

## US health authority says Moderna vaccine effective in under-fives

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US health authorities confirmed on Friday that data provided by drugmaker Moderna on the efficacy of its COVID-19 vaccine among very young children were accurate, ahead of a decision next week on whether to authorize two inoculations against the virus in kids aged six months to five years.



The Food and Drug Administration (FDA), which independently analyzed data from clinical trials conducted by Moderna, said vaccine efficacy against symptomatic cases of COVID-19 was 51 percent in babies aged six months to less than two years old, and 37 percent in children aged two to five years.

The figures are lower than those recorded during clinical trials on adults, but that is only because the trials for the very <u>young children</u> were conducted during a wave linked to the Omicron variant, according to the FDA.

"Although the VE (vaccine efficacy) ... in children six months to five years is lower than that observed in the pivotal adult or older pediatric studies, it is highly consistent with real-world vaccine effectiveness observed against Omicron in adults," the FDA said in a statement.

Even though Moderna's vaccine has proven less effective against the Omicron variant, it remains very good at protecting against severe cases of the disease, the FDA pointed out.

That is why the FDA concluded that the Moderna data "support the administration" of the vaccine in two doses of 100 micrograms each in adolescents aged 12 to 17, 50 micrograms for six to 11 year olds, and 25 micrograms in children aged six months to five years.

In the United States, Moderna's vaccine is currently only authorized for people aged 18 and older.

The latest document, stretching to more than 100 pages and published by the US agency, will serve as a basis for the authorization discussions next week.

An advisory committee of experts must meet over two days to study the



request for authorization of the vaccine, as well as that of Pfizer, and make its recommendation.

The FDA is expected to publish its independent analysis of data from Pfizer early next week.

Pfizer has filed an application for authorization for children aged six months to four years, although its vaccine will be administered in three doses.

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