2022-23 Pre-Budget Submission

The return of freedoms for many Australians is a dramatic shift in our approach to COVID-19 and it is largely due to months of ground-breaking, innovative work across the healthcare sector.

We are a vaccinated nation, and this has been made possible through unparalleled collaboration and timely, common-sense decision making. What seemed a moon-shot 18 months ago has now become a reality. Pfizer recently surpassed two billion doses of our vaccine shipped to more than 150 countries worldwide. Results like this demonstrate the value of science, of innovation and the capacity of collective partners to quickly respond in a time of crisis.

Each and every Pfizer colleague is immensely proud of the role we have played in delivering a safe and effective COVID vaccine and additional booster doses that are helping to protect Australians and their loved ones at this pressing time. Now we have also been able to deliver one of Australia's first oral medications that will protect the most vulnerable Australians against serious COVID symptoms.

The Federal Government deserves credit for recognising the need to have fast and efficient approval process that made vaccines, diagnostics and treatments available to the community as quickly as possible.

Australia's national vaccine rollout has set the groundwork for Australia's economic recovery and all indications are that the economy will bounce back strongly in 2022. However, the healthcare sector is under immense strain, with staff shortages and disrupted supply chains impacting services. It is fair to say that Australians want to move forward, but they want to do so with confidence that a return to a normal life can be done safely. On the policy front this requires economic and health policy to be in lockstep.

This Budget and the upcoming Federal election will focus on how Australia can chart a course out of the pandemic to ensure we are better prepared for the next global threat, and importantly, that we can embed the innovation, the ingenuity, and collaboration that helped shelter Australia from the full weight of COVID-19.

Investing in Australia's health security will be paramount. This will involve, stimulating the life sciences sector, reinforcing supply chains, and ensuring the global movement of goods. Countries around the world are rebuilding their health infrastructure and Australia should be no different.

It is equally important to ensure the long-term health of Australians. The medicines sector plays 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.

The year ahead presents an opportunity for pragmatic reform that can address some of the current obstacles to affordable access and lay the foundation for the 'world's best healthcare system'.

Reform that will deliver timely access to medicines and vaccines

Since its inception in 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. It has been a staple of the National Medicines Policy that has established a strong working relationship between the Federal Government and the medicines industry and delivered world class health outcomes for Australians.

2022 Pre-Budget Submission

Prior to the 2019 Federal election there was bipartisan support for a review of the National Medicines Policy. There had been a growing push to review the overarching policy for some time. The policy is more than 20 years old and the review was recognition that the way medicines are developed and delivered today, is vastly different to twenty years ago. This review is now underway, and Pfizer along with many stakeholders has made a detailed submission calling for this policy to be modernised, for it to be adaptive and to be focused on accommodating the next generation of medicines.

The same attention must be given to the approval process for medicines and vaccines. The PBS has proved a robust model for the consideration of health interventions, and it has delivered great value to Government. However, in Pfizer's experience, Australia's reimbursement system is not keeping pace. The emergence of innovative, targeted therapies has tested the limits of our health technology assessment process and created tension between payers, industry, clinicians and patients.

At the heart of these issues is a lack of transparency, a lack of flexibility and consistency in decision making and no clear measurable targets that demonstrate faster access to new medicines for patients. Pfizer would like to commend the Department of Health for recent reforms to address these issues, but we need to do more to ensure Australian patients do not fall behind the rest of the world. Attempts to address this have led to increasing layers of red tape. The result is a system that is increasingly complex, rigid and costly.

The volume of submissions made to the recent parliamentary inquiry into the approval process for novel medicines and medical technologies reinforces this. The written and verbal testimony of patient groups, clinicians and voices from across the medicines value chain is the clearest indication yet that our system is failing patients.

The collective response to the pandemic and the decisions made to expedite approval of COVID vaccines, diagnostics and treatments demonstrates where there is a pressing need, there are solutions that can be found to improve access to medicines. We must keep moving forward and the question we must now ask is this: How do we harness this cutting-edge science and collaboration and apply this agility and innovation to address some of the most pressing health issues of our time - cancer, obesity, dementia and rare disease?

Pfizer is a proud member of Medicines Australia which recently signed a new five-year Strategic Agreement with the Commonwealth to begin on 1 July 2022. Outlined in the agreement is an ambitious reform agenda that will strengthen the role of patients in Australia's HTA process and prepare Australia's HTA system for the next generation of treatments. Pfizer supports Medicines Australia's Pre-Budget submission which calls for the Government to set a specific target to demonstrate improved time to access of new medicines for patients, in agreement with Medicines Australia and that the appropriate departmental resources be committed to the reform process stipulated in the Strategic Agreement. It would be a huge, missed opportunity if at the end of this Strategic Agreement in 2027 we are citing the same inertia with the PBS and that this reform process didn't deliver meaningful change for Australian patients.

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

> *"Currently, our health system is fundamentally focused on the treatment of illness and disease. During COVID-19, the profile of public health and prevention has been significantly elevated. Data from around the world and in Australia has demonstrated that individuals with preventable chronic conditions and vulnerabilities such as cardiovascular disease, smoking, and obesity, were at greater risk of adverse outcomes associated with COVID-19. This was a wakeup call to health systems worldwide, as it demonstrated that significantly more needs to be done outside of a pandemic to keep people healthy and well. We need to rebalance the health system; we need to invest more in prevention."* [i] National Preventive Health Strategy (2021).

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. On average, OECD countries allocate less than 3% of health spending on public health and prevention activities. Most countries fall within a band of 2% - 4%, which has remained stable over the long-term.[ii] Australia sits at just 1.34% which equates to approximately $89 per person. In fact, of the 31 OECD countries reporting spending on prevention in 2013, Australia ranked 16th in terms of per capita spending. Pfizer notes that the National Preventive Health Strategy includes a goal to increase this investment to 5% of total health expenditure across Commonwealth, state and territory governments by 2030.[iii] This is promising, however this level of under-investment must be redressed sooner than that to help drive Australia's economic recovery.[iv]

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 expanding the community's access to funded vaccines and maximising the uptake of vaccines for which funded access is already established.

While Australia has very high coverage rates for children, the rates are much lower for adolescents and adults. 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 influenza and pneumococcal disease, particularly in populations at greater risk of infection, such as those who are older and those with chronic diseases.[v] In 2020, Australia reached its target of 95% immunisation of five-year-olds for the first time ever. Targets for adolescents and adults would be a first step in lifting the lagging coverage rates for these groups. [vi] Pfizer notes that last year's Budget papers identify this need [vii] and the National Preventive Health Strategy also highlights the importance of establishing a benchmark and targets for adults at increased risk of vaccine preventable diseases due to age or underlying medical conditions and working towards meeting those targets.[viii] Establishing these targets in 2022 will set a benchmark to work towards to address this issue in coming years.

COVID-19 has highlighted the important role of community pharmacy in providing access to vaccines. This is particularly relevant in regional and rural areas where access to a GP can be difficult. Excluding COVID-19, Queensland currently offers nine separate vaccines through community pharmacy, compared to four in Victoria and Western Australia, and three in all the other states and territories. A harmonised national approach that adopts the best practice of vaccine access will help to deliver the above preventive benefits and improve patient equity across Australia.

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 several 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 the pandemic as COVID continues to evolve.[ix]

Trial of a novel reimbursement model to address the threat of AMR

The World Health Organisation has said that the global pipeline of antimicrobials is insufficient to tackle the increasing challenge of antimicrobial resistance (AMR).[x] New antimicrobials are faced with very challenging access dynamics. In order to preserve their effectiveness for as long as possible, use is restricted through the important process of antimicrobial stewardship, hence volumes are low. They are also undervalued by traditional HTA techniques as it is difficult to economically evaluate the importance of holding new antimicrobials in reserve as well as the overall value of having a wide range of antimicrobials available to protect against outbreaks of resistant bacteria.

The threat of AMR on the future of our healthcare system cannot be underestimated. Last year, CSIRO Biosecurity Research Director Dr Paul de Barro stated "I don't think I'm exaggerating to say it's the biggest human health threat, bar none. COVID is not anywhere near the potential impact of AMR." [xi]

2022 Pre-Budget Submission

A recently released study on the burden of AMR attributed 1.27 million deaths globally to bacterial AMR[xii] and this figure is expected to worsen. AMR is on track to claim 10 million lives per year globally and put at risk a cumulative US$100 trillion of economic output if no action is taken by 2050.[xiii] In Australia, the estimated annual impact of AMR on the economy by 2050 will be between A$142 billion and A$283 billion. [xiv] Australia is also vulnerable to novel antimicrobial shortages due to geographic isolation and the high costs and difficult logistics in international drug supply chains.

New antimicrobials are urgently needed to treat drug-resistant infections and the growing threat of AMR, however current regulatory and reimbursement policies deter investment in antimicrobial research. A novel policy response is required to encourage investment in this important research, to ensure the antibiotic pipeline is refilled to prevent the predicted AMR crisis.

Many countries are investigating how to assess the value of novel antimicrobials to include the broader value they bring to society. In the UK, the Government has partnered with industry to pilot a model of reimbursement that will de-link the revenue of an antimicrobial from the volume sold, and base it instead on the antimicrobial's value to the NHS and wider public health. This means companies will be paid for antimicrobials based on how valuable they are rather than by the quantity being used or sold. This pilot will also help to reduce the financial uncertainty in antimicrobial research and elevate incentives to develop novel anti-biotics. Other countries including the US and Sweden are also progressing new models for the way they assess this class of medicine.

Pfizer is a member of the Australian Anti-Microbial Resistance Network (AAMRNet) and we fully support their Pre-Budget submission which includes a proposal for AAMRNet to work with the Department of Health in identifying an appropriate economic model to introduce novel antimicrobials that suits the Australian context.

Make clinical trial harmonisation a priority consideration in 2022

COVID-19 has shone an extremely bright spotlight on the critical importance of life sciences research, and the commercialisation of life sciences innovations, as mechanisms for effective pandemic response.

Australia is known globally to have high quality research skills and capabilities. Our early-stage clinical discovery work is world-class and the quality and professionalism of our investigators and institutions make us a desirable destination for clinical trial activity. Many countries compete for clinical trial investment as it provides an early access option to novel, innovative medicines for 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. More than $1.1 billion was invested in gross expenditure into Australian clinical 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. [xv]

Despite the value of clinical trials, Australia operates a fractured system of ethics approvals and clinical trial governance utilising different approval processes and software systems across different states and territories. This presents a considerable obstacle to foreign investment as many clinical trials need to attract patients from multiple jurisdictions. If Australia is to remain competitive on this global stage, we need to continue to advance the environmental conditions for clinical trials.

The Department of Prime Minister and Cabinet recently released their 10 priorities for the Government's deregulation agenda. The workplan includes Clinical Trial reform and proposes a 'single front door option' be developed by end of March 2022. We are encouraged by the inclusion of clinical trial reform in this process and appreciate the leadership shown by the Commonwealth in attempting to unify the states and territories to operate clinical trials within a single administrative framework. This is an important reform that cannot be delayed any further as it 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.

2022-23 Pre-Budget Submission

Pfizer's operations in Australia

Pfizer Australia is one of the nation's leading providers of prescription medicines and vaccines. 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. 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.

Pfizer is proud to be part of an industry that helps prevent, treat, cure, and eradicate life-threatening diseases. We play an active role across the Australian healthcare spectrum working with patient organisations and government for the benefit of each patient. Our workforce of more than 1,300 colleagues are based at two commercial and two manufacturing sites across the country and we support thousands of additional jobs across the medicines value chain.

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. As part of the immediate pandemic response the TGA developed a list of medicines used for Intensive Care patients which contained 78 medicines. Pfizer supplies 53 of these medicines, and for many we are the sole supplier.

Pfizer's supply chain is one of the most sophisticated supply chain systems in the industry, it is a global operation with more than 40 sites and over 200 suppliers round the world. In Australia we have two manufacturing locations, Perth, and Mulgrave which manufacture medicines for use domestically and around the world. These facilities export to more than 60 countries worldwide.

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