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## Covid-19: UK approves Novavax's protein based vaccine

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The UK's regulator has approved Novavax's covid-19 vaccine that uses an established technology and so may prove attractive to people who are reluctant to be vaccinated.

Nuvaxovid is the fifth covid vaccine authorised by the Medicines and Healthcare Products Regulatory Agency and the first protein based vaccine for the UK. It was approved by the European Medicines Agency in December.

At the start of the pandemic there was much excitement about the Novavax vaccine, but its development and approval has been beset by delays.<sup>1</sup>

A phase III trial involving 15 000 people in the UK showed the vaccine to be 89.7% effective at preventing symptomatic disease caused by the original Wuhan virus and the alpha variant.<sup>2</sup> A study conducted in the US and Mexico with almost 30 000 people showed that the vaccine offers 90.4% overall efficacy against illness and 100% efficacy against serious disease. The incidence of serious adverse events was low in both studies.

A recent phase II study, published as a preprint and not peer reviewed, suggests that its protection holds up much better against omicron than that of most other vaccines.<sup>3</sup> The vaccine is stable in a refrigerator at 2-8°C, making it easy to distribute.

The MHRA approval authorises the use of the vaccine in people aged 18 and over for a first and second dose. The manufacturer said it will shortly be applying for approval for it to be used as a booster and for adolescents.

In August 2020 the UK government agreed to buy 60 million doses of the vaccine. The Joint Committee on Immunisation and Vaccination must still decide how the vaccine will be used as part of the covid vaccination programme.

Paul Heath, principal investigator of the UK arm of the Novavax vaccine trial and director of the Vaccine Institute at St George's University of London, told a Science Media Centre briefing that although 84% of people in the UK had now had two doses of a covid vaccine, it could still have an important role. "Anecdotally we believe there are people out there who have been waiting for a vaccine that has been developed with a more traditional platform."

He added, "The vaccine may also be more acceptable to pregnant women, as it uses the same technology as the pertussis or influenza vaccines that they already receive routinely."

The vaccine uses the full length spike protein. Filip Dubovsky, chief medical officer at Novavax, told the briefing that the vaccine contains antibody targets that are common to a wide range of covid variants.

"It broadens the immune response. It generates high levels of neutralising antibodies," he said.

Commenting on the approval, Clive Dix, former chair of the UK Vaccine Taskforce, said, "This is excellent news as the clinical data on this vaccine is excellent and the strong cellular response should make this an excellent vaccine for boosting next winter. Not only do we expect a strong durable response but also good stability at fridge temperature so it can be rolled out with the flu vaccine next winter as part of the winter campaign."

He added, "This should replace the need to buy more Pfizer and Moderna vaccines and save the UK government a considerable amount of money."

Peter English, a retired consultant in communicable disease control, former editor of *Vaccines in Practice*, and past chair of the BMA's public health medicine committee, said, "The more alternative vaccines there are the better, both for resilience reasons and because it allows us to see which vaccines, or combinations, are most effective in the short and long terms."

1 Tinari S, Riva C. Covid-19: Whatever happened to the Novavax vaccine? *BMJ* 2021;375:n2965. doi: 10.1136/bmj.n2965 pmid: 34880071

2 Mallory R, Formica N, Pfeiffer S, et al. Immunogenicity and safety following a homologous booster dose of a SARS-CoV-1 recombinant spike protein vaccine (NVX-CoV2373): a phase 2 randomized placebo controlled trial. *MedRxiv*. doi: 10.1101/2021.12.23.21267374.

3 Heath PT, Galiza EP, Baxter DN, et al. 2019nCoV-302 Study Group. Safety and efficacy of NVX-CoV2373 Covid-19 vaccine. *N Engl J Med* 2021;385:1172-83. doi: 10.1056/NEJMoa2107659 pmid: 34192426

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