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EMA evaluating data on booster dose of COVID-19 vaccine Comirnaty in adolescents

EMA has started evaluating an application for the use of a booster dose of Comirnaty (BioNTech/Pfizer's vaccine) in adolescents aged 12 to 15 years. An application in older adolescents aged 16 to 17 years is also ongoing.

Booster doses are given to vaccinated people (i.e. people who have completed their primary vaccination) to restore protection after it has waned. A booster dose of Comirnaty may currently be given in individuals 18 years of age and older.

EMA's human medicines committee (CHMP) will carry out an accelerated assessment of data submitted by the company that markets Comirnaty, including results from real world evidence from Israel. EMA will communicate the outcome of the assessment in due course.

Advice on how vaccinations should be given remains the prerogative of the national immunisation technical advisory groups guiding the vaccination campaigns in each EU Member State. National public health bodies may issue official recommendations on the use of booster doses, and on associated travel certification requirements, taking into account emerging effectiveness data and the limited safety data.

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. More information about the vaccine is available here.

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