

Communication of the President of the Office of 1 September 2022 on the recommendation of the European Medicines Agency (EMA) for approval of the first adapted COVID-19 booster vaccines in the European Union.

Submitted by m.koszewski on Thu, 01/09/2022 - 15:22



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**Urzędu Rejestracji Produktów Leczniczych,
Wyrobów Medycznych i Produktów Biobójczych**

Grzegorz Cessak

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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 an important tool for controlling the pandemic 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 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 similar 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.

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.

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 the immune response to a booster dose with Comirnaty Original/Omicron BA.1 in adolescents would be at least equal to that in adults.

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.

More information available on the website: <https://www.ema.europa.eu/en/news/first-adapted-covid-19-booster-vaccines-recommended-approval-eu> [1]

Grzegorz Cessak

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

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Published on Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (<https://archiwum.urpl.gov.pl>)

office-1-september-2022-recommendation-european-medicines-agency-ema

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[1] <https://www.ema.europa.eu/en/news/first-adapted-covid-19-booster-vaccines-recommended-approval-eu>