Novavax COVID-19 vaccine approved for 12 to 17s by MHRA

News story

The Medicines and Healthcare products Regulatory Agency has concluded that Nuvaxovid is safe and effective in this age group

Nuvaxovid, the COVID-19 vaccine developed by Novavax, has today been granted an extension to its existing UK approval, for 12- to 17-year-olds. This extension has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA).

The approval follows a review of the safety, quality and effectiveness of the vaccine in this age group, and expert advice from the government's independent scientific advisory body, the Commission on Human Medicines.

Dr June Raine, MHRA Chief Executive, said:

> Following our review of the safety, quality and effectiveness of Nuvaxovid in 12- to 17-year-olds, I am pleased to confirm that that the vaccine has now been authorised in this age group. In reaching this decision, we have taken advice from the government's independent scientific advisory body, the Commission on Human Medicines.

The 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).

Nuvaxovid is authorised in children aged 12-17 years in Northern Ireland under the CMA extension granted by the European Medicines Agency on 1 July 2022.

Notes to Editor

1. Nuvaxovid was authorised for use by the MHRA for those aged 18 and over on 3 February 2022.

2. As of 26 August 2022, Nuvaxovid has not been deployed in the UK's COVID-19 vaccination programme. The Joint Committee on Vaccination and Immunisation (JCVI) determines which vaccines are deployed, and which age groups are offered a vaccination.

3. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. The MHRA is an executive agency of the Department of Health and Social Care.

4. The Commission on Human Medicines (CHM) advises ministers and the MHRA on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care.
5. More information can be found in the product information.

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