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COVID-19 Vaccine Janssen: authorities in EU take steps to safeguard vaccine quality

Authorities in the EU are aware that a batch of the active substance for COVID-19 Vaccine Janssen had been contaminated with materials for another vaccine manufactured at the same site.

The contamination occurred at a manufacturing site for the active substance in Maryland, United States, owned by Emergent Biosolutions. The batch concerned was not for the EU market.

Based on available information, batches of the vaccine released in the EU are not affected by the cross contamination. However, as a precaution and to safeguard the quality of vaccines, the supervisory authorities[1] have recommended not releasing vaccine batches containing the active substance made at around the same time that the contamination occurred.

Authorities in the EU are doing everything possible to safeguard supplies and mitigate the effects of any delay in the delivery of this vaccine.

EMA and national authorities are also aware of an inspection of the Emergent manufacturing site by the U.S. Food and Drug Administration (FDA). Authorities will continue to work with FDA and other international partners to ensure that vaccines in the EU meet the highest standards of quality.

The manufacturing issues at Emergent Biosolutions are not related to EMA's recent review of very rare cases of blood clots and low blood platelets.

More about the vaccine

COVID-19 Vaccine Janssen is a vaccine for preventing coronavirus disease 2019 (COVID-19) in people aged 18 years and older. COVID-19 is caused by SARS-CoV-2 virus. COVID-19 Vaccine Janssen is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making a protein from SARS-CoV-2. COVID-19 Vaccine Janssen does not contain the virus itself and cannot cause COVID-19.

The most common side effects with COVID-19 Vaccine Janssen are usually mild or moderate and improve within a few days after vaccination. More information is available on the vaccine's webpage.

[1] The supervisory authorities are the medicines authorities in Belgium and the Netherlands who are responsible for batch release in the EU.

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