

Novavax today announced the submission of a request to the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) to expand the conditional marketing authorization (CMA) of Nuvaxovid™ (NVX-CoV2373) COVID-19 vaccine ▼ as a homologous and heterologous booster dose for individuals aged 18 and over.

This request for expanded CMA is supported by data from Novavax' [Phase 2 trial](#) conducted in Australia, from a separate Phase 2 trial conducted in South Africa, and from the UK-sponsored COV-BOOST trial. As part of the Phase 2 trials, a single booster dose of Nuvaxovid was administered to healthy adult participants approximately six months after their primary two-dose vaccination series of Nuvaxovid. The third dose produced increased immune responses comparable to or exceeding levels associated with protection in Phase 3 clinical trials. In the COV-BOOST trial, Nuvaxovid induced a robust antibody response when used as a heterologous third booster dose.

In the Novavax-sponsored trials, following the booster, local and systemic reactions were generally short-lived with a median duration of approximately two days. The incidence of Grade 3 or higher events remained relatively low. Safety reporting of reactogenicity events showed an increasing incidence across all three doses of Nuvaxovid, reflecting the increased immunogenicity seen with a third dose. Medically attended adverse events, potentially immune-mediated medical conditions, and severe adverse events occurred infrequently following the booster dose and were balanced between vaccine and placebo groups.

The MHRA granted CMA in [February 2022](#) for Nuvaxovid's use in individuals aged 18 and over and Novavax filed for expanded CMA for use in adolescents aged 12 through 17 in [April 2022](#).

### **Authorization in the U.S.**

The Novavax COVID-19 vaccine (NVX-CoV2373) has not yet been authorized for use in the U.S. and the trade name Nuvaxovid™ has not yet been approved by the U.S. Food and Drug Administration (FDA). The U.S. FDA's Vaccines and Related Biological Products Advisory Committee will review the Novavax COVID-19 vaccine for active immunization against SARS-CoV-2 during a [meeting](#) scheduled for June 7, 2022.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. If you are concerned about an adverse event, it should be reported on a Yellow Card. Reporting forms and information can be found at <https://coronavirus-yellowcard.mhra.gov.uk/> or search for MHRA Yellow Card in the Google Play or Apple App Store. When reporting please include the vaccine brand and batch/Lot number if available.

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<https://ir.novavax.com/Novavax-Files-in-the-United-Kingdom-for-Expanded-Conditional-Marketing-Authorization-of-COVID-19-Vaccination-as-a-Booster-in-Adults-Aged-18-and-Over>