Johnson & Johnson's COVID-19 Vaccine Under Scrutiny at EMA after 4 'Serious Cases' of Unusual Blood Clots

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AstraZeneca's COVID-19 vaccine has dominated headlines as reports of rare blood clots mounted, but now European drug safety regulators are investigating potential clotting risks from Johnson & Johnson's vaccine.

So far in the J&J vaccine's U.S. rollout, EU officials have tracked three cases of unusual blood clots with low blood platelets following vaccination, the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee said Friday. Another case came in a clinical trial. One of the cases was fatal.

All four were "serious cases," the committee says. The reports "point to a 'safety signal,' but it is currently not clear whether there is a causal association," PRAC says. The group will decide whether any regulatory steps, such as a warning about side effects, are appropriate.

A J&J spokeswoman said the company is working with regulators as more data come in and supports the "open communication" of any new findings with healthcare providers so they can monitor for risks.

> "We are aware that thromboembolic events including those with thrombocytopenia have been reported with all COVID-19 vaccines," J&J's spokeswoman said. "Our close tracking of side effects has revealed a small number of very rare events following vaccination. At present, no clear causal relationship has been established between these rare events and the Janssen COVID-19 vaccine."

So far, the vaccine is only available in the U.S., but European officials recently authorized it and rollouts there are expected to start soon. It wasn't immediately clear whether the U.S. FDA is also reviewing the cases. The agency had not responded to questions by press time.

Meanwhile, the U.S. vaccine rollout has run into some issues in recent weeks. Just 700,000 doses are set to ship out to states next week, down from 4.9 million this week, The Wall Street Journal reported Friday. And two vaccination sites, in Colorado and North Carolina, temporarily closed after adverse reactions in a limited number of recipients, CBS News

reports.

J&J's vaccine has also been in the news lately due to manufacturing missteps at its partner Emergent BioSolutions. Weeks ago, workers at an Emergent plant in Baltimore ruined a large batch of vaccines containing millions of doses, and in response the Biden administration put J&J in charge at the plant. That forced AstraZeneca, which had also partnered with Emergent, to look for a new manufacturing partner.

About 14.5 million J&J vaccine doses have been delivered to states so far, and 4.9 million doses have been administered, according to the latest Centers for Disease Control and Prevention data. The vaccine is given as a single dose.

As for AstraZeneca's shot, European regulators this week added a warning over rare blood clots after reviewing 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis in the EU as of March 22. As of that date, around 25 million people had received the vaccine.

But in a new revelation Friday, the EMA's safety committee says it's looking into five cases of capillary leak syndrome after vaccination with AZ's shot. It isn't clear whether the cases are linked to the vaccine, but, again, the reports "point to a 'safety signal,'" PRAC said.

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Featured image: A Johnson & Johnson vaccine factory in Leiden, Netherlands, is one of the facilities producing its COVID-19 shot. (J&J)

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