

EU to decide on Moderna for kids within 2 months

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The EU's drug watchdog said on Wednesday it expects to decide within two months whether to approve Moderna's COVID vaccine for children aged six to 11.



The move comes despite several countries including France and Germany advising against use of the jab in people under 30 due to a small risk of heart inflammation.

The US biotechnology company announced on Tuesday that it had applied to the European Medicines Agency (EMA) for authorisation for <u>younger people</u>.

"The current timeline for evaluation foresees an opinion in approximately two months, unless supplementary information or analysis is needed," the Amsterdam-based EMA said in a statement.

"This is a shortened timetable compared to similar types of reviews outside of a pandemic."

Moderna's jab is currently approved for people 12 and older in Europe.

In October, Moderna reported positive results from its <u>clinical trials</u> for children aged six to 11, with the vaccine eliciting a strong immune response with "robust" levels of neutralising antibodies detected.

But concerns about the rare side effect of myocarditis, or inflammation of the heart muscle, in adolescents and <u>young people</u> have led Germany and France to recommend against its use in people aged under 30.

Moderna said the application for <u>younger children</u> in the 27-nation EU was its "first submission for the use of our vaccine in this age group".

The firm had announced in late October that it would delay its application for US approval for kids six to 11 until the FDA had completed its review for the 12-17 age group, which could take until January.



The EMA has separately said it expects to decide in December whether to authorise the Pfizer vaccine for children aged five to 11. Similar rare side effects have been reported with the Pfizer jab.

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