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First adapted COVID-19 booster vaccines recommended for approval in the EU

EMA's human medicines committee (CHMP) has recommended authorising two vaccines adapted to provide broader protection against COVID-19. Comirnaty Original/Omicron BA.1 and Spikevax Bivalent Original/Omicron BA.1 are for use in people aged 12 years and above who have received at least primary vaccination against COVID-19. These vaccines are adapted versions of the original vaccines Comirnaty (Pfizer/BioNTech) and Spikevax (Moderna) to target the Omicron BA.1 subvariant in addition to the original strain of SARS-CoV-2.

Vaccines are adapted (i.e., updated) to better match the circulating variants of SARS-CoV-2. Adapted vaccines can broaden protection against different variants and are therefore expected to help maintain optimal protection against COVID-19 as the virus evolves.

Studies showed that Comirnaty Original/Omicron BA.1 and Spikevax Bivalent Original/Omicron BA.1 can trigger strong immune responses against Omicron BA.1 and the original SARS-CoV-2 strain in people previously vaccinated. In particular, they were more effective at triggering immune responses against the BA.1 subvariant than the original vaccines.

Side effects observed with the adapted vaccines were comparable to those seen with the original ones and were typically mild and short-lived.

The two CHMP opinions will now be sent to the European Commission, which will adopt a final decision.

As the pandemic 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 a plurality of options to meet their needs when they design their vaccination strategies. 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. Other adapted vaccines incorporating different variants, such as the Omicron subvariants BA.4 and BA.5, are currently under review by EMA or will be submitted soon, and, if authorised, will further extend the arsenal of available vaccines. The clinical data generated with the original/BA.1 bivalent vaccines recommended today will support the evaluation and authorisation of further adapted vaccines.

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The original vaccines, Comirnaty and Spikevax, are 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.

Evidence supporting use of Comirnaty Original/Omicron BA.1

Comirnaty Original/Omicron BA.1 can be used in people aged 12 years and older, at least 3 months after the last dose of a COVID-19 vaccine.

The CHMP's opinion on Comirnaty Original/Omicron BA.1 is based on 2 studies. One study in adults over 55 years old who had previously received 3 doses of Comirnaty (primary vaccination and a booster) found that the immune response to the Omicron BA.1 subvariant was higher after a second booster dose of Comirnaty Original/Omicron BA.1 than after a second dose of the original Comirnaty vaccine (as measured by the level of antibodies against Omicron BA.1). In addition, the immune response to the original SARS-CoV-2 strain was comparable for both vaccines. The study involved more than 1,800 people, of whom about 300 received Comirnaty Original/Omicron BA.1 in its final composition.

Further data from a study involving over 600 people aged between 18 and 55 years who had previously received 3 doses of Comirnaty showed that the immune response to Omicron BA.1 was higher in people who received a booster with a vaccine containing only the Omicron BA.1 component than in those given a booster with the original Comirnaty vaccine.

Based on these data, it was concluded that the immune response to Omicron BA.1 following a booster with Comirnaty Original/Omicron BA.1 in people aged 18 to 55 years would be at least equal to that in people aged over 55. Further, based on previous data in younger people, it was also concluded that that the immune response to a booster dose with Comirnaty Original/Omicron BA.1 in adolescents would be at least equal to that in adults.

Evidence supporting use of Spikevax Bivalent Original/Omicron BA.1

Spikevax bivalent Original/Omicron BA.1 can be used in adults and adolescents from the age of 12 years, at least 3 months after primary vaccination or a booster dose with a COVID-19 vaccine.

The CHMP's opinion on Spikevax Bivalent Original/Omicron BA.1 is based on data from a study involving more than 800 adults aged 18 years and above. The study found that a booster dose of Spikevax bivalent Original/Omicron BA.1 induced a stronger immune response against the SARS-CoV-2 strain and the Omicron subvariant BA.1 compared with a booster dose of the original Spikevax vaccine. The study compared the level of antibodies in people previously vaccinated with a primary series and booster dose of Spikevax, and who were given a second booster dose of either Spikevax or Spikevax bivalent Original/Omicron BA.1. It was also concluded that Spikevax bivalent Original/Omicron BA.1 could be used as a first booster after primary vaccination and that the immune response induced by a booster dose of Spikevax bivalent Original/Omicron in adolescents aged 12-17 years would be at least equal to that in adults, given that previous data with Spikevax have shown a comparable effect.

How the adapted vaccines work

The adapted vaccines work in the same way as the original vaccines.

Both adapted vaccines work by preparing the body to defend itself against COVID-19. Each vaccine contains molecules called mRNA which have instructions for making the spike proteins of the original SARS-CoV-2 and the Omicron subvariant BA.1. 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 one of these vaccines, 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 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.

The mRNA molecules from the vaccines do not stay in the body but are broken down shortly after vaccination.

More about the procedures

The companies marketing Spikevax and Comirnaty submitted applications (called variation applications) to change the current marketing authorisations of the authorised vaccines Comirnaty and Spikevax and include the use of adapted vaccines. These applications included data on the quality and safety of the adapted vaccines, and their ability to trigger immune responses against various strains 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.