

European regulator recommends Pfizer shot for children 12-15

28 May 2021, by Frank Jordans and Maria Cheng



In this Tuesday, Feb. 23, 2021 file photo, a sign is pasted into an upper window at Pfizer manufacturing center in Puurs, Belgium. The European Union cemented its support for Pfizer-BioNTech and its novel COVID-19 vaccine technology, Saturday, May 8, 2021 by agreeing to a massive contract extension for a potential 1.8 billion doses through 2023. The new contract, which has the backing of the EU member states, will entail not only the production of the vaccines, but also making sure that all the essential components should be sourced from the EU. Credit: AP Photo/Virginia Mayo, File

The European Medicines Agency on Friday recommended that the use of the coronavirus vaccine made by Pfizer and BioNTech be expanded to children ages 12 to 15, a decision that offers younger and less at-risk populations across the continent access to a COVID-19 shot for the first time.

The Pfizer-BioNTech vaccine was the first one granted authorization across the European Union in December, when it was given the green light for use in anyone 16 and over. Since then, about 173 million doses have been administered in the EU, which is about three-quarters of all vaccine shots given so far in the 27-nation bloc.

"Extending the protection of a safe and effective vaccine in this younger population is an important step forward in the fight against this pandemic," Marco Cavaleri, head of health threats and vaccine strategy at the Amsterdam-based EMA, said.

The EU regulator authorized the vaccine for younger adolescents after receiving data from the United States showing it to be highly effective against infection. In a study involving 2,000 adolescents, none of those who received the vaccine got COVID-19, compared with 16 in a control group that received a placebo, Cavaleri said.

"The vaccine was well-tolerated, and the side effects in this age group were very much similar (to) what we've seen in young adults and not raising major concern at this point in time," he said.

The EMA decision needs to be rubber-stamped by the European Commission, and national regulators can decide whether the vaccine will be offered to children under 16 in each country.

The recommendation follows similar decisions by regulators in Canada and the U.S. last month, as rich countries slowly approach their vaccination targets for adults and look to immunize as many people as possible.

Researchers will continue to monitor the Pfizer-BioNTech vaccine's long-term protection and safety in study participants for another two years. Cavaleri acknowledged that rare adverse effects may not have been picked up in the relatively small study on which authorization was based.



In this Friday, April 23, 2021 file photo, European Commission President Ursula von der Leyen, second left, speaks with Pfizer CEO Albert Bourla, center right, during an official visit to the Pfizer pharmaceutical company in Puurs, Belgium. The European Union cemented its support for Pfizer-BioNTech and its novel COVID-19 vaccine technology on Saturday, May 8, 2021 by agreeing to a massive contract extension for a potential 1.8 billion doses through 2023. The new contract, which has the backing of the EU member states, will entail not only the production of the vaccines, but also making sure that all the essential components should be sourced from the EU. Credit: John Thys/Pool via AP, File

"Once the vaccine will be deployed, it will be important to continue monitoring the performance of the vaccine and to determine if there is any safety issue," he said, adding that recent months had shown Europe's reporting system is able to detect possible problems in vaccines.

The EMA last month added warnings about the possible risk of rare blood clots in people who had received a dose of vaccines made by AstraZeneca or [Johnson & Johnson](#), after some countries reported a very small number of the millions vaccinated had experienced rare blood clots.

Most COVID-19 vaccines worldwide have been authorized for adults, who are at higher risk of severe disease and death from the coronavirus. But vaccinating children of all ages could be critical to stopping outbreaks, since some research has shown older children may play a role in spreading

the virus even though they don't typically fall seriously ill with COVID-19.

In the U.S., children represent about 14% of the country's coronavirus cases and at least 316 have died, according to the American Academy of Pediatrics. Doctors have also identified a rare inflammatory syndrome in a very small proportion of children sickened by COVID-19.

Immunizing children against COVID-19 might also give authorities more confidence to reopen schools, as getting children to wear masks and engage in social distancing has been challenging at times.

But the World Health Organization has criticized rich countries for moving on to vaccinate their younger and less at-risk populations, saying that the extremely limited number of COVID-19 vaccines should instead be shared with poor countries so they too can protect their health workers and those most vulnerable.

"I understand why some countries want to vaccinate their children and adolescents, but right now I urge them to reconsider and to instead donate vaccines to COVAX," WHO chief Tedros Adhanom Ghebreyesus said earlier this month, referring to the U.N.-backed initiative to distribute vaccines fairly. Of the more than 1 billion COVID-19 shots administered globally, fewer than 2% have gone to poor countries.

Other vaccine makers also are studying whether their shots are safe and effective in children. Earlier this week, Moderna Inc. said its shot strongly protects children as young as 12; it said it would submit a request for emergency use authorization to the U.S. Food and Drug Administration next month. Another U.S. company, Novavax, has a COVID-19 vaccine in late-stage development and just began a study in 12- to 17-year-olds.

Both Moderna and Pfizer-BioNTech have been testing their vaccines in children from ages 6 months to 11; they get a lower dose than what teens and adults receive. China's Sinovac has also submitted early data to the country's regulators, hoping to prove its vaccine is safe in children as young as 3.

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