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Covid-19: US suspends Johnson and Johnson vaccine rollout over blood clots

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US regulators have paused the rollout of the Janssen (Johnson & Johnson) covid-19 vaccine after reports of a small number of blood clot cases in those who had been vaccinated.

Six cases of blood clots in combination with low platelets have been reported in the US, out of more than 6.8 million doses administered. All six cases were in women aged between 18 and 48, with symptoms occurring six to 13 days after vaccination.

Johnson & Johnson announced it is investigating the cases alongside regulators and has “proactively delayed” rollout of its one dose vaccine in Europe, which was expected to begin this week. This comes after the European Medicines Agency said it was investigating the cases.

The EMA and the UK Medicines and Healthcare Products Regulatory Agency have investigated similar cases in people who had received the Oxford 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

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.”

In a joint statement, the US Food and Drug Administration and Centre for Disease Control said people vaccinated with the Janssen vaccine should seek medical attention if they experience severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination.³

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 6-9 April 2021. www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-6-9-april-2021.

3 Joint CDC and FDA statement on Johnson & Johnson covid-19 vaccine. April 2021. www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine.

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