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Committee Secretary
Parliamentary Joint Committee on Law Enforcement
PO Box 6100
Parliament House
Canberra ACT 2600
Dear Sir/Madam

Re: Vaccine related fraud and security risks

Thank you for providing Pfizer Australia with the opportunity to comment on this important issue.

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.

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 two 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. Australia's economic recovery will be predicated on access to a variety of safe and effective vaccines. Critical to this, is building vaccine confidence and ensuring Australians can make an informed decision.

The COVID-19 pandemic has left many fearful and anxious to protect themselves. We are cognisant that in this type of environment – fuelled by the ease and convenience of e-commerce and anonymity afforded by the Internet – there will be an increase in the prevalence of fraud, counterfeit and other illicit activity as it relates to vaccines and treatments for COVID-19.

In this submission Pfizer will provide some further detail on the steps we are taking to protect against counterfeit and product diversion to ensure a robust and secure vaccine supply chain. There are levers too available to Government to assist in this effort and to help build public confidence into the safety and security of the vaccination rollout. 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 extensive experience in criminal risk mitigation and is collaborating with BioNTech to take meaningful steps to help reduce the risk of illicit COVID-19 Vaccine activity. Our designated team of ex-law enforcement and forensic science specialists are tracking trends very carefully and have processes in place to identify threats to the legitimate supply chain. We continue to work with governments, law enforcement, healthcare providers and others to combat this illegal trade.

We have experts available to discuss this work in further detail should this be of interest to the Committee.

Yours sincerely,

Anne Harris
Managing Director, Pfizer Australia and New Zealand

Physical security in the production, transport and supply of COVID-19 vaccines in Australia

At Pfizer, we are relying on our years of experience protecting against counterfeiting and product diversion to anticipate and help prevent any potential threats to the Pfizer-BioNTech COVID-19 Vaccine supply chain. Our sole focus for ensuring product integrity is the safety of all individuals who take our medicines and vaccines.

As our COVID-19 Vaccine continues to be made available around the world, the extensive security measures that we have – and continue to take – are of growing importance.

Illicit and counterfeit products can pose real health and financial risks to individuals who unknowingly purchase these products. Sophisticated counterfeit products are often difficult for both healthcare professionals and the general public to identify, making it essential that all vaccines and treatments – including those for COVID-19 – are obtained from legal and authorised distributors. Around the world, Pfizer and BioNTech are working in partnership with government agencies to safely and efficiently distribute the vaccine. There are currently no legitimate COVID-19 vaccines produced by any manufacturer that are available for purchase by individuals.

Pfizer is informing all Governments and agencies we are working with of the following:

- The Pfizer-BioNTech COVID-19 Vaccine is not sold online. Any sales of COVID-19 vaccines and treatments over the Internet, including from online pharmacies, are not legitimate.
- It cannot be purchased in individual doses.
- It is only available through government-authorised vaccination centres – such as hospitals, outpatient clinics, pharmacies and community vaccination locations (and may include non-traditional venues such as sports arenas, supermarkets, etc. as established by federal, state and local governments).
- The Vaccine can only be administered by licensed healthcare professionals, or other individuals that are approved vaccinators, at government-authorised vaccination sites. The Vaccine is not taken orally and is not available in a capsule or tablet form.
- Doses are largely shipped from Pfizer's manufacturing sites in Puurs, Belgium and Kalamazoo, Michigan directly to vaccination centres. We are also using our existing distribution centre in Pleasant Prairie, Wisconsin. The Vaccine is not being shipped from any other countries, including China and India, at this time.

Measures to prevent and protect against COVID vaccine-related fraud and security risks

Pfizer has robust systems in place to help preserve the security of our medicines and vaccines. For the Pfizer-BioNTech COVID-19 Vaccine we continue to:

- Maintain key partnerships with anti-counterfeiting coalitions and Law Enforcement around the world. We identify, attempt to validate, and investigate suspect activity where we can and then refer those cases to the appropriate law enforcement entity.
- Leverage detailed logistical plans and tools to support effective Vaccine transport, storage and continuous temperature monitoring. Our distribution model is built on a flexible, just-in-time system to ship the vaccine from our manufacturing site or storage facility directly to the points of vaccination.
- Ship multi-dose vials of the Pfizer-BioNTech COVID-19 Vaccine in specially designed, fit for purpose packaging.
- Implement robust security features to product packaging. We utilise GPS-enabled thermal sensors with a dedicated Pfizer control tower that tracks the location and real-time temperature of each Vaccine shipment across its pre-set routes, 24 hours a day, seven days a week. These GPS-enabled temperature devices allow Pfizer to proactively prevent unwanted deviations and act before they happen.
- Perform security assessments of key manufacturing and distribution locations and processes. We use specific transportation partners to ship the Vaccine by air to major hubs within a country/region and by ground transport to dosing locations.
- Work closely with distributors to ensure our products are safe including providing a Pfizer Security Liaison.

Related matters:

Intellectual property and its importance to supply chain 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 risk-taking 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.

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.

TRIPS Waiver before the WTO

The waiver proposal at the WTO incorrectly portrays IP as a barrier to rapid innovation, R&D collaboration and access to COVID-19 vaccines and other products. On the contrary, IP rules are enabling an unprecedented amount of innovation and facilitating collaboration between biopharma innovators and partners.

Eliminating IP protections would not speed up vaccine production. Manufacturing of our vaccine involves the use of over 280 materials. These materials come from 86 suppliers in 19 different countries. If any one of the 280 different components from suppliers, however trivial, is not provided, we cannot manufacture or release the vaccine. Not only would waiving the TRIPS commitments send the wrong message to future innovators in the next pandemic, it could make it harder to resolve the current one, particularly if companies begin to buy up scarce inputs in the hopes of manufacturing a vaccine using technology developed by others. Greater demand pressures on inputs from new market entrants will make it harder, not easier, to manufacture COVID-19 vaccines in the near term.

Another industry concern, shared by public health experts, is that the waiver would increase the risk that patients around the world could be exposed to unsafe products, since it may invite copycat medicines from suppliers that lack the knowhow to manufacture vaccines safely. It would also create confusion that could potentially undermine public confidence in vaccine safety and create a barrier to information sharing.

Finally, we are concerned that the waiver proposal is a distraction from the real solutions to improve vaccine access: strengthening and maintaining health infrastructure to deliver the vaccine; supporting frontline health workers to administer the vaccine; and vaccine hesitancy campaigns to increase acceptance of the vaccine. We look forward to working with governments, the WTO and other stakeholders on solutions that will address the challenges of vaccine access that do not undermine the IP system, vaccine production or negatively impact public health.