Communication of the President of the Office of 6 December 2022 on the EMA's ETF recommendation on the use of a bivalent adapted vaccine against Omicron BA.4/5 subvariants and original SARS-CoV-2 virus in primary vaccination.

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PREZES
Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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EMA’s Emergency Task Force (ETF) considers that adapted mRNA bivalent vaccines targeting the original strain and Omicron BA.4-5 subvariants of SARS-CoV-2 may be used for primary (initial) vaccination. These vaccines are currently only authorised as boosters.

In reaching this conclusion, the EFT reviewed laboratory (non-clinical) studies and data on the immune response following natural infection with Omicron BA.4-5 in unvaccinated people who had not been previously infected with SARS-CoV-2.

The data suggest that primary vaccination with these adapted bivalent vaccines should give rise to a broad immune response in people who have not yet been exposed to, or vaccinated against, SARS-CoV-2.

The ETF further noted that the safety profile of the adapted vaccines when used as boosters is comparable to that of the original mRNA vaccines, for which the safety profile is well established.

The ETF therefore considered that the bivalent original/Omicron BA.4-5 vaccines may be used in previously unvaccinated children and adults.

Based on these considerations, national authorities may decide to use these adapted bivalent vaccines for primary vaccination in their national vaccination campaigns, should it become necessary. Further clinical research and observational studies are expected to provide additional information on the safety and effectiveness of the bivalent vaccines for primary vaccination.

The ETF’s statement has been issued in the context of its public health emergency response activities. It does not reflect a change to the product information of the authorised vaccines.

Two adapted vaccines targeting the Omicron subvariants BA.4 and BA.5 in addition to the original strain of SARS-CoV-2 are authorised for use in the EU as booster doses.

Adapted vaccines work in the same way as the originally authorised vaccines. They work by preparing the body to defend itself against COVID-19.

The bivalent original/Omicron BA.4-5 vaccines contain molecules called mRNA which have instructions for making the spike proteins of the original strain of SARS-CoV-2 and the Omicron

subvariants BA.4-5. The spike proteins in the Omicron subvariants BA.4 and BA.5 are identical. 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. By adapting vaccines, the aim is to broaden protection against different variants.

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 those proteins 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 proteins on its surface and be prepared to attack the virus. 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 the infected ones.

More information available on the website: https://www.ema.europa.eu/en/news/etf-concludes-bivalent-original-omicron-ba4-5-mrna-vaccines-may-be-used-primary-vaccination [1]

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

Odnośniki
[1] https://www.ema.europa.eu/en/news/etf-concludes-bivalent-original-omicron-ba4-5-mrna-vaccines-may-be-used-primary-vaccination