Communication of the President of the Office of 20 October 2022 on the recommendation of the Committee for Medicinal Products for Human Use (CHMP) EMA on the use of COVID-19 Comirnaty and Spikevax vaccines in children aged 6 months and older.

Submitted by m.koszewski on Thu, 20/10/2022 - 08:45

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EMA’s human medicines committee (CHMP) has recommended extending the use of Comirnaty and Spikevax, which both target the original strain of SARS-CoV-2, to include 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 already authorised age groups, the dose of both vaccines in these new younger age groups will be lower. In children from 6 months to 4 years of age, Comirnaty should 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 aged from 6 months to 4 years 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 aged 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.

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 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 recommendation will now be sent to the European Commission, which will issue a final decision applicable in all EU Member States.

More information available on the website: https://www.ema.europa.eu/en/news/ema-recommends-approval-comirnaty-spikevax-covid-19-vaccines-children-6-months-age [1]

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Links
[1] https://www.ema.europa.eu/en/news/ema-recommends-approval-comirnaty-spikevax-covid-19-vaccines-children-6-months-age