Pfizer Australia

2021-22 Pre-Budget Submission

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.

Our goal is to be a key contributor to the industry that will develop breakthrough medicines and vaccines to protect humankind from the escalating COVID-19 pandemic, and to work with government to ensure Australia is better prepared for future global health crises.

Pfizer has a proud history in Australia. We commenced operations here in 1956 with just six colleagues, and more than 60 years later, we now have more than 1,500 colleagues working at two commercial sites and three manufacturing facilities across the country.

Each and every one of these colleagues is incredibly proud that Pfizer has been able to develop a safe and effective COVID-19 vaccine in record time. The announcement from the Prime Minister on 25 January 2021 means the Pfizer/BioNTech vaccine is approved for use in Australia. Pfizer will soon be in a position to commence delivery of doses that will help protect frontline healthcare workers and some of the most vulnerable members of our community, and importantly, it means Australia can take significant strides forward in recovering from the impacts of the COVID-19 pandemic.

Australia's economic recovery will be predicated on access to a variety of successful vaccines. However, there are other levers available to the Government that can act as a catalyst for the healthcare sector and the economy more broadly. Pfizer Australia's submission argues that 'health security' should be of paramount importance in Australia's economic roadmap out of COVID-19.

This includes:

- Establishing high quality reliable infrastructure for Australia's vaccine rollout
- Expanding access to vaccines through government programs including targets for adolescent and adult populations
- Reviewing simplified price disclosure and its impact on critical, life-saving medicines
- A trial of a novel reimbursement model for anti-microbials and support for AAMRNet
- Consideration given to reinforcing the National Medical Stockpile with essential medicines and vaccines
- A harmonised approach to clinical trials being delivered in 2021
- Resolution of the comparator selection issue as agreed in the current Strategic Agreement between Medicines Australia and Government without further delay.

Pfizer Australia is a member of Medicines Australia (MA), the peak body representing innovative pharmaceutical companies in Australia.

Pfizer is also a founding member of the Australian Antimicrobial Resistance Network and fully supports the strategic priorities they have identified in their submission to address this pressing global health issue.

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Introduction

The emergence of the coronavirus disease 2019 (COVID-19) quickly re-shaped daily life for much of the world's population and drove the global economy into recession. Governments and institutions around the world needed to act quickly to face the unprecedented public health, social and economic challenge that COVID-19 presented.

Australia by comparison has navigated the COVID-19 pandemic better than most other nations. There are a range of factors contributing to this outcome, including Australia's island geography and remote location, coupled with our well-established public health infrastructure which allowed the Federal and State Governments to act quickly to suppress the domestic threat of COVID-19.

In the 2020-21 Budget the Federal Government took decisive action to brace our economy and lay a foundation for growth. As a result, the OECD has upgraded its outlook for the Australian economy. [i]

Pfizer would like to take this opportunity to commend the Federal Government on their landmark step to introduce a guaranteed PBS new medicines funding guarantee within the 2020 Budget and to commit to the removal of the cost-offset policy for the listing of new medicines.[ii] These were critical commitments to support new advancements and innovation across the medicines sector.

As the response to the COVID-19 pandemic has demonstrated, the innovative medicines sector can play a key leadership role in Australia's economic recovery through contributing to a healthy society. Innovation in precision medicine promises substantial benefits but will change the way in which some health services are delivered and evaluated. Beyond the COVID-19 pandemic there are still important issues that require careful consideration in order to accommodate the next generation of medicines.

A large number of innovative medicines are targeted, personalised and 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.

Assessing the value of these medicines is a challenge that market access systems around the world are currently grappling with. In Australia this is no different with a key issue linked to the application of comparator selection. Pfizer urges the resolution of this issue as agreed in the current Strategic Agreement between Medicines Australia and Government signed in 2017.

The National Medicines Policy Review and the House of Representatives Health Committee inquiry into novel medicines and medical technologies will also provide an opportunity to look beyond the immediate COVID-19 threat and implement lasting reforms to reinforce our healthcare system and ensure Australians have access to the latest medical interventions and breakthroughs in a timely manner.

More broadly, we look forward to collaboration between the Governments, the Department of Health and medicines industry that is critical to ensuring Australia remains at the forefront of global efforts to recover from the devastation of 2020.

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COVID-19 Vaccine

The global experience with COVID-19 has shown that vaccines are a crucial part of the long-term solution for ending the pandemic. As part of Pfizer's Five-Point Plan to battle COVID-19, we are committed to bringing our deep heritage in vaccine development and manufacturing, our considerable reach and scale, and capital resources to serve the millions of people around the world impacted by this devasting illness.

On 5 November 2020, the Federal Minister for Health, the Hon Greg Hunt MP, announced the signing of an agreement for the purchase of the Pfizer/BioNTech COVID-19 vaccine candidate, subject to clinical success and regulatory approval. The comprehensive purchasing agreement was signed by the Commonwealth and Pfizer on 24 December 2020. On 25 January 2021, which marked exactly one year since Australia's first recorded case of COVID-19, the Government announced the Therapeutic Goods Administration (TGA) had granted provisional approval to Pfizer's vaccine deeming it safe and effective for use.

Pfizer is committed to supply 10 million doses of our vaccine for COVID-19 over 2021, according to the Government's preferred channel and designated locations. Pfizer will continue to work closely with the Government to support their vaccine implementation plans. The Pfizer/BioNTech vaccine is just one of many in development and we remain hopeful that there will be several successful vaccines approved for use in Australia by the TGA, to meet the extraordinary demand as quickly as possible.

The Australian Government will need to rapidly establish high-quality and reliable infrastructure, systems and processes in partnership with all States and Territories to ensure that approved vaccines can be made available, distributed and administered to the Australian public across the country as soon as possible. Importantly, this will include both the pandemic and post-pandemic phases.

Pfizer Australia acknowledges the Commonwealth Government's COVID-19 Vaccine and Treatment Strategic Approach, and the five key pillars of this strategy, specifically pillar five "Immunisation administration and monitoring" that states the Australian Technical Advisory Group on Immunisation (ATAGI) is preparing advice to support planning for the allocation and use of safe and effective vaccines.[iii] This work will be critical to ensure successful distribution, uptake, administration and monitoring. The recent Federal Government announcement of a $23 million information campaign for the COVID-19 vaccination roll-out will help to build public confidence and maximise vaccine uptake rates.

More broadly, this pandemic and the emphasis it places on the importance of vaccination presents an opportunity for reform in the way vaccines are valued and accessed in Australia – particularly vaccines for adults and at-risk groups. Pfizer is enthusiastic to participate in a dialogue with government on the development and rapid implementation of policy reforms that can drive improved patient outcomes through increased access to proven preventative treatments.

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, anchored by prioritisation of preventative health measures, such as immunisation. The long-term economic health of the country will depend on the long-term health of our people and we encourage the government to invest in programs targeting prevention, protection and health promotion even while 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,[iv] the Australasian College for Emergency Medicine, Cancer Council Australia[v] 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 the prevention, screening 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. 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.[vi] 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. This level of under-investment must be redressed to help drive Australia's economic recovery.[vii]

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.[viii] In December, Australia reached its target of 95% immunisation of five year-olds for the first time ever. 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. [ix] Pfizer notes that the introduction of mandatory reporting of vaccines on the NIP to the Australian Immunisation Register will improve monitoring and reporting of adult vaccination coverage rates which will assist in this goal. [x]

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 this pandemic.[xi]

We urge investment in health system infrastructure and a greater focus on prevention policy that supports immunisation for all ages, including expanded access to vaccines through government programs and a focus on improving the infrastructure, support and education for adult vaccines.

Supply of critical medicines

As the largest hospital supplier of sterile injectable products in the country, and a major supplier of Pharmaceutical Benefits Scheme, National Immunisation Programme and National Blood Authority listed products, it was critical that during the onset of the COVID-19 outbreak Pfizer successfully maintained a strong and sustainable supply of crucial medicines, vaccines, blood products and other medical therapies.

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The importance of Pfizer's portfolio in the hospital setting cannot be underestimated. Early in the pandemic response, the TGA 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. One of the most pleasing aspects of the initial pandemic response was seeing our sector work so closely with government and key agencies to ensure continuity of supply.

As a result of these efforts Pfizer did not see a disruption in our supply chain, and all our plants in impacted areas around the world remained operational, meaning that patients in Australia and around the world have continued to have access to essential medicines during the pandemic.

While COVID-19 placed increased pressure on the medicine supply chain it is important to note sustainable access to these medicines is not a new issue. There is a very clear need to ensure that the system is appropriately valuing high volume, low-cost medicines which are often critical lifesaving medicines used in the hospital setting. 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. These pricing pressures have acted to reduce the number of available brands, placing additional pressure on the remaining manufacturers which can lead to supply constraints that threaten patient access to essential medicines.

Manufacturing anti-infective medicines is 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.[xii]

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 among others. 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.

Trial of a novel reimbursement model for anti-microbials and support for AAMRNet submission

The World Health Organisation has said that the global pipeline of antimicrobials is insufficient to tackle the increasing challenge of antimicrobial resistance.[xiii] 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. Only recently, 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." [xiv] 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.[xv] In Australia, the estimated annual impact of AMR on the economy by 2050 will be between A$142 billion and A$283 billion [xvi]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 supports the Australian Antimicrobial Resistance Network (AAMRNet) and their proposal that the Federal Government allocate sufficient funds to develop and implement an innovative reimbursement pilot for novel antimicrobials for the Australian market. The pilot fund would provide access and support the appropriate use of novel antimicrobials for clinicians to prescribe to the right patient at the right time. It would also encourage investment in AMR R&D and would demonstrate Australia's leadership in the face of a looming global health crisis.

Reinforcing the National Medical Stockpile with essential medicines and vaccines

In the immediate response to the COVID-19 outbreak much of the focus on the National Medical Stockpile has been on stockpiles of respirators, masks and personal protective equipment (PPE) given the critical need for this equipment across the country. In the 2020-21 Federal Budget the Government invested $3.3 billion to replenish expiring antiviral, chemical, biological, radiological and nuclear inventory items, along with pharmaceuticals and PPE – including face masks, respirators, gloves, face shields and gowns – and medical supplies and equipment.[xvii]

Despite this investment, there has been little focus on the medicine and vaccines reserves in the National Medical Stockpile and the demand for access to these reserves. 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 challenge with intense pressure on supply chains into and out of the country in times of crisis.

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 developed quickly.

There needs to be consideration given to replenishing and strengthening the hold of medicines in the National Medical Stockpile to ensure it is fit for purpose and capable of responding to a future pandemic or biosecurity threat. Inaction in this regard presents an ongoing risk that the next global threat could see Australia competing for scarce resources at a critical time, paying a premium to secure medicines and PPE and/or being unable to meet the needs of Australia's population.

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

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. This attractiveness has further increased as a result of Australia's response to the COVID-19 pandemic and low levels of community transmission.

Many countries compete for clinical trial activity 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. 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. [xviii]

If Australia is to remain competitive on this global stage, we need to continue to advance the environmental conditions for clinical trials. An important first step in this regard would be to reduce red-tape around how clinical trials are structured and administered.

During his address to the Committee for Economic Development in Australia in 2020, 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.[xix] 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. Recently, the CSIRO stated that 'without a thriving science and technology sector, Australia will not generate the innovation that spurs economic growth'.

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. This is an important reform that should be completed in 2021 to 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.

Comparator price erosion and lowest cost comparator

Companies continue to face challenges and uncertainty in the listing of new medicines on the national formulary, the Pharmaceutical Benefits Scheme (PBS). In general, on-patent medicines sit in the F1 formulary and off-patent medicines sit in the F2 formulary, and the prices of medicines in the F2 formulary reflect competition in the market.

One particular market access issue of increasing concern is comparator price erosion and the application of 'lowest cost comparator', which is having a negative impact on patient access by undermining the price of innovative new medicines.

- Comparator price erosion - Where there has been little innovation in a particular therapeutic area for a long time, comparing the new medicine to the one most commonly used in clinical management will involve comparison with generic or biosimilar medicines in F2, whose prices are typically far lower than

prices for new, innovative medicines. When the price of the new medicine is determined using an incremental approach, compared to the existing medicine, it is challenging to achieve a price that is appropriate for the innovation. For example, a new medicine in breast cancer might be compared to an older medicine that costs less than $100 per treatment. The solution lies in allowing new, innovative medicines to be valued appropriately for innovation in today's world. Otherwise, comparator price erosion will place a threshold on the value of an innovation, providing little incentive for manufacturers to bring these treatments to market.

- Lowest cost comparator – The price of a new medicine has traditionally been determined by comparison to the medicine or treatment most commonly used in clinical practice. Reference to the lowest cost comparator (or "least costly comparator") by the PBAC is increasingly common. In this situation, a new medicine, that has not been demonstrated to have a significant improvement over existing therapies, has its price determined by comparison to the cheapest clinical alternative, rather than the therapy most commonly used in clinical practice. This is increasingly used by the PBAC where a number of products in the same therapeutic class have been listed over time, with some in F1 (on-patent) and some in F2 (off-patent). The PBAC can agree that a medicine is the clinical comparator and then recommend that another, the cheapest in the group, should be used for the purposes of price setting.

Use of the "lowest cost comparator" can lead to two important, adverse outcomes for innovative pharmaceutical companies:

- It means that the PBS list price of the new medicine may be relatively low on PBS-listing and not in line with appropriate pricing for an innovative medicine. In some cases, the low price attainable for new medicine prevents PBS listing.
- It can impact other on-patent medicines that are already listed on the PBS in F1 and reference-priced to the new medicines, as the lower price achieved for the new medicine is flowed on to existing medicines. This is due to the fact that reference pricing within F1 is well established for medicines considered to deliver comparable outcomes.

The relatively low prices discussed above can also impact on other markets, due to international reference pricing of PBS list prices. Australian PBS prices are referenced by numerous other countries. Ultimately, this can result in medicines not being PBS listed in Australia.

Pfizer recommends resolution of the comparator selection issue as agreed in the current Strategic Agreement between Medicines Australia and Government without further delay. This could include establishing a clinical and pricing comparator before lodgement of a PBAC submission and the application of shadow pricing to allow F1-like price for F2 medicines that have undergone significant price reduction.

Conclusion

In 2020 Australia's health security was threatened like never before. The long-term health security of the nation is paramount. Vaccines and medicines in general can play a critical role in this regard; we also need to take specific and targeted steps to ensure we are prepared for the next global threat which experts believe will be growing resistance to antibiotics across the globe. We must urgently stimulate growth in our life sciences sector through clinical trial reform and take steps to protect the supply of critical life-saving medicines, in our hospitals, in the community and to take a strategic approach to medicines we hold in reserve. Beyond the response to COVID-19 we also need to ensure there are clear and consistent pathways and valuation for innovative medicines.

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Pfizer and the medicines industry can provide valuable insights 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 or through future reform discussions. 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.

Australia's healthcare system delivers world leading outcomes and does many things well. COVID-19 and the ongoing impact of the pandemic present an opportunity for reform, for new thinking and ideas about how we will contend with the economic and healthcare challenges of today, and tomorrow.

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