# Communication of the President of the Office, of the 30th of August 2023, on the EMA's recommendation for marketing authorization of Comirnaty's adapted vaccine against Omicron subvariant XBB.1.5 for adults and children 6 months and older.

Wysłane przez m.koszewski w Śro, 30/08/2023 - 14:37


Grzegorz Cessak

**Communication of the President of the Office, of the 30th of August 2023, on the EMA's recommendation for marketing authorization of Comirnaty's adapted vaccine against Omicron subvariant XBB.1.5 for adults and children 6 months and older.**

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

The vaccine – known as Comirnaty Omicron 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 three 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 Comirnaty and its other adapted vaccines, including data on safety, efficacy and immunogenicity (how well they trigger immune responses). In addition, the Committee assessed new laboratory data showing a strong response of the adapted vaccine against XBB.1.5 and related strains of the virus that causes COVID-19.

More data on emerging variants are expected and the Committee will assess these data when they are available.

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 Comirnaty, authorities have gained extensive knowledge about the safety of the vaccine. Side effects are typically mild and short-lived. They include headache, diarrhoea, joint and muscle pain, tiredness, chills, fever and pain or swelling at the injection site.

More serious side effects may occur rarely.

EMA will now send the CHMP's recommendation to the European Commission for an EU-wide legally binding decision.

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.

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

This vaccine contains molecules called mRNA which have 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 proteins. 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.

Comirnaty was first authorised in the EU in December 2020, with adapted versions targeting BA.1 and BA.4-5 strains obtaining further authorisation in September 2022.

More information available on the website: https://www.ema.europa.eu/en/news/comirnaty-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

**Źródłowy URL:** https://archiwum.urpl.gov.pl/pl/node/7800

**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/comirnaty-ema-recommends-approval-adapted-covid-19-vaccine-targeting-omicron-xbb15