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Vulnerable Supply Chains study Productivity Commission Locked Bag 2, Collins St East Melbourne Vic 8003

Dear Sir/Madam

RE: Productivity Commission - Vulnerable Supply Chains Study

Thank you for providing Pfizer Australia with the opportunity to comment on this interim report.

Pfizer Australia is one of Australia'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. We are proud of the active role we play in Australia's health system and the wider contribution we make as an innovator, employer and manufacturer.

As 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, 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.

In addition to this Pfizer maintains a sophisticated and complex global manufacturing network of more than 40 sites and over 200 suppliers round the world. In Australia we have two manufacturing locations, Perth and Melbourne which manufacture medicines for use domestically and export to more than 60 countries worldwide.

As the response to the COVID-19 pandemic has demonstrated, the innovative medicines sector can play a key role in Australia's economic recovery. A healthy economy will require a healthy nation. This will be predicated on access to a variety of successful vaccines and the continued supply of medicines to hospitals, GP clinics, pharmacies, and patients across the country.

The pragmatic and collaborative approach to the pandemic saw common sense decisions to expedite processes, to remove red-tape and work together to deliver medicines to patients. It is important we take this experience and learn from it, to ensure we are better placed to address a future threat or crisis.

Pfizer has taken this opportunity to provide a brief comment to the Commission that we hope will provide some insights into the key issues we experienced in response to COVID-19 that can assist in this goal.

Yours sincerely,

Anne Harris
Managing Director, Pfizer Australia and New Zealand

ATTACHMENT 1: Productivity Commission – Vulnerable Supply Chains Study

Pfizer welcomes the Productivity Commission's interim report into vulnerable supply chains and the development of a framework to assess the severity of supply disruptions. We are also supportive of the approach the Commission has taken to detail some of the key considerations for supply interventions.

As the report framework demonstrates, medicines manufacture is classified as vulnerable, essential and critical and would constitute one of the most important sectors to maintain during a threat or crisis. Shortages or failure to supply some of these critical medicines during this period could have had a catastrophic impact on the healthcare system. Onshoring manufacturing is a solution for products with less complexity; however, for more complex products, which require access to a global supply network, regulatory flexibility is required, particularly during supply disruptions.

Maintaining the integrity of Pfizer's supply chain during the pandemic was not only resource intensive but it required considerable engagement and advocacy with external stakeholders. One of the key aspects to the success story of the medicines supply chain during COVID-19 has been the collaboration and pragmatic approach across the healthcare system that has ensured we can continue to deliver medicines to patients in a timely manner.

The following projects reflect this unique level of collaboration and provide valuable insight and lessons into how we can respond as a sector to any future threat of this scale.

- Regular meetings of the Medicines Shortages Working Group, a joint initiative of Medicines
 Australia and the Generic and Biosimilars Medicines Association: Pfizer was one of two
 industry representatives on this working group, which also included the National
 Pharmaceutical Services Association, Therapeutic Goods Administration, Department of
 Health, GBMA, Pharmacy Guild and medicine wholesalers. The group met regularly to
 discuss supply constraints, broader policy issues and challenges specific to COVID-19.
- Government intervention to ensure global trading relationships were maintained: This included maintaining freight routes out of specific Australian locations to enable the continued importation of medicines and ingredients as well as export of finished product.
- The Australian Trusted Trader membership program, an Australian Border Force initiative which helps products move more freely into and out of the country: Pfizer found these discussions invaluable to overcome challenges specific to the global distribution of medicines
- Implementing new COVID-19 protocols for the logistics and distribution of medicines in close consultation with medicines wholesalers, logistics partners and the Pharmacy Guild of Australia
- Working with National Cabinet and State hospital purchasers to avoid stockpiling behaviour and to temporarily suspend hospital tendering processes.
- Working with the European Federation of Pharmaceutical Industries and Associations, and the EU Commission to manage 'green pass' shipments for medicines across locked borders in the EU.
- Working with other manufacturers under the supervision of the ACCC to respond to supply shortages and minimise market disruption where possible.

Free movement of trade

What COVID-19 has laid bare is that Australia's island geography can serve as an advantage by using our borders to quarantine 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.

If we are to take steps to make Australia more resilient in a global supply chain environment, there needs to be a recognition that ingredients and components of the end product come from many sources and have multiple conversion points from raw material to finished product. Pfizer's COVID-9 vaccine for example consists of 280 components from more than 19 countries around the world.

In distributing our COVID-19 vaccine to countries around the world we have been clear with all stakeholders that the free movement of goods and supply across borders is critical to Pfizer and the patients we serve, particularly during this devastating global pandemic.

National Medical Stockpile

Pfizer acknowledges the interim report details the key stockpiling considerations for firms and Government. Across Pfizer's broader portfolio, the early stages of COVID-19 saw an extraordinary increase in demand for certain products, 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.

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. This should include consideration of broad spectrum anti-infectives that are used as a last-line treatment in the hospital setting. 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.

Intellectual property and its importance to supply resilience

A robust intellectual property (IP) policy environment that includes, for example, a strong patent system and regulatory data protection is critical to incentivise and drive the extensive investments and risks involved in the development of innovative medicines and vaccines. A country's record on intellectual property is an influential factor when determining long-term investment decisions that drive local employment and patient access to breakthrough therapies. A strong IP system will also be critical to provide certainty for industry to be able to respond to future pandemics.

The incentives provided by the IP system enabled Pfizer to build the expertise and infrastructure that allowed us to quickly mobilise and devote the resources, technical knowledge and know-how required to combat the pandemic and has facilitated the advancement of cutting-edge technologies, such as mRNA vaccines. The IP system has also enabled an unprecedented number of collaborations between biopharmaceutical innovators and governments, universities and other research partners to speed up progress on finding solutions.

Pfizer would be concerned with any changes to weaken IP provisions as an intervention to supply disruptions. In the case of our COVID-19 vaccine for example, weakening IP rules will not necessarily get vaccines to patients faster. The weakening of IP rules has the potential to adversely impact on quality and regulatory standards. It may also make it harder to secure the scarce inputs needed to manufacture more doses for the world and could also stifle continued research and collaboration needed to find solutions for special populations like children or to overcome new variants of the virus.

We appreciate Australia's recognition of the critical role the IP system has played—and will continue to play—in ensuring the innovative biopharmaceutical industry can continue to innovate and collaborate in an effort to end this pandemic.