Communication of the President of the Office of 13 September 2022 on the recommendation of the European Medicines Agency (EMA) for approval of a bivalent vaccine adapted against Omicron BA.4/5 subvariants and primary SARS-CoV-2 virus.

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EMA's human medicines committee (CHMP) has recommended authorising an adapted bivalent vaccine targeting the Omicron subvariants BA.4 and BA.5 in addition to the original strain of SARS-CoV-2. This recommendation will further extend the arsenal of available vaccines to protect people against COVID-19 as the pandemic continues and new waves of infections are anticipated in the cold season.

Comirnaty Original/Omicron BA.4-5 is for use in people aged 12 years and above who have received at least a primary course of vaccination against COVID-19. This vaccine is an adapted version of the COVID-19 vaccine Comirnaty (Pfizer/BioNTech).

Vaccines are adapted to better match the circulating variants of SARS-CoV-2 and are expected to provide broader protection against different variants. Prompt assessment of the available data on these adapted vaccines will enable their timely deployment in the autumn vaccination campaigns.

In its decision to recommend the authorisation of Comirnaty Original/Omicron BA.4-5, the CHMP took into account all the available data on Comirnaty and its adapted vaccines, including the recently authorised [1] adapted vaccine Comirnaty Original/Omicron BA.1 as well as investigational vaccines against other variants of concern.

The CHMP based its opinion in particular on the clinical data available with Comirnaty Original/Omicron BA.1. Apart from containing mRNA matching different, but closely related, Omicron subvariants, Comirnaty Original/Omicron BA.4-5 and Comirnaty Original/Omicron BA.1 have the same composition. Clinical studies with Comirnaty Original/Omicron BA.1 showed that the vaccine was more effective at triggering an immune response against the BA.1 subvariant than Comirnaty, and was as effective as Comirnaty against the original strain. Side effects were comparable to those seen with Comirnaty. This was further supported by data from investigational vaccines targeting other variants which have also shown similar safety profiles and predictable immune responses against the strains they target.

The CHMP's opinion for Comirnaty 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, immunogenicity data (the ability of the vaccine to trigger an immune response) from laboratory (non-clinical) studies provided supportive evidence that Comirnaty Original/Omicron BA.4-5 triggers adequate immunity against the strains it targets.

Based on all these data, the CHMP concluded that Comirnaty Original/Omicron BA.4-5 is expected to be more effective than Comirnaty 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 the BA.1 adapted vaccine, and of Comirnaty itself for which a large amount of data is available.

Clinical studies with Comirnaty Original/Omicron BA.4-5 are ongoing and the CHMP will receive emerging clinical data as they are being generated.

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

Together with the Original/Omicron BA.1 adapted vaccines recently authorised, 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, Comirnaty, 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.

Last week, EMA and the European Centre for Disease Prevention and Control (ECDC) issued a joint statement [2] providing updated public health considerations on the use of the newly authorised adapted COVID-19 vaccines to support Member States in their planning for autumn and winter vaccination campaigns. Although adapted vaccines are authorised for use in people aged 12 years and above who have received at least primary vaccination against COVID-19, the ECDC and EMA advised that these boosters be directed as a priority to people who are more at risk of progressing to severe disease because of certain risk factors.

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.

More information available on the website: https://www.ema.europa.eu/en/news/adapted-vaccine-targeting-ba4-ba5-omicron-variants-original-sars-cov-2-recommended-approval [3]

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Links
[1] https://www.ema.europa.eu/en/news/first-adapted-covid-19-booster-vaccines-recommended-approval-eu
[2] https://www.ema.europa.eu/en/news/ecdc-ema-statement-booster-vaccination-omicron-adapted-bivalent-covid-19-vaccines
[3] https://www.ema.europa.eu/en/news/adapted-vaccine-targeting-ba4-ba5-omicron-variants-original-sars-cov-2-recommended-approval