EUROPEAN MEDICINES AGENCY
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# EMA recommends authorisation of booster doses of Comirnaty from 12 years of age

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EMA's human medicines committee (CHMP) has recommended that a booster dose of the COVID-19 vaccine Comirnaty may be given where appropriate to adolescents from 12 years of age. Comirnaty is already authorised in the EU as a 2-dose primary course in adolescents[1] (as well as adults and children from 5 years of age) and a booster dose is currently authorised from 18 years of age.

The CHMP opinion follows an evaluation of interim safety and efficacy data from a clinical trial of a booster dose of the vaccine in those aged 16 and over, together with published literature and post authorisation data plus real-world evidence from the use of booster doses in young recipients in Israel.

Booster doses are given to vaccinated people (i.e. people who have completed their primary vaccination course) to restore protection after it has waned. The Committee considered that the available evidence was sufficient to conclude that the immune response to a booster dose in adolescents would be at least equal to that in adults. No new safety concerns were identified from the data available.

Further data are expected from studies and analyses in adolescents in the coming months. EMA will continue to monitor and evaluate the evidence and to update the product information or take other appropriate regulatory action as required.

The Agency's decision will support the national vaccination campaigns in those Member States that decide to offer booster vaccinations to adolescents. However, the decision on whether and when to offer boosters in this age group will need to take into account such factors as the spread and likely severity of the disease (especially with the Omicron variant) in younger persons, the known risk of side effects (particularly the very rare but serious complication of myocarditis) and the existence of other protective measures and restrictions. Just as with previous decisions on vaccination, it will thus be for the experts guiding the vaccination campaign in each Member State to advise on the optimum decision and timing for their country.

The CHMP opinion will now be forwarded to the European Commission, which will issue a final decision shortly.

Comirnaty is a vaccine for preventing COVID-19. It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein, known as the spike protein, naturally present in SARS-CoV-2, the virus that causes COVID-19. The vaccine works by preparing the body to defend itself against SARS-CoV-2.

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**Notes**

[1]A primary course of the vaccine has been authorised in adolescents aged 16 to 17 years since February 2021 and from 12 years of age since May 2021; in those Member States in which vaccination campaigns are most advanced, over 80% of 16 to 17 year olds have now completed their primary course [ECDC data]

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