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Government Covid-19 Response Inquiry  
Department of PM&C  
PO Box 6100  
Parliament House  
Canberra ACT 2600

Dear Panel Members,

Thank you for providing Pfizer Australia with the opportunity to contribute to the inquiry into the Government's COVID-19 response.

Pfizer Australia is one of the nation's leading providers of prescription medicines. We research, develop and 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.

Pfizer has had operations in Australia since 1956. We have more than 1,000 employees in Australia and operate across two commercial sites in Sydney and Melbourne, and a manufacturing facility in Melbourne that exports to more than 60 countries worldwide.

Pfizer is proud of our role in the pandemic and also of our collaboration with the Australian Government to deliver timely and reliable access to our COVID-19 vaccine and COVID-19 antiviral. We look forward to continuing that partnership to ensure Australia is even better prepared for future threats to public health.

It is important to note, however, that having regard to competition law restrictions and due to the confidential nature of Pfizer's contractual agreement with the Commonwealth to supply our vaccine, we are not able to discuss specific details of the supply agreement. Similarly, the details of our agreements with other countries, including details on price, remain confidential. This means we cannot share the terms and conditions of those agreements.

Please find below Pfizer's response to the relevant terms of reference of the inquiry.

Thank you for the opportunity to contribute. We value the work of the Panel Members and the Taskforce in scrutinising the key decisions that have impacted our nation during the pandemic response to ensure lessons are learnt, and measures are put in place to ensure we are better prepared for the next threat.

Yours sincerely



**Anne Harris**  
Managing Director, Pfizer Australia and New Zealand

## Key Health Response Measures

### Vaccination

At the start of 2020, as the SARS-CoV-2 virus began rapidly spreading across the globe, Pfizer and our partner BioNTech recognised the urgency and need to play a leadership role in addressing the global public health crisis. On March 17, 2020, just six days after the World Health Organization declared COVID-19 a pandemic, Pfizer signed a letter of intent with BioNTech to co-develop a potential COVID-19 vaccine. We worked to safely accelerate the development, manufacture, and distribution of an mRNA-based coronavirus vaccine for active immunisation to prevent COVID-19 infection. In less than a year it received Emergency Use Approval from the US Food and Drug Administration (FDA), the first COVID-19 vaccine to be granted authorisation.

On 5 November 2020, then 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 ordering an initial 20 million doses, and on 25 January 2021, the Government announced the Therapeutic Goods Administration (TGA) had granted provisional approval to Pfizer's vaccine deeming it safe and effective for use.

In April 2021 the Government purchased an additional 20 million doses which Pfizer committed to deliver in Q4, 2021, bringing the total to 40 million doses delivered by the end of 2021. Pfizer Australia also entered into an agreement with the Government to provide 85 million further doses to support the vaccination program.

Vaccine manufacturing is a biological production that is extraordinarily complex. Pfizer's COVID-19 vaccine requires 280 components and relies upon 86 suppliers located in 19 different countries. The ability for true end to end sovereign manufacturing in which all components are sourced from within the same country is improbable. As a result, the maintenance of strong and reliable global supply chains is crucial to the ongoing production and availability of the vaccine.

Pro-innovation policy settings, including strong intellectual property rules, are essential to Pfizer's ability to commit the R&D investment required to make breakthroughs. Large-scale pandemics like COVID-19 are likely to recur. Epidemiologists forecast the frequency and scale of future pandemics will steadily increase. As such, near-term pandemic readiness efforts are critical to responding to a future pandemic and/or public health emergency at both the domestic and global levels. In addition to the public health benefit, vaccine access has also had a tremendous economic benefit in Australia. Modelling from a peer-reviewed paper<sup>1</sup> in the scientific journal *Vaccines* found the timely rollout of COVID-19 vaccinations reduced the impact of the pandemic on the Australian economy, resulting in a positive incremental benefit of \$181 billion, contributing to positive flow on effects for tourism exports, education exports, employment and government finances.

Pfizer has a strong and constructive relationship with the Federal Government with continuous engagement in support of the Australian Government's national vaccination program for COVID-19. Pfizer has met its contractual commitments to date and is on track to continue delivering vaccine doses to the Australian Government.

### Antivirals

While primary series vaccinations and boosters remain one of the first lines of defence to help protect people against COVID-19, it is important that treatment options are available to support patients who contract COVID-19 and are at high risk of developing severe disease.

Certain antiviral treatments, such as protease and polymerase inhibitors, can prevent a virus from replicating and thereby may help reduce the symptoms associated with COVID-19 and the risk of significant health complications. Clinical data and real-world evidence for Pfizer's antiviral Paxlovid® (nirmatrelvir and ritonavir) have shown that it can be an important tool in helping to reduce hospitalisations and deaths in those at increased risk of serious illness from COVID-19.

The Federal Government moved quickly to obtain access to doses of Paxlovid® under pandemic circumstances, becoming one of the first countries to secure doses - purchasing a million treatment courses, all of which were delivered in 2022. The contract was signed in December 2021 for 500,000 Paxlovid treatment courses to be delivered in 2022. In April 2022, the Australian Government then ordered an additional 500,000 Paxlovid treatment courses for 2022 with the option to procure additional doses if required. On 1 May 2022 Paxlovid® was listed on the PBS (with the Department of Health as the Responsible Person) to ensure equitable and timely patient access through community pharmacies. The eligibility for PBS access expanded over the course of 2023 to enable more Australians to access Paxlovid in the event of COVID-19 illness. Pfizer is planning to take on the PBS sponsorship to ensure ongoing supply and equitable access of Paxlovid®.

### **Supply of critical medicines**

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

The importance of Pfizer's portfolio in the hospital setting cannot be underestimated. Early in the pandemic response, the TGA developed a list of 78 medicines used for Intensive Care patients during COVID-19. 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 closely with government and key agencies to ensure continuity of supply.

Efforts to ensure the integrity of the medicines supply chain included:

- Regular dialogue through the Medicines Shortages Working Group, established by Medicines Australia and the Generic Biosimilars Manufacturers Association. This group included representatives from the National Pharmaceutical Services Association, Therapeutic Goods Administration, Department of Health and medicine wholesalers.
- Meetings of the trusted trader membership program: An Australian Border Force initiative which helps products move more freely into and out of the country.
- Working with National Cabinet and state hospital purchasers to avoid stockpiling behaviour and temporarily suspend hospital tendering processes.
- Working with other manufacturers under the supervision of the ACCC to respond to supply shortages.

As a result of these efforts there was minimal disruption in our supply chain, and all our plants remained operational, meaning that patients in Australia and around the world continued to have access to essential medicines throughout the pandemic.

While COVID-19 placed increased pressure on the medicine supply chain, it is important to note sustainable access to essential 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.

## International policies to support Australians at home and abroad & mechanisms to better target future responses to the needs of particular populations

The ongoing COVID-19 pandemic is a stark reminder of the importance of building more resilient health systems that are better prepared for a wide variety of public health threats. Pfizer recognises the opportunity to use the lessons we've learned to strengthen our preparedness against future pandemic health threats. We must continue to invest in R&D for pathogens with pandemic potential and nurture an overall R&D ecosystem that values and incentivises innovation, including by providing strong intellectual property (IP) protections. IP is not and has never been an obstacle to manufacturing scale-up or equitable global access to COVID-19 vaccines or therapeutics. IP is foundational to innovation and enabled us to collaborate with BioNTech in the first place, as well as governments and academic institutions, knowing that our IP will be upheld. To achieve equitable global access, we need to focus on issues at the local level such as health system infrastructure, trained healthcare professionals, low vaccines confidence and countering misinformation.

Voluntary licensing initiatives work and are always preferable to compulsory ones. Pfizer's voluntary license agreement with the Medicines Patent Pool is a critical example. The protection of IP is a critical component of innovation, and one of the main reasons we have vaccines and therapeutics available today to tackle COVID-19. It is also a key principle of collaboration for our industry.

Pfizer calls on all WTO Members including Australia to support the existing IP system underpinned by the TRIPS Agreement, which drove the development of the COVID-19 vaccines and treatments. Waiving these protections will undermine the incentives to both the continued improvement of COVID-19 vaccines and treatments, and the industry's response to the next pandemic.

Pfizer and BioNTech have shipped to date more than 4.6 billion vaccines to 181 countries and territories around the world, including more than 1.8 billion doses to 112 low- and middle-income countries. Our equitable access strategy focuses on low-income and middle-income economies because approximately two thirds of the 1.3 billion people living in poverty are in middle-income countries.

Lower-middle-income and upper-middle-income countries are currently home to 75% of the world's population and 62% of the world's poor. Pfizer has worked with governments and international health partners, like COVAX and UNICEF, to support supply and donation of more than 576 million doses to 128 countries.

As COVID-19 remains a global threat to health, we will continue to work closely with governments and partners to supply doses in alignment with demand through our agreements with governments and international partners while also providing our expertise and resources for novel approaches that can help to strengthen healthcare systems where greater support may be needed.

In addition to vaccine supply, we are engaging in several other access initiatives. In May 2022 we launched "An Accord for a Healthier World", a global initiative focused on reducing health inequities between the lowest countries and the rest of the world by providing all of Pfizer's patented, high-quality medicines and vaccines available on a non-for-profit basis to 1.2 billion people in 45 developing countries.

The Halton Review into the procurement of Australia's COVID-19 vaccines observed that Australia's COVID-19 vaccine rollout was on par with other advanced countries<sup>ii</sup>. However, the review strongly reinforced a portfolio approach to procurement 'will continue to be needed to mitigate the risk of supply shortage, delays, lack of success in clinical trials, manufacturing or regulatory failure.'

The significant public health and societal costs of the COVID-19 pandemic are wide-ranging and have been observed across geographies. Since 2020, COVID-19 has infected over 687 million people and resulted in more than 6.8 million deaths globally<sup>iii</sup>. The resulting global economic impacts of the COVID-19 pandemic are also unprecedented and may continue for years.

As the world shifts away from the emergency response to COVID-19, the risk of another pandemic remains. The probability of a pandemic with similar impact to COVID-19 is around 2% in any given year<sup>iv</sup>, meaning someone born in the year 2000 would have a 38% likelihood of having already experienced a pandemic by 2023. Societal trends that increase connectedness between countries, like globalisation and travel, can further accelerate the spread of high-risk pathogens. Recognising this, the world is moving urgently to achieve future pandemic health security.

A mission-led approach to pandemic response is key. Pfizer is proud of the role it continues to play, along with State and Federal Governments and many other key stakeholders in a public private partnership to turn the tide against COVID-19 and shelter the economy and the Australian community from an even more devastating fallout.

In order to improve Australia's response to the next pandemic it will require proactive planning and broader, earlier availability of vaccines and treatments. The time for action is during non-pandemic times, enabling a more effective response in an emergency.

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<sup>i</sup> Fox, N.; Adams, P.; Grainger, D.; Herz, J.; Austin, C. The Value of Vaccines: A Tale of Two Parts. *Vaccines* 2022, 10, 2057. <https://doi.org/10.3390/vaccines10122057>

<sup>ii</sup> Review of COVID-19 Vaccine and Treatment Purchasing and Procurement – Summary and recommendations. <https://www.health.gov.au/resources/publications/review-of-covid-19-vaccine-and-treatment-purchasing-and-procurement-summary-and-recommendations>. Accessed on 14 December 2023.

<sup>iii</sup> COVID-19 Cases, Recoveries and Deaths World wide (<https://www.statista.com/statistics/1087466/covid19-cases-recoveries-deaths-worldwide/>). Accessed on 14 December 2023.

<sup>iv</sup> Marani M, Katul GG, Pan WK, Parolari AJ. Intensity and frequency of extreme novel epidemics. *PNAS*. 2021;118(35). doi:10.1073/PNAS.2105482118