

## Australia reports no specific risk for Pfizer vaccine in elderly patients

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**The case reports were discussed at a recent meeting of the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee**



On January 14, 2021 the Therapeutic Goods Administration (TGA) received reports of about 30 deaths in over 40,000 elderly individuals in Norway vaccinated with the Pfizer BioNTech vaccine. The deaths were recorded among very frail patients, including some who were anticipated to only have weeks or months to live.

The TGA was advised promptly of the Norwegian deaths and has worked closely with the European Medicines Agency and Pfizer on further investigations.

The case reports were discussed at a recent meeting of the European Medicines Agency (EMA) Pharmacovigilance Risk Assessment Committee, which concluded that there was not a specific safety concern, and no causal link between vaccination and deaths could be established. In addition, wider discussions with regulators in North America, the UK and Europe reached a similar conclusion.

The TGA therefore has concluded that there is no specific risk of vaccination with the Pfizer-BioNTech COVID-19 vaccine in elderly patients.

On January 24 the TGA provided provisional approval to the Pfizer-BioNTech vaccine, COMIRNATY, "to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older". Elderly patients can receive this vaccine and there is no cap on the upper age limit.

The product information for healthcare professionals contains the following advice: "The data for use in the frail elderly (>85 years) is limited...the potential benefits of vaccination versus the potential risk and clinical impact of even relatively mild systemic adverse events in the frail elderly should be carefully assessed on a case-by-case basis."

The TGA will continue to monitor the safety of COVID-19 vaccines as they are rolled out in Australia and internationally. Australia co-chairs the global regulatory (International Coalition of Medicines Regulatory Agencies) network for safety

monitoring of COVID-19 vaccines and therefore has very timely access to international vaccine safety reports.

For all approved COVID-19 vaccines, the existing extensive Australia-wide vaccine and medicine safety monitoring system is being scaled up to include the new vaccine.