REPUBLIC OF CYPRUS
MINISTRY OF HEALTH
Press release

EMA starts evaluating use of COVID-19 vaccine Spikevax in children aged 6 to 11

EMA has started evaluating an application to extend the use of Moderna's COVID-19 vaccine, Spikevax, to children aged 6 to 11.

Spikevax is a vaccine for preventing COVID-19, currently authorised for use in people aged 12 years 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 6 to 11, in order to decide whether to recommend extending its use. The timeline of any evaluation always depends on the data that are submitted. The current timeline for evaluation foresees an opinion in approximately 2 months, unless supplementary information or analysis is needed. This is a shortened timetable compared to similar types of reviews outside of a pandemic.

EMA will communicate on the outcome of its evaluation. The CHMP's opinion will then be forwarded to the European Commission, which will issue a final decision.

Spikevax was first authorised in the EU in January 2021. More information about the vaccine is available on the EMA website.

Ministry of Health
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