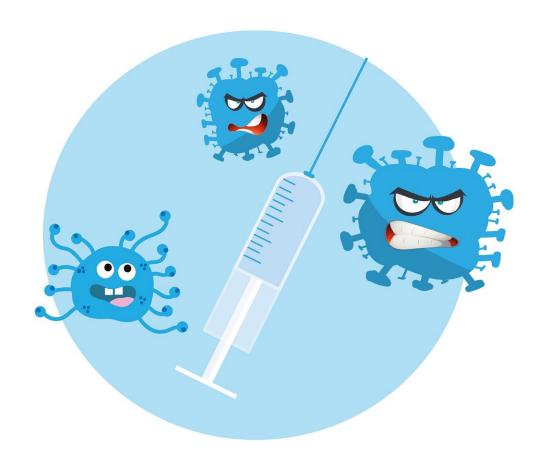


Moderna seeks EU approval of Covid vaccine for kids aged 6-11

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Moderna has applied to the European Union's medicine regulator for approval of its COVID-19 vaccine for children aged six to 11, the US biotechnology company announced Tuesday.

The dosage for the two injections administered four weeks apart has been adjusted to 50 micrograms, compared with the 100 micrograms for shot recipients in older age groups.

"We are pleased to announce the submission of this variation to the EMA," the European Medicines Agency, Moderna's chief executive Stephane Bancel said in a statement.

"This marks our first submission for the use of our vaccine in this age group."

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

But several countries, including France on Monday, advised against its use in people below a certain age (30 years old in France), because of concerns about the risks of myocarditis, or inflammation of the heart muscle.

The rare side effect has been detected in adolescents and <u>young adults</u>, especially males.

Late last month, 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 neutralizing antibodies detected.

The EMA is also reviewing data from Pfizer, which has filed for European approval of its own vaccine for children aged five to 11. That review could be concluded in December, the agency reported last week.



Pfizer's <u>vaccine</u> is already licensed for use in <u>young children</u> in the United States, where Moderna's is only approved for those 18 and up.

Moderna 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.

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