

# EU regulator prepares to issue advice on use of J&J vaccine

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In this April 13, 2021, file photo, a box of Johnson & Johnson vaccines are shown by pharmacist Zsolt Szenasi at a warehouse of Hungaropharma, a Hungarian pharmaceutical wholesale company, in Budapest, Hungary. Experts at the European Medicines Agency are preparing to present the conclusions of their investigation later on Tuesday, April 20, 2021, into possible links between the Johnson & Johnson coronavirus vaccine and very rare cases of unusual clotting disorders detected in the U.S. (Szilard Koszticsak/MTI via AP, File)

Experts at the European Medicines Agency are preparing to present Tuesday the conclusions of their investigation into possible links between the Johnson & Johnson coronavirus vaccine and very rare cases of unusual clotting disorders detected in the U.S.

Last week, [J&J halted its European rollout](#) of its one-dose vaccine after the U.S. Food and Drug Administration recommended [officials pause its use](#) while the [rare blood clot cases](#) are examined. Officials identified six cases of the highly unusual blood clots among nearly 7 million people who were immunized with the shot in the U.S.

Johnson & Johnson advised European governments to store their doses until the EU drug regulator issued guidance on their use; widespread use of the shot in Europe has not yet started.

The delay was a further blow to vaccination efforts in the European Union, which have been plagued by supply shortages, logistical problems and concerns over unusual blood clots also in a small number of people who received the AstraZeneca COVID-19 vaccine. Experts worry the temporary halt on J&J's shot could further shake vaccine confidence and complicate worldwide COVID-19 immunization efforts.

Last week, South Africa suspended its use of the vaccine in the wake of the U.S. pause, and countries including Italy, Romania, the Netherlands, Denmark and Croatia put their J&J doses into storage.



Exterior view of the European Medicines Agency, EMA, in Amsterdam's business district, Netherlands, Tuesday, April 20, 2021. Experts at the European Medicines Agency are preparing to present the conclusions of their investigation later on Tuesday into possible links between the Johnson & Johnson coronavirus vaccine and very rare cases of unusual clotting disorders detected in the U.S. (AP Photo/Peter Dejong)

The blood clots linked to the J&J vaccine are occurring in unusual parts of the body, such as veins that drain blood from the brain. Those patients also have abnormally low levels of blood platelets, a condition normally linked to bleeding, not clotting.

With the AstraZeneca vaccine, scientists in Norway and Germany have suggested that some people are experiencing an abnormal immune



system response, forming antibodies that attack their own platelets.

It's not yet clear if there might be a similar mechanism with the Johnson & Johnson vaccine. But both the J&J and AstraZeneca vaccines, as well as a Russian COVID-19 vaccine and one from China, are made with the same technology. They train the immune system to recognize the spike protein that coats the coronavirus. To do that, they use a cold virus, called an adenovirus, to carry the spike gene into the body.



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"Suspicion is rising that these rare cases may be triggered by the adenovirus component of the AstraZeneca and J&J vaccines," said Eleanor Riley, a professor of immunology and infectious diseases at the University of Edinburgh. She said that while more data was needed, "it remains the case that for the vast majority of adults in Europe and the USA, the risks associated with contracting COVID-19 far, far outweigh any risk of being vaccinated."

On Monday, World Health Organization Director-General Tedros Adhanom Ghebreyesus said more than 5 million new coronavirus cases were confirmed worldwide last week, the highest-ever number in a single week. He noted that cases and hospitalizations among younger people were "increasing at an alarming rate."

The European Medicines Agency, which regulates drugs used in European Union member nations, said last month there was a "possible link" between the AstraZeneca vaccine and rare blood clots but said the benefits of vaccination far outweighed the risks of COVID-19. It noted the risk is less than the blood clot risk that healthy women face from birth control pills.



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The European Union ordered 200 million doses of the Johnson & Johnson for 2021 and EU officials had hoped the one-shot vaccine could be used both to boost the continent's lagging vaccination rates and to protect hard-to-reach populations, like migrant workers and the homeless.

Last month, the African Union announced it signed a deal to buy up to

400 million doses of the J&J vaccine. Johnson & Johnson also has a deal to supply up to 500 million doses to the U.N.-backed COVAX initiative that helps get vaccines to the world's poor.

Any concerns about the J&J vaccine would be another unwelcome complication for COVAX and for the billions of people in developing countries depending on the program. COVAX recently was hit by supply issues after its biggest supplier, the Serum Institute of India, announced it would delay exports of the AstraZeneca vaccine for several months due to a surge of cases on the subcontinent.

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