pandemic or global crisis could require a tightening of international trade by certain countries which could, in turn, block or restrict the supply of medicines to our shores. Australia has a highly skilled and capable medicines manufacturing sector, but we cannot expect to rely on domestic supply to meet a potential shortfall across the many medicines that are integral to healthcare today. The highly specialised nature of medicines manufacturing means the capability and capacity does not exist and cannot be created overnight.

This Budget must include another multi-year commitment to review, replenish and strengthen the National Medical Stockpile to ensure it is fit for purpose and capable of responding to a future pandemic or biosecurity threat. Otherwise there is an ongoing risk that the next global threat will see Australia having to compete for scarce resources at a critical time, paying a premium to secure medicines and PPE and/or being unable to meet Australia's needs.

### **Return skilled migration to previous quotas and invest in bridging programs to address skills shortages**

The Government's renewed focus on skills policy is an important component of the post-COVID-19 economic recovery. With unemployment expected to hit record levels in the months ahead there will undoubtedly be a focus on pathways for local jobs for the thousands of Australians who have been directly impacted by COVID-19.

Pfizer Australia supports these efforts and is enthusiastic to work with governments to provide an industry perspective on current gaps in graduate job readiness. Significant gaps remain in local capability of essential roles in our highly technical manufacturing facilities. These roles rely on temporary skilled migration to plug those gaps and to train up local colleagues to improve local capability.

In recent years Pfizer has been partnering with a number of groups to establish bridging programs, like the Medicines Manufacturing Innovation Centre at Monash University, to narrow the gap between emerging graduates and these roles. These programs have shown potential, and a stronger role for industry in curriculum development will help to prepare graduates with the necessary skills to immediately become productive contributors to the economy after exiting the classroom. This program has included the successful reskilling of former automotive manufacturing workers to become highly skilled medicines manufacturing colleagues.<sup>xi</sup>

## 2020-21 Pre-Budget Submission

Skilled migration will always have an important role to play in advanced manufacturing, with some highly technical skills in very short supply in Australia. As the Government examines the workforce and any potential policy change to skilled migration, we would strongly advocate that industry representatives are involved in the determination of certain roles that remain open to skilled workers.

The importation of those skills on temporary migration visas is fundamental to training up local capabilities towards a more self-sufficient local skills base. When COVID-19 allows, it is crucial for skilled migration opportunities to return so as to facilitate the quickest local economic recovery. Pfizer would be happy to provide more information on how skilled workers are currently adding value across our supply chain in Australia if required.

### Make clinical trial harmonisation a priority consideration of National Cabinet in 2021

During his address to the Committee for Economic Development in Australia in June this year, Minister Hunt announced that he will be asking the National Cabinet to expedite the move towards “a one stop shop” for ethics approval of clinical trials in Australia. This is in response to the reality that clinical trials for modern medicines often target small patient populations that exist over state boundaries. The investment in these trials can be deterred by differing state approvals processes and unnecessary red tape.

Pfizer has long supported Medicines Australia’s advocacy on this issue and this reform is critically important. COVID-19 has had a significant impact on local clinical trials and the life sciences sector. A large number of non-critical clinical trials – up to 90% of clinical trials run by the medicines industry - were put on hold as a result of COVID-19.<sup>xii</sup>

Clinical trials provide an early access option to novel, innovative medicines for Australian patients, and studies with local data provide a unique insight into the longer-term potential of these medicines to improve patient outcomes. There are also economic benefits to a robust clinical trial network. Australia invested \$1.1 billion in gross expenditure on ongoing trials in 2015, which included \$930 million from industry sponsors with the exciting potential to surpass \$2 billion in the next 10 years. This investment helped support 6,900 jobs with a potential for up to 6,000 new highly skilled jobs to be created by 2025.<sup>xiii</sup>

Recently, the CSIRO stated that ‘without a thriving science and technology sector, Australia will not generate the innovation that spurs economic growth’. Pfizer wholly supports Minister Hunt and the National Cabinet prioritising this discussion in 2021 as it is important reform that will help reinvigorate clinical trials activity and protect jobs in the sector in the short-term and make Australia an attractive destination for this research activity in the future.

### Support for Medicines Australia Budget Submission: Removal of the cost-offset policy as an essential step to enable future growth to the PBS

Prior to the bushfire crisis and COVID-19, there were pressing issues with the reimbursement of medicines that remain a priority for resolution. The health technology assessment and PBS reimbursement system are at pinch points. We are on the cusp of a new range of therapies that will require new thinking and adaptability to ensure that they are valued appropriately for manufacturers and Government.

Most importantly, we must ensure these medicines are available to the patients who need them, in a timely manner. Consumers are becoming more informed and empowered to take control of their own health; their demand for access to the latest interventions will only increase in the years ahead.

## 2020-21 Updated Pre-Budget Submission

Medicines Australia's analysis indicates that the current PBS structure will struggle to meet the ongoing needs and expectations of the Australian community. This is exacerbated as the investment in net PBS expenditure, as a proportion of GDP, continues to decrease into the forward estimates, while pressure on the PBS increases with emerging breakthrough medicines, and a growing and ageing population.<sup>xiv</sup>

Pfizer is aligned with Medicines Australia that an important step should be removing the cost-offset policy which will allow the medicines sector to invest with confidence in the treatments of tomorrow and ensure we can bring our patients the best medicines of today.

A large number of today's innovative medicines are targeted and personalised to treat highly complex conditions, such as cancer and rare diseases. Specialty medicines can provide great value in some of the hardest-to-treat diseases and may offer a more targeted treatment, meaning they may be more effective or better tolerated than other available options. They are developed under the strictest clinical guidelines and this research and development presents significant risk and cost to the manufacturer.

Government and other payers around the world are currently grappling with the challenge of assessing the value of these medicines. Innovation in precision medicine promises substantial benefits and it will change the way in which some health services are delivered and evaluated. As biomarker discovery accelerates and artificial intelligence-based technologies emerge, refinements to the methods and processes of evidence assessments will help to adapt and maintain the objective of investing in healthcare that provides value for money.<sup>xv</sup>

In Australia this is no different. Increasingly, manufacturers are facing challenges and uncertainty in the listing of new medicines on the PBS. These challenges are compounded by an "offset" policy that requires every new dollar spent on new medicines to be counterbalanced by an equivalent offset, determined in advance, from within the existing health budget.

There is no question that the implementation of a cost-offset policy is delivering savings across the PBS. It is, however, evident that we are approaching a point where the continued downward pressure on pricing, combined with the need to continually find space within the existing budget for new listings, will limit timely access to medicines for the patients that need them.

Looking ahead, we must have the right systems in place to deliver the best healthcare outcomes in this rapidly changing environment. Removal of the requirement to fund new medicines via cost-offsets is an important step in this regard and will deliver growth to the PBS budget through the listing of new medicines, the value of which will still be appropriately evaluated by the PBAC.

### Conclusion

We are at a critical juncture for the future of the medicines industry in Australia. The collaboration and cooperation between industry and Government to arrest the impact of COVID-19 demonstrates a shared commitment to deliver the latest medicines and vaccines to Australian patients at an affordable price and to take the necessary steps to get our nation back on its feet.

Despite the obvious threat COVID-19 poses to this goal there are challenges that cannot be ignored. The current cost-offset policy risks constraining the future of the PBS and making it increasingly difficult for manufacturers to bring forward new and innovative medicines. Increased costs of manufacturing and supply are also impacting the supply of medicines to patients and the pricing of these medicines needs to be assessed to ensure sustainable access.

# Pfizer Australia

## 2020-21 Pre-Budget Submission



Consideration must also be given to how we protect our nation's health in the future and ensure we are ready to rapidly respond to the next pandemic or threat to our nation. The long-term health security of the nation is paramount. Vaccines can play a critical role in this regard; we also need to take steps to ensure we are prepared for the next global threat.

Pfizer and the medicines industry can provide valuable insight to Government on ways this could be addressed in the short-term and we would welcome further discussion on any of the issues outlined in this submission.

Australia's healthcare system delivers world leading outcomes and does many things well. Common-sense reform can address some of the current obstacles to affordable access and lay a foundation that can help deliver economic growth that can set Australia on the path to recovery.

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<sup>i</sup> See RACGP Media Release, 3 August 2020: <https://www.racgp.org.au/gp-news/media-releases/2020-media-releases/july-2020/fears-for-culturally-and-linguistically-diverse-pa>

<sup>ii</sup> See ABC News report available at: <https://www.abc.net.au/news/2020-05-14/coronavirus-medical-testing-delays-could-lead-to-future-sickness/12241812>

<sup>iii</sup> Gmeinder, M., Morgan, D. and Mueller, M. (2017). How much do OECD countries spend on prevention? OECD Working Papers, No. 101. Available at: <https://www.snop.it/attachments/article/775/OECD%20%20spese%20prevenzione.pdf>

<sup>iv</sup> Jackson H, Shiell A. (2017) Preventive health: How much does Australia spend and is it enough? Canberra: Foundation for Alcohol Research and Education.

<sup>v</sup> Menzies R et al. (2017). Vaccine myopia: adult vaccination also needs attention. *Med J Aust* 2017; 206 (6): 238-239.

<sup>vi</sup> Preaud E et al. (2014). Annual public health and economic benefits of seasonal influenza vaccination: a European estimate. *BMC Public Health*, 14(813).

<sup>vii</sup> The Australian Government's National Immunisation Strategy states that for the population aged ≥65 years, 74.6% were vaccinated against seasonal influenza and 54.4% against pneumococcal disease.

<sup>viii</sup> Sanyaolu A, Okorie C, Marinkovic A, et al. Comorbidity and its Impact on Patients with COVID-19 [published online ahead of print, 2020 Jun 25]. *SN Compr Clin Med*. 2020;1-8. doi:10.1007/s42399-020-00363-4

<sup>ix</sup> <https://www.theage.com.au/healthcare/patients-will-die-if-they-dont-fix-this-hospitals-rationing-stockpiling-firstline-antibiotics-amid-drug-shortage-20161209-gt7wyd.html>

<sup>x</sup> [https://www.anao.gov.au/sites/g/files/net4981f/AuditReport\\_2013-2014\\_53.pdf](https://www.anao.gov.au/sites/g/files/net4981f/AuditReport_2013-2014_53.pdf)

<sup>xi</sup> <https://lens.monash.edu/2018/07/27/1355955/out-of-the-car-and-into-the-pharmacy>

<sup>xii</sup> MTPConnect COVID-19 Impact Report - The Impact of COVID-19 on the Australian Medical Technology, Biotechnology & Pharmaceutical Sector, June 2020

<sup>xiii</sup> <https://www.mtpconnect.org.au/clinicaltrials>

<sup>xiv</sup> See Medicines Australia's 2020-21 Pre-Budget Submission

<sup>xv</sup> The Future of Precision Medicine: Potential Impacts for Health Technology Assessment (December 2018) - Love-Koh, Peel et al. *PharmacoEconomics*, Volume 36, Issue 12, pp 1439–1451.