



**REPUBLIC OF CYPRUS
MINISTRY OF HEALTH**

EMA recommends approval of Spikevax for children aged 6 to 11

EMA's human medicines committee (CHMP) has recommended granting an extension of indication for the COVID-19 vaccine Spikevax to include use in children aged 6 to 11. The vaccine, developed by Moderna, is already approved for use in adults and children aged 12 and above.

The dose of Spikevax in children from 6 to 11 years of age will be lower than that used in people aged 12 and above (50 µg compared with 100 µg). As in the older age group, the vaccine is given as two injections in the muscles of the upper arm, four weeks apart.

A main study in children aged 6 to 11 showed that the immune response to the lower dose of Spikevax (50 µg) was comparable to that seen with the higher dose (100 µg) in 18- to 25-year-olds, as measured by the level of antibodies against SARS-CoV-2.

The most common side effects in children aged 6 to 11 are similar to those in people aged 12 and above. They include pain, redness and swelling at the injection site, tiredness, headache, chills, nausea, vomiting, swollen or tender lymph nodes under the arm, fever and muscle and joint pain. These effects are usually mild or moderate and improve within a few days of vaccination.

The evidence indicates that the efficacy and safety of Spikevax in children aged 6 to 11 are similar to those in adults. The CHMP therefore concluded that the benefits of Spikevax in this age group outweigh the risks, particularly in those with conditions that increase the risk of severe COVID-19.

The safety and efficacy of the vaccine in both children and adults will continue to be monitored closely as it is used in vaccination campaigns in EU Member States through the EU pharmacovigilance system and ongoing and additional studies conducted by the company and by European authorities.

The CHMP will now send its recommendation to the European Commission, which will issue a final decision.

How Spikevax works

Spikevax works by preparing the body to defend itself against COVID-19. It contains a molecule called messenger RNA (mRNA) which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with the SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.

The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

Where to find more information



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The product information approved by the CHMP for Spikevax contains prescribing information for healthcare professionals, a package leaflet for members of the public and details of conditions of the vaccine's authorisation.

An assessment report, with details of EMA's evaluation of use of Spikevax in young children, will be published on the EMA website.

The studies in children were carried out in accordance with Spikevax's paediatric investigation plan (PIP), which was agreed by EMA's Paediatric Committee (PDCCO). Clinical trial data submitted by the company in the application for the paediatric extension of indication will be published on the Agency's clinical data website in due course.

More information is available in an overview of the vaccine in lay language, including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.

Monitoring the safety of Spikevax

In line with the EU's safety monitoring plan for COVID-19 vaccines, Spikevax is closely monitored and subject to several activities that apply specifically to COVID-19 vaccines. Although large numbers of people have already received COVID-19 vaccines, certain side effects may still emerge as more and more people receive the vaccine.

The company that markets this vaccine in the EU is required to provide regular updates and conduct studies to monitor the safety and effectiveness of the vaccine as it is used by the public. Authorities also conduct additional studies to monitor the vaccine.

These measures allow regulators to swiftly assess data emerging from a range of different sources and take appropriate regulatory action to protect public health if needed.

Ministry of Health

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