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EMA recommends approval of second adapted Spikevax vaccine

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.

Evidence supporting use of Spikevax bivalent Original/Omicron BA.4-5

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. In addition, non-clinical laboratory data show that the adapted vaccine is able to trigger an adequate immune response.

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 more effective than the originally authorised vaccine 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 is available.

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

Use of COVID-19 vaccines

Together with Spikevax bivalent Original/Omicron BA.1, this new adapted vaccine is expected to help maintain optimal protection against COVID-19 as the virus evolves.

The EU's strategy is to have a broad range of adapted vaccines that target different SARS-CoV-2 variants so Member States have various options to meet their needs when they design their vaccination campaigns. This is a key element in the overall strategy to combat the pandemic as it is not possible to predict how the virus will evolve in the future and which variants will be circulating this winter.

Like all the currently authorised vaccines against COVID-19, Spikevax is still effective at preventing severe disease, hospitalisation and death associated with COVID-19 and will continue to be used within vaccination campaigns in the EU, in particular for primary vaccinations.

National authorities in the EU Member States will determine who should receive which vaccines and when, taking into account factors such as infection and hospitalisation rates, the risk to vulnerable populations, vaccination coverage and vaccine availability.

How Spikevax bivalent Original/Omicron BA.4-5 works

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

Spikevax bivalent Original/Omicron BA.4-5 contains 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 and BA.5. 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. The spike proteins in the Omicron subvariants BA.4 and BA.5 are identical. 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 about the procedure

The company marketing Spikevax submitted an application (called a variation application) to change the current marketing authorisation of Spikevax and include the use of the adapted vaccine targeting the Omicron subvariants BA.4 and BA.5 in addition to the original strain of SARS-CoV-2.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use. The CHMP opinion has been forwarded to the European Commission, which will issue a final legally binding decision applicable in all EU Member States.