Communication of the President of the Office of 20 October 2022 on the recommendation of the EMA's Committee for Medicinal Products for Human Use (CHMP) to authorise the marketing of the second adapted bivalent vaccine Spikevax against subvariants BA.4-5

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EMA’s human medicines committee (CHMP) has recommended authorising an adapted Spikevax COVID-19 vaccine targeting the Omicron subvariants BA.4 and BA.5 in addition to the original strain of SARS-CoV-2.

The adapted vaccine, Spikevax bivalent Original/Omicron BA.4-5, is recommended for adults and children from 12 years of age who have already had a primary vaccination course against COVID-19. This is the second adapted Spikevax vaccine that EMA has recommended for approval. An adapted Spikevax vaccine targeting Omicron BA.1 and the original strain was authorised in September 2022.

Adapted vaccines are vaccines that have been updated so they better match the circulating variants of SARS-CoV-2. They are expected to broaden protection against different variants and help maintain optimum levels of protection against COVID-19 as the virus evolves.

In its decision to recommend the authorisation of Spikevax bivalent Original/Omicron BA.4-5, the CHMP took into account all the available data on Spikevax and its recently authorised adapted vaccine Spikevax bivalent Original/Omicron BA.1.

Apart from containing mRNA matching different but closely related Omicron subvariants, both adapted vaccines have the same composition.

A study found that a booster dose of Spikevax bivalent Original/Omicron BA.1 induced a stronger immune response against the SARS-CoV-2 original strain and the Omicron subvariant BA.1 than a booster dose of the originally authorised Spikevax vaccine.

The CHMP’s opinion for Spikevax bivalent Original/Omicron BA.4-5 is also based on data on its quality and manufacturing process, which confirmed that it meets the EU standards for quality.

Based on all these data and the similar composition of the adapted vaccines, the CHMP concluded that Spikevax bivalent Original/Omicron BA.4-5 is expected to be effective at triggering an immune response against the BA.4 and BA.5 subvariants. The vaccine’s safety profile is expected to be comparable to that of Spikevax bivalent Original/Omicron BA.1 and the originally authorised Spikevax, for which a large amount of data are available.

The CHMP opinion on Spikevax bivalent Original/Omicron BA.4-5 will now be sent to the European Commission, which will adopt a final decision.

More information available on the website:

https://www.ema.europa.eu/en/news/ema-recommends-approval-second-adapted-spikevax-vaccine [1]

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

Links
[1] https://www.ema.europa.eu/en/news/ema-recommends-approval-second-adapted-spikevax-vaccine