

EU regulator recommends using J&J's one-shot vaccine

March 11 2021, by Maria Cheng



This Saturday, March 6, 2021 file photo shows vials of Johnson & Johnson COVID-19 vaccine in the pharmacy of National Jewish Hospital for distribution in east Denver. The European Medicines Agency is meeting Thursday March 11, 2021, to discuss whether Johnson & Johnson's one-dose coronavirus vaccine should be authorized, a move that would give the European Union a fourth licensed vaccine to try to curb the pandemic amid a stalled inoculation drive. (AP Photo/David Zalubowski, File)

The European Medicines Agency on Thursday gave the green light to Johnson & Johnson's one-dose coronavirus vaccine, handing the European Union's 27 nations a fourth vaccine to try to speed up the bloc's much-criticized vaccination rollout.

The EU medicines regulator advised that the vaccine be cleared for use in all adults over 18 "after a thorough evaluation" of J&J's data found the vaccine met the criteria for efficacy, safety and quality.

"With this latest positive opinion, authorities across the European Union will have another option to combat the pandemic and protect the lives and health of their citizens," said Emer Cooke, EMA's executive director.

The EMA has already recommended COVID-19 vaccines made by [Pfizer-BioNTech](#), [Moderna](#) and [AstraZeneca](#) —but all of those vaccines require two doses, several weeks apart. Production delays have also plagued all three vaccine manufacturers.

In its statement Thursday, the EMA said the J&J vaccine was about 67% effective. The most common side effects were pain at the injection site, headache, tiredness, muscle pain and nausea.

The European Commission quickly granted a conditional marketing authorization to the vaccine.

"The entry on the market of the (J&J) vaccine ensures that we have access to a total of up to 1.8 billion doses of approved vaccines from different technology platforms," Health Commissioner Stella Kyriakides said.

The U.S. Food and Drug Administration gave an [emergency authorization](#) to the J&J shot in late February. Health experts hope that having a one-

dose vaccine will speed efforts to immunize the world against COVID-19, especially given the recent infection spikes in Europe driven by worrying new variants.

The EU has struggled to quickly roll out shots and immunize its most vulnerable citizens. It ranks far behind countries including Israel, Britain, Chile and the U.S.

J&J said it has committed to providing the EU with its pre-ordered 200 million doses starting in the second quarter.

"The greatest barrier to rolling out the vaccines so far has been the availability of vaccines," said Dr. Peter English, who previously chaired the British Medical Association's Public Health Medicine Committee.

"This new addition can only add to the quantity of vaccine available in the EU, as well as providing another alternative if there are hitches with the supply or use of other products."

Europe recorded 1 million new COVID-19 cases last week, an increase of 9% from the previous week and a reversal that ended a six-week decline in new infections. The World Health Organization's European office [blamed that surge](#) partly on virus variants, including one first identified in Britain that is thought to be 50% more transmissible.

A massive study that spanned three continents found the J&J vaccine was 85% effective in protecting against severe illness, hospitalizations and death. That protection remained strong even in countries like South Africa, where variants have been identified that appear to be less susceptible to other vaccines, including the one made by AstraZeneca.

The J&J vaccine can be stored at normal refrigerator temperatures, similar to the AstraZeneca vaccine, which should make rolling out its use easier than vaccines made by Pfizer and Moderna, which require colder

storage.

J&J's shot uses a cold virus like a Trojan horse to carry the spike gene of the coronavirus into the body, where cells make harmless copies of the protein to prime the immune system in case the real virus comes along. It's similar to COVID-19 shots made by AstraZeneca and China's CanSino Biologics.

J&J is also seeking emergency authorization of its vaccine in Britain and by the World Health Organization. It has already been approved for use in Bahrain and Canada.

Thomas Mertens, the head of Germany's independent vaccine advisory panel, said he expected the shot's use to be recommended in Germany.

However, Mertens wouldn't rule out that the panel might recommend using the vaccine only for certain groups within the population, as it initially did by limiting the AstraZeneca shot to under 65s - a restriction it later lifted after receiving more data.

J&J has faced production delays in the U.S. and Europe but has recently signed agreements with rival pharmaceuticals who will help make their vaccine. In February, Sanofi Pasteur said it would be able to make about 12 million doses of the J&J vaccine at one of its French production sites once the shot is cleared by the EMA. It is aiming to make 1 billion doses this year.

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Citation: EU regulator recommends using J&J's one-shot vaccine (2021, March 11) retrieved 25 April 2024 from <https://medicalxpress.com/news/2021-03-eu-jj-one-shot-vaccine.html>

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