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EMA recommends approval of adapted Nuvaxovid COVID-19 vaccine targeting Omicron XBB.1.5

EMA's human medicines committee (CHMP) has recommended authorising an adapted Nuvaxovid vaccine targeting the Omicron XBB.1.5 subvariant of the SARS-CoV-2 virus.

The vaccine, known as Nuvaxovid XBB.1.5, is to be used for preventing COVID-19 in adults and children from 12 years of age.

In line with previous recommendations by EMA and the European Centre for Disease Prevention and Control (ECDC), adults and adolescents from 12 years of age who require vaccination should have a single dose, irrespective of their COVID-19 vaccination history.

In its decision to recommend the authorisation, the CHMP assessed laboratory data showing that the adapted vaccine is able to trigger an adequate immune response against XBB.1.5. The Committee also considered data from a study in previously vaccinated adults showing that when Nuvaxovid was adapted to target another related strain, Omicron BA.5, it was able to trigger a strong immune response against this strain. Based on these data, the Committee concluded that Nuvaxovid XBB.1.5 is expected to trigger an adequate immune response against XBB.1.5.

The safety profile of Nuvaxovid XBB.1.5 is expected to be similar to that of the originally authorised Nuvaxovid. This was also supported by clinical data available with the version of the vaccine targeting Omicron BA.5. The most common side effects with Nuvaxovid XBB.1.5 are pain and tenderness at the injection site, tiredness, headache, muscle pain and feeling generally unwell.

EMA has sent the CHMP's recommendation to the European Commission for an EU-wide legally binding decision.

Targeting Omicron XBB.1.5

COVID-19 vaccines are adapted so that they better match the circulating variants of the SARS-CoV-2 virus.

This vaccine was developed to target Omicron XBB in line with recommendations from EMA's Emergency task force (ETF) as well as other international regulators and the World Health Organization.

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As Omicron XBB.1.5 is closely related to other currently circulating variants, the vaccine is expected to help maintain optimal protection against COVID-19 caused by these other variants as well as Omicron XBB.1.5.

As with other COVID-19 vaccines, national authorities in EU Member States will determine how to use this vaccine in national vaccination campaigns, taking into account factors such as infection and hospitalisation rates, the risk to vulnerable people and vaccine availability.

How the vaccine works

Adapted vaccines work in the same way as the original vaccines.

This adapted vaccine works by preparing the body to defend itself against COVID-19. It contains a version of the spike protein of the Omicron XBB.1.5 subvariant, which has been produced in the laboratory. It also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system will identify the protein in the vaccine as foreign and produce natural defences — antibodies and T cells — against it.

If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on its surface and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, preventing its entry into the body's cells and destroying infected cells.

Nuvaxovid was first authorised in the EU in December 2021. Adapted versions of Nuvaxovid targeting the Omicron variant BA.5 were developed but not submitted for marketing authorisation.