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First COVID-19 vaccine safety update published

Today EMA has released its first safety update on a COVID-19 vaccine — Comirnaty. It concludes that safety data collected on Comirnaty use in vaccination campaigns is consistent with the known safety profile of the vaccine, and no new side effects were identified.

The safety update reflects data collected and assessed since Comirnaty's authorisation, including data from EudraVigilance (the EU's centralised database of suspected side effects) and data received from other sources, including the company's monthly safety report required for COVID-19 vaccines. EMA will publish monthly safety updates for all authorised COVID-19 vaccines, in line with exceptional transparency measures for COVID-19.

This safety update includes the assessment by EMA's safety committee (PRAC) of deaths reported after vaccination with Comirnaty, including deaths in frail, elderly people. PRAC carried out an analysis of the cases and took into account the presence of other medical conditions and the death rate for corresponding age groups in the general population. PRAC concluded that the data did not show a link to vaccination with Comirnaty and the cases do not raise a safety concern. Further reports will continue to be carefully monitored.

The safety and effectiveness of Comirnaty will continue to be monitored as it is used across the Member States and globally, through the EU pharmacovigilance system, additional studies by the company and independent studies coordinated by European authorities. These measures will allow regulators to swiftly assess data emerging from a range of different sources and take appropriate regulatory action to protect public health, if needed.

More about the vaccine

Comirnaty is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 16 years and older.

It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein from SARS-CoV-2, the virus that causes COVID-19. The vaccine works by preparing the body to attack the spike protein on the surface of SARS-CoV-2.

More information is available on the vaccine's page on EMA website.

Reporting side effects

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Vaccinated individuals and healthcare professionals should report suspected side effects via national reporting systems. These reports help regulators understand more about Comirnaty and complement the knowledge already generated by clinical trials and other studies.

Information on how to report side effects in individual Member States is available in the package leaflet. For a full list, see National competent authorities.

For more information, see Reporting side effects.