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Department of Health
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Friday, 25 February 2022

Dear NMTF Secretariat,

Re: Towards a National Medicines Traceability Framework Consultation Paper

Thank you for providing Pfizer Australia with the opportunity to comment on the proposed National Medicines Traceability Framework consultation paper.

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.

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. We also partner with hundreds of other providers upstream and downstream to ensure the safe, effective, and prompt delivery of medicines to clinicians and patients.

Pfizer supports implementing a traceability model across the medicines supply chain and has experience implementing serialisation in more than 50 countries already. This has provided valuable insight into the benefits but also the challenges in moving towards traceability. Of the three models presented in the consultation paper a full track and trace model is our preferred option.

However, Pfizer is concerned that the proposed options in the NMTF consultation paper do not fully encapsulate how resource intensive and costly serialisation is and the risks posed to the integrity of the supply chain of not staging the implementation of a preferred model appropriately. For Pfizer this would be a major undertaking and would constitute a three-to-five-year project. During this time, there is the potential for disruptions to the business and supply without careful advanced planning. Suppliers downstream, including wholesalers, logistics suppliers, hospitals and pharmacies would also face significant cost and complexity to implement.

Successfully introducing a traceability model will be heavily predicated on ensuring the whole end-to-end supply chain is actually ready and able to invest in and manage the change. The pressure for manufacturers to implement seems premature if the rest of the supply chain does not have the capability or funding to invest in it. Questions remain too on how the central data repository would be built and managed and what contribution would be required from industry.

That is why Pfizer supports a letter from Medicines Australia to the Department of Health which calls for the medicines industry and other key contributors across the supply chain to be further consulted on the preferred model and implementation strategy to safeguard from any threats to the continued, reliable supply of medicines that could arise from rushing this process.

We are hopeful that we can work collaboratively towards a suitable outcome and timeframe for implementation that suits all parties whilst maintaining the integrity of the end-to-end medicines supply chain.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Anne Harris', with a long horizontal flourish extending to the right.

Anne Harris
Managing Director, Pfizer Australia and New Zealand