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

EMA's human medicines committee (CHMP) has recommended authorising an adapted Spikevax vaccine targeting the Omicron XBB.1.5 subvariant.

The vaccine — known as Spikevax XBB.1.5 — is to be used for preventing COVID-19 in adults and children from 6 months of age.

In line with previous recommendations by EMA and the European Centre for Disease Prevention and Control (ECDC), adults and children from 5 years of age who require vaccination should have a single dose, irrespective of their COVID-19 vaccination history. Children from 6 months to 4 years of age may have one or two doses depending on whether they have completed a primary vaccination course or have had COVID-19.

In its decision to recommend the authorisation, the CHMP considered all the available data on Spikevax and its other adapted vaccines. In addition, the committee assessed laboratory data showing that the adapted vaccine is able to trigger an adequate immune response against XBB.1.5.

The CHMP also considered data from a study in which adults were given Spikevax XBB.1.5 as a booster. The study showed that the vaccine produced an immune response against the Omicron XBB.1.5 subvariant, as measured by a rise in the level of antibodies against this strain. The vaccine also produced an immune response against a number of other strains of the virus that causes COVID-19, including the currently circulating Omicron XBB.1.16 subvariant.

EMA will now send 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.

This vaccine was developed to target Omicron XBB in line with recommendations from EMA and the ECDC as well as other international regulators and the World Health Organization.

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.

Since the first authorisation of Spikevax, authorities have gained extensive knowledge about the safety of the vaccine. Side effects are typically mild and short-lived. They include redness, pain and swelling at the injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea (feeling sick) and vomiting. More serious side effects may occur rarely.

As with other COVID-19 vaccines, national authorities in the 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 vaccine contains a molecule called mRNA which has instructions for making the spike protein of the Omicron XBB.1.5 subvariant. The spike protein is a protein on the surface of the virus which the virus needs to enter the body's cells and can differ between variants of the virus.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognise this protein as foreign and activate natural defences — antibodies and T cells — against them.

If, later on, the vaccinated person comes into contact with the virus, 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.

Spikevax was first authorised in the EU in January 2021, with adapted versions targeting the Omicron BA.1 and BA.4-5 subvariants obtaining further authorisations in September 2022 and October 2022, respectively.