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Comirnaty COVID-19 vaccine: EMA recommends approval for children aged 5 to 11

EMA's human medicines committee (CHMP) has recommended granting an extension of indication for the COVID-19 vaccine Comirnaty to include use in children aged 5 to 11. The vaccine, developed by BioNTech and Pfizer, is already approved for use in adults and children aged 12 and above.

In children from 5 to 11 years of age, the dose of Comirnaty will be lower than that used in people aged 12 and above (10 µg compared with 30 µg). As in the older age group, it is given as two injections in the muscles of the upper arm, three weeks apart.

A main study in children aged 5 to 11 showed that the immune response to Comirnaty given at a lower dose (10 µg) in this age group was comparable to that seen with the higher dose (30 µg) in 16- to 25-year-olds (as measured by the level of antibodies against SARS-CoV-2). The efficacy of Comirnaty was calculated in almost 2,000 children from 5 to 11 years of age who had no sign of previous infection. These children received either the vaccine or a placebo (a dummy injection). Of the 1,305 children receiving the vaccine, three developed COVID-19 compared with 16 out of the 663 children who received placebo. This means that, in this study, the vaccine was 90.7% effective at preventing symptomatic COVID-19 (although the true rate could be between 67.7% and 98.3%).

The most common side effects in children aged 5 to 11 are similar to those in people aged 12 and above. They include pain at the injection site, tiredness, headache, redness and swelling at the site of injection, muscle pain and chills. These effects are usually mild or moderate and improve within a few days of vaccination.

The CHMP therefore concluded that the benefits of Comirnaty in children aged 5 to 11 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.