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Covid-19: EU investigates four reports of blood clots after Janssen vaccine

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The European Medicines Agency is investigating four reported cases of unusual blood clots with low platelets in people who have received the Janssen (Johnson & Johnson) covid-19 vaccine.

Three cases have been reported during the vaccine rollout in the US, while one case occurred in a clinical trial. One case was fatal.

The EMA and the UK Medicines and Healthcare Products Regulatory Agency has investigated similar cases in people who had received the Oxford University-AstraZeneca vaccine. No link has been found between this vaccine and the blood clot cases, with the EMA concluding that they were a "possible" side effect but "extremely rare." The EMA and MHRA said that no restrictions were needed in relation to the vaccine's rollout and that its benefits outweighed the risks.[1]

Like the AstraZeneca vaccine, the Janssen vaccine uses a viral vector platform. In Janssen's case researchers used adenovirus type 26, the same as used in Russia's Gamaleya Research Institute vaccine.

In its latest announcement the EMA's Pharmacovigilance Risk Assessment Committee said, "These reports point to a 'safety signal,' but it is currently not clear whether there is a causal association between vaccination with [Janssen's vaccine] and these conditions."[2]

While rollout of the vaccine has not yet started in the EU, it was expected to begin in the next few weeks. The EMA's committee said it would decide whether regulatory action was needed once evaluation had concluded but said this "usually consists of an update to the product information."

1 Mahase E. AstraZeneca vaccine: Blood clots are "extremely rare" and benefits outweigh risks, regulators conclude. *BMJ* 2021;373:n931. doi: 10.1136/bmj.n931 pmid: 33832929

2 Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 6-9 April 2021. https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-6-9-april-2021.