



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA starts evaluating use of COVID-19 vaccine Comirnaty in children aged 5 to 11

EMA has started evaluating an application to extend the use of BioNTech/Pfizer's COVID-19 vaccine, Comirnaty, to children aged 5 to 11.

Comirnaty is a vaccine for preventing COVID-19, currently authorised for use in people aged 12 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 review the data on the vaccine, including results from an ongoing clinical study involving children aged 5 to 11, in order to decide whether to recommend extending its use. The CHMP's opinion will then be forwarded to the European Commission, which will issue a final decision.

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

Comirnaty was first authorised in the EU in December 2020. More [information about the vaccine](#) is available on the EMA website.

