From:	SKERRITT, John
To:	GHuntMP; s22 s22
Subject:	Draft TGA media statement on Norwegian deaths - grateful for your feedback and I can organise to go up on the TGA website today [SEC=OFFICIAL]
Date:	Sunday, 17 January 2021 11:53:56 AM
Attachments:	Norwegian warning of COVID vaccine risks 17 1 21.docx

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Norwegian investigation of COVID-19 vaccination risks for elderly, very frail patients

In recent days the TGA has received reports of about 30 deaths in over 40,000 elderly individuals in Norway vaccinated with the Pfizer BioNTec vaccine. The deaths were recorded among very frail patients, including some who were anticipated to only have weeks or months to live. Norwegian authorities report that in recent years in aged care an average of around 400 deaths typically occur each week.

The deaths were associated with fever, nausea and diarrhoea, which are relatively common short-lived effects that a number of people experience after vaccination. It is not expected that these common adverse reactions following immunisation will be of risk in the vast majority of individuals vaccinated with the Pfizer BioNTec vaccine.

The TGA was advised promptly of the Norwegian deaths and is working closely with the European Medicines Agency (of which Norway is a member) and Pfizer on further investigations. Because of Australia's close working relationship with European regulators the TGA is one of the first non-European regulators to routinely receive early notification of any possible serious adverse events with COVID-19 vaccines.

We will continue to work with European regulators over the coming days to investigate this report and determine whether specific warnings about risks of vaccination in the very frail elderly or terminally ill should be potentially included in the product information for the Pfizer BioNTec vaccine, which will be made available to all doctors and vaccinators.

The TGA's processes for vaccine approvals is extremely rigorous and comprehensive. The TGA is evaluating all of the scientific and clinical information provided by the vaccine's sponsor, Pfizer, as well as other available evidence (including from international experience with emergency use of the vaccine) prior to making a regulatory decision.

A vaccine will only be approved for use if it is demonstrated to be safe and effective in clinical trials and if the manufacturer can show it can be produced in a high quality, consistent and controlled manner. For any approved vaccines, the existing extensive Australia-wide vaccine and medicine safety monitoring system will immediately be scaled up to include the new vaccine.