EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Report: How EU ensured safety of medicines during COVID-19

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Preparedness for intensified monitoring, methodologies based on established pharmacovigilance tools as well as on innovative approaches and the flexibility and commitment of all the stakeholders involved were key factors to allow the European medicines regulatory network to effectively respond to the pandemic. These activities are detailed in a report published today.

EMA and EU member states deployed a wide range of measures and tools to proactively collect, analyse and assess the unprecedented volumes of safety data generated during the COVID-19 vaccination campaigns and take the necessary actions.

Preparedness started with the design of a comprehensive safety monitoring plan in November 2020, before any COVID-19 vaccine was authorised.

National competent authorities and EMA encouraged spontaneous reporting of suspected side effects through dedicated campaigns and communication materials.

During 2021 and 2022, nearly one billion doses of vaccines were administered in the European Union (EU), and about two million individual case safety reports were received by the system for collecting and analysing information on suspected side effects, EudraVigilance. Adverse events of special interest for COVID-19 vaccines were monitored in a near real-time manner right after authorisation. Additionally, marketing authorisation holders of COVID-19 vaccines were asked to provide monthly reports on their safety profile for at least six months after authorisation, as a tool to scrutinise data from real-world use as well as from other sources, such as the scientific literature. In total, 56 such reports were assessed by EMA's safety committee (PRAC) until December 2022.

Real-world evidence (RWE) studies complemented these intensified monitoring activities by helping to better characterise important safety issues and collect more information on the impact of vaccines and treatments in specific populations (e.g. pregnant women) as well as on the characteristics of COVID-19 disease itself. 11 RWE studies were commissioned to international research consortia, of which six were finalised at the end of the period covered by the report. Those studies contributed to the collective body of evidence supporting the favourable benefit-risk of COVID-19 vaccines and are publicly available in the EU PAS register.

Overall, the safety monitoring of COVID-19 vaccines highlighted that the vast majority of side effects are mild or moderate. The EU network was able to promptly identify a few rare but serious side effects associated with COVID-19 vaccines, affecting less than one in 10,000 vaccinated people, and take action in a timely manner to mitigate these risks. A notable example is the identification of a new rare clinical entity that was found to be associated with adenoviral vector COVID-19 vaccines, i.e. thrombosis with thrombocytopenia syndrome, usually abbreviated as TTS.

The pandemic also triggered a surge in demand for access to data on suspected side effects that are available through the public interface of the EudraVigilance database. This was visited 10.5 million times in 2022, which is over four times the number of visits in 2019.

EMA implemented extraordinary transparency, communication and engagement measures between 2021 and 2022, with the publication of over 50 monthly updates on the safety of COVID-19 vaccines, the organisation of over 30 press briefings and 4 public meetings, as well as other ad hoc communications activities.

The report also emphasises how the collaboration and exchange of information with other international regulators significantly increased during the pandemic. Existing and ad hoc confidentiality agreements allowed EMA to receive and share information in real time on important safety issues and enabled unprecedented collaboration with regulators across the globe.

Lastly, the report also details other activities carried out by the EU network between 2019 and 2022 to ensure the safety of all the other medicines authorised in the EU and improve the processes in place. It highlights in particular how the EU network prioritised tasks and managed to carry out all the core regulatory activities despite the challenges and disruption brought by the COVID-19 pandemic.

## Related documents

Report on pharmacovigilance tasks from EU Member States and the European Medicines Agency (EMA) 2019-2022 (PDF/1.68 MB) (new)

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## Related content

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- Coronavirus disease (COVID-19)
- International activities
- Data Analysis and Real World Interrogation Network (DARWIN EU)
- Pharmacovigilance: Overview

## External links

- European Union electronic register of post-authorisation studies (EU PAS Register)
- Suspected adverse drug reactions database

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