

# MHRA approves the Moderna COVID-19 vaccine 'Spikevax' for use in 6 to 11-year olds

News story

Use of the Moderna COVID-19 vaccine or 'Spikevax' has been approved for 6 to 11s after meeting the required safety, quality and effectiveness standards



The Medicines and Healthcare products Regulatory Agency (MHRA) has approved an update to the current UK approval of the Moderna COVID-19 Vaccine, or 'Spikevax', that allows its use in Great Britain (GB) in 6 to 11 year-olds.

This approval takes into account the extension to use in children aged 6 to 11 years already approved by the European Medicines Agency on 2 March 2022, as the original GB licence for Spikevax in adults was approved by relying on the EU decision.

Spikevax is authorised in children aged 6 to 11 in Northern Ireland under the update granted by the European Medicines Agency on 2 March.

**Dr June Raine, MHRA Chief Executive, said:**

I am pleased to confirm that that the COVID-19 vaccine made by Moderna, 'Spikevax', has now been authorised in Great Britain in 6 to 11 year olds. The vaccine is safe and effective in this age group.

We have in place a comprehensive surveillance strategy for monitoring the safety of all UK-approved COVID-19 vaccines and this surveillance includes those aged 6 to 11.

It is for the Joint Committee on Vaccination and Immunisation (JCVI) to advise in due course on whether 6 to 11s should be

offered vaccination with the COVID-19 vaccine made by Moderna as part of the deployment programme.

## Notes to editors

- The Spikevax vaccine was authorised [in adults aged 18 years and over](#) on 8 January 2021, and for those [aged 12-17](#) on 17 August 2021
- No important new side effects were identified in those aged 12-17 and the safety data in children were comparable with those 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 [Spikevax Product Information](#)
- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines, vaccines and medical devices in the UK. All MHRA's work is underpinned by robust and fact-based judgements to ensure that the benefits outweigh any risks.

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