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EMA evaluating the use of COVID-19 Vaccine Moderna in young people aged 12 to 17

EMA has started evaluating an application to extend the use of the COVID-19 Vaccine Moderna to include young people aged 12 to 17.

COVID-19 Vaccine Moderna is a vaccine for preventing COVID-19. It is currently authorised for use in people aged 18 and older. It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein known as the spike protein, which is 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 in the application, including results from a large ongoing clinical study involving adolescents from 12 to 17 years of age. This study was carried out in accordance with the paediatric investigation plan (PIP) for COVID-19 Vaccine Moderna, which was agreed by EMA's Paediatric Committee (PDCO).

The CHMP's opinion on extending the use of the vaccine, together with any requirements for further studies and additional safety monitoring, 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 the outcome of its evaluation, which is expected in July unless supplementary information is needed.

COVID-19 Vaccine Moderna has been authorised in the EU since January 2021. More information about the vaccine is available.

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