



COVID-19 vaccines: Making sure they are safe

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All medicines, including vaccines, are **closely monitored in the EU** after they are authorised and put on the market.

Statistically, side effects are rare or very rare. The safety and effectiveness of authorised COVID-19 vaccines will be **rigorously monitored, as for all medicines**, through the EU's established medicines monitoring system.

Europe already has a **robust system to ensure long-term vaccine safety**, and the European Medicines Agency has a solid track record in **keeping Europe safe**.



CONSTANT MONITORING



The European Medicines Agency (EMA) **constantly monitors reports of any side effects** after a vaccine is used.

EUROPE-WIDE DATABASE



The EMA has a **Europe-wide database** of reports from patients, health professionals and researchers.

The database allows EMA experts to **quickly identify and act** on potential risks while medicines are in use.

GLOBAL PROTECTION



The EMA regularly **exchanges information** with the World Health Organization and with medicines regulatory agencies of other countries, to keep track of issues that have arisen in other parts of the world.

This increases the level of medicines' safety in Europe even more.

COVID-19 vaccines will be rigorously monitored, with large scale activities during the pandemic

LARGE-SCALE MONITORING



Exceptionally high numbers of people are expected to receive the vaccines at the same time. The European Medicines Agency has **mobilised extra resources** to carry out its regular monitoring activities more rapidly and on a bigger scale.

FOLLOW-UP STUDIES AND TESTS



A conditional authorisation may be granted for a medicine or vaccine to be made available in **emergency situations** such as COVID-19.

Manufacturers commit to do **more studies and tests** after the vaccine is launched.

FREQUENT SAFETY REPORTS



Usually, vaccine manufacturers must send a **safety report** to the European Medicines Agency **every six months**.

For COVID-19 vaccines, the safety report must be sent **every month**.

MAXIMUM TRANSPARENCY



The European Medicines Agency ensures **maximum transparency** in its work on COVID-19 vaccines.

Once a vaccine is approved, the EMA will publish **additional regular updates** summarising safety reports.



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