Communication of the President of the Office, of the 14th of September 2023, on the recommendation of the CHMP Committee (EMA) for the marketing authorization of the adapted Spikevax vaccine against Covid-19, targeting the Omicron subvariant XBB.1.5.

Wysłane przez m.koszewski w Czw, 14/09/2023 - 21:14

Grzegorz Cessak

Communication of the President of the Office, of the 14th of September 2023, on the recommendation of the CHMP Committee (EMA) for the marketing authorization of the adapted Spikevax vaccine against Covid-19, targeting the Omicron subvariant 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 [1] 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.

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 [2] 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.

More information available on the website: https://www.ema.europa.eu/en/news/spikevax-ema-recommends-approval-adapted-covid-19-vaccine-targeting-omicron-xbb15 [3]

Grzegorz Cessak

President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Odnośniki
[1] https://www.ema.europa.eu/en/news/ema-ecdc-statement-updating-covid-19-vaccines-target-new-sars-cov-2-virus-variants
[2] https://www.ema.europa.eu/en/documents/other/ecdc-ema-statement-updating-covid-19-vaccines-composition-new-sars-cov-2-virus-variants_en.pdf
[3] https://www.ema.europa.eu/en/news/spikevax-ema-recommends-approval-adapted-covid-19-vaccine-targeting-omicron-xbb15