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EMA recommends approval of Comirnaty and Spikevax COVID-19 vaccines for children from 6 months of age

EMA's human medicines committee (CHMP) has recommended extending the use of Comirnaty and Spikevax targeting the original strain of SARS-CoV-2. The Committee recommended including the use in children aged 6 months to 4 years for Comirnaty and use in children aged 6 months to 5 years for Spikevax. Comirnaty and Spikevax are already approved in both adults and children aged from 5 and 6 years, respectively.

Compared to the doses for already authorised age groups,[1] the doses of both vaccines in these new younger age groups will be lower. In children from 6 months to 4 years of age, Comirnaty can be given as primary vaccination consisting of three doses (of 3 micrograms each); the first two doses are given three weeks apart, followed by a third dose given at least 8 weeks after the second dose. In children from 6 months to 5 years of age, Spikevax can be given as primary vaccination consisting of two doses (of 25 micrograms each), four weeks apart. For children within these age groups, both vaccines are given as injections in the muscles of the upper arm or the thigh.

For Comirnaty, a main study in children from 6 months to 4 years of age showed that the immune response to the lower dose of Comirnaty (3 micrograms) was comparable to that seen with the higher dose (30 micrograms) in 16- to 25-year-olds. For Spikevax, a main study in children from 6 months to 5 years of age showed that the immune response to the lower dose of Spikevax (25 micrograms) was comparable to that seen with the higher dose (100 micrograms) in 18- to 25-year-olds. Both studies evaluated the immune response triggered by the vaccines by measuring the level of antibodies against SARS-CoV-2.

The most common side effects for both vaccines, in children aged from 6 months to 4 or 5 years, were comparable to those seen in older age groups. Irritability, sleepiness, loss of appetite, rash and tenderness at the injection site were also common side effects in children aged 6 to 23 months with Comirnaty, while irritability, crying, loss of appetite and sleepiness were common side effects in children aged 6 to 36 months with Spikevax. For both vaccines, these effects were usually mild or moderate and improved within a few days of vaccination.

[1] For a primary vaccination course with Comirnaty, adults and adolescents from the age of 12 are given 30 micrograms per dose; children aged 5 to 11 years are given 10 micrograms per dose. For a primary vaccination course with Spikevax, adults and adolescents from the age of 12 are given 100 micrograms per dose; children aged 6 to 11 years are given 50 micrograms per dose.

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The CHMP therefore concluded that the benefits of Comirnaty and Spikevax in children aged from 6 months to 4 and 5 years, respectively, outweigh the risks.

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

The originally authorised vaccines, Comirnaty and Spikevax, are both effective at preventing severe disease, hospitalisation and death associated with COVID-19 and continue to be used within vaccination campaigns in the EU, in particular for primary vaccinations. National authorities in the EU Member States will determine who is recommended to be vaccinated and when, taking into account factors such as infection and hospitalisation rates, the risk to vulnerable populations, vaccination coverage and vaccine availability.

The CHMP recommendations will now be sent to the European Commission, which will issue final decisions applicable in all EU Member States.

How the vaccines work

Both vaccines work by preparing the body to defend itself against COVID-19. Each vaccine 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 after vaccination.

Where to find more information

The product information approved by the CHMP for Comirnaty and Spikevax contains prescribing information for healthcare professionals and a package leaflet for members of the public.

Assessment reports, with details of EMA's evaluations of the use of Comirnaty and Spikevax in children from 6 months of age, will be published on the EMA website.

The studies in children were carried out in accordance with the paediatric investigation plan (PIP) for each vaccine, which was agreed by EMA's Paediatric Committee (PDCO). Clinical trial data submitted by the companies in their applications for the paediatric extensions of indication will be published on the Agency's clinical data website in due course.

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

Monitoring the safety

In line with the EU's safety monitoring plan for COVID-19 vaccines, Comirnaty and Spikevax are closely monitored and subject to several activities that apply specifically to COVID-19 vaccines. Independent studies of COVID-19 vaccines coordinated by EU authorities will give more information on the vaccines' long-term safety and benefits in the general population.

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.