Novavax asks EU drug regulator to OK its COVID vaccine

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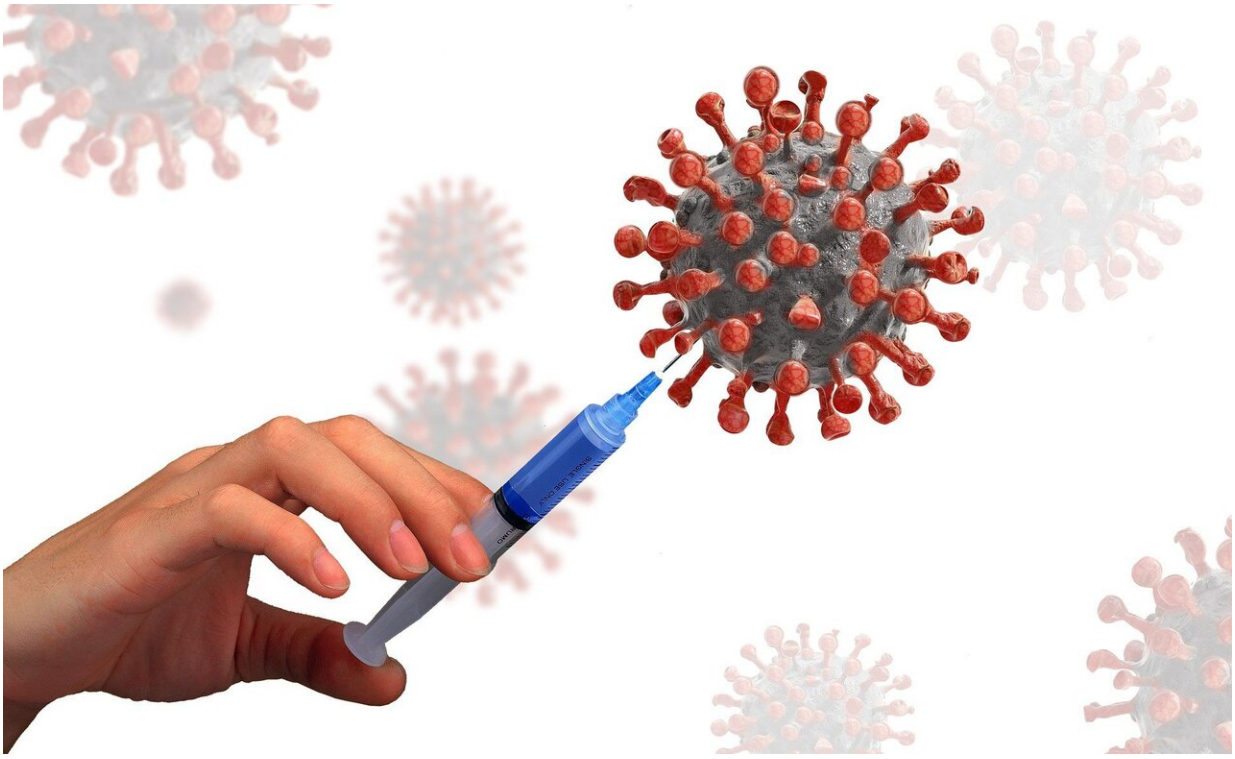

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The European Union's drug regulator said it received an application from Novavax to authorize the American biotechnology company's coronavirus vaccine, a request that could significantly boost the continent's vaccine supplies if it's granted.

In a statement on Wednesday, the European Medicines Agency said it had begun evaluating data submitted by Novavax for its two-dose vaccine. An expedited review process could produce a decision within weeks "if the data submitted are sufficiently robust and complete to show the efficacy, safety and quality of the vaccine," the agency said.

Novavax's COVID-19 vaccine is made using a different technology than others currently on the market, including those made by AstraZeneca and Johnson & Johnson, and the messenger RNA vaccines produced by Moderna and Pfizer-BioNTech.

Novavax's shot is made with lab-grown copies of the spike protein that coats the coronavirus, which then trigger an immune response.

In June, Maryland-based Novavax announced the vaccine had proven about 90% effective against symptomatic COVID-19 in a study of nearly 30,000 people in the United States and Mexico. It also worked against variants circulating in those countries at the time, the company said.

The company said side effects were mild and included tenderness at the injection site, headache, aches and pains, and fatigue.

To date, the European Medicines Agency has authorized the vaccines made by Pfizer-BioNTech, Moderna, AstraZeneca and Johnson & Johnson. It is currently reviewing vaccines made by China's Sinovac and France's Sanofi Pasteur, as well as Russia's Sputnik V.

Novavax said previously it would prioritize getting clearance in developing countries because its vaccine is easier to transport; Indonesia gave the green light earlier this month. The vaccine is pending authorization by the World Health Organization and countries that include the United Kingdom, Australia and Canada.

Europe, which had more than two thirds of the COVID-19 cases confirmed worldwide in the last week, is currently the epicenter of the pandemic. National authorities are considering reimposing lockdown restrictions and working to speed up immunization efforts.

In October, Novavax addressed concerns that a lack of raw materials and other issues had slowed production of its vaccine. The company said it planned to "achieve a capacity of 150 million doses per month by the end of the fourth quarter" through partnerships with Serum Institute of India, SK Bioscience in South Korea and Takeda in Japan, among others.