

Moderna COVID-19 vaccine approved by MHRA in 12-17 year olds

Press release

The UK regulator has confirmed the vaccine is safe and effective in this age group.



An extension to the current UK approval of the Spikevax vaccine (formerly COVID-19 Vaccine Moderna) that allows its use in 12- to 17-year-olds has today been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA).

This Conditional Marketing Authorisation (CMA) extension granted by the MHRA is valid in Great Britain only and was approved via the [European Commission \(EC\) Decision Reliance Route](#). This is when the marketing authorisation application made by the company references the decision made by the EMA's Committee for Medicinal Products for Human Use (CHMP).

Spikevax is authorised in children aged 12-17 years in Northern Ireland under the CMA extension granted by the European Medicines Agency on 23 July 2021.

Dr June Raine, MHRA Chief Executive said:

I am pleased to confirm that that the COVID-19 vaccine made by Moderna has now been authorised in 12-17 year olds. The vaccine is safe and effective in this age group.

We have in place a comprehensive safety surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this surveillance will include the 12- to 17-year age group.

It is for the Joint Committee on Vaccination and Immunisation

(JCVI) to advise on whether this age group should be vaccinated with the COVID-19 vaccine made by Moderna as part of the deployment programme.

Background

- The Spikevax vaccine is already [authorised in adults aged 18 years and over](#).
- No new side effects were identified and the safety data in children was comparable with that seen in young adults. As in young adults, the majority of adverse events were mild to moderate and relating to reactogenicity, such as a sore arm or tiredness.
- More information can be found in the [Product Information](#).

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