

# EU regulator evaluating if COVID vaccine booster is needed

September 6 2021

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In this Thursday, Sept. 2, 2021 file photo, a health worker prepares Pfizer vaccines during the national COVID-19 vaccination campaign in Pamplona, northern Spain. In a statement Monday Sept. 6, 2021, the European Medicines Agency says it has started an expedited evaluation on whether to recommend a booster dose of the coronavirus vaccine made by Pfizer-BioNTech. Credit: AP Photo/Alvaro Barrientos, File

The European Union's drug regulator said Monday that it has started an expedited evaluation on whether to recommend a booster dose of the coronavirus vaccine made by Pfizer-BioNTech.

The European Medicines Agency said in a statement that it's considering whether a third dose of the vaccine should be given six months after people age 16 and older have received two doses, "to restore protection after it has waned."

EMA's experts are carrying out an "accelerated assessment" of data submitted by Pfizer and BioNTech, including results from an ongoing trial in which about 300 healthy adults received a booster shot about six months after their second dose.

Pfizer has already submitted an application to the U.S. Food and Drug Administer for authorization of a third dose and the U.S. government said last month that boosters would likely be available in late September. Israel has already started administering booster doses and similar plans are under consideration in other countries for vulnerable populations, including Britain, France and Germany.

The World Health Organization has pleaded with rich countries not to use booster doses until at least the end of September, saying there is no scientific data that proves the shots are necessary. It says COVID-19 vaccines would be put to better use in developing countries, which have received fewer than 2% of the more than 5 billion doses administered.

Several studies have showed that protection from authorized COVID-19 vaccines against the highly infectious delta variant drops months after people have been immunized, but the shots still offer strong protection against severe disease, hospitalization and death.

The Amsterdam-based EMA said it expects to make a decision about

whether or not to recommend a third dose of the Pfizer vaccine in the next few weeks.

It said it was also reviewing the use of a third dose of the COVID-19 vaccines made by Pfizer-BioNTech and Moderna in people with weak immune systems. It said those people might need an extra dose "as part of their primary vaccination" programs.

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Citation: EU regulator evaluating if COVID vaccine booster is needed (2021, September 6)  
retrieved 19 November 2023 from

<https://medicalxpress.com/news/2021-09-eu-covid-vaccine-booster.html>

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