3 May 2021
EMA/248495/2021

EMA starts evaluating use of COVID-19 vaccine Comirnaty in young people aged 12 to 15

EMA has started evaluating an application to extend the use of the COVID-19 vaccine Comirnaty to include young people aged 12 to 15.

Comirnaty is a vaccine for preventing COVID-19. It is currently authorised for use in people aged 16 and older. 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.

EMA's human medicines committee (CHMP) will carry out an accelerated assessment of data submitted by the company that markets Comirnaty, including results from a large ongoing clinical study involving adolescents from 12 years of age, in order to decide whether to recommend the extension of indication. The CHMP's opinion will then be forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.

EMA will communicate on the outcome of its evaluation, which is expected in June unless supplementary information is needed.

Comirnaty was first authorised in the EU in December 2020. More information about the vaccine is available.

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