Communication of the President of the Office of 6 September 2022 on the publication of a statement by ECDC and EMA on booster vaccination with the bivalent vaccine against COVID-19 variant Omicron.

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Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych

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The European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) are providing updated public health considerations on the use of the newly authorized adapted COVID-19 vaccines to support the planning of the autumn and winter vaccination campaigns.

This statement is based on the assessment of current epidemiological trends and available scientific evidence. National Immunisation Technical Advisory Groups (NITAGs) will ultimately make national recommendations on the use of COVID-19 vaccines, taking into account the epidemiological situation in their countries.

On 1 September 2022 Comirnaty Original/Omicron BA.1 and Spikevax Bivalent Original/Omicron BA.1 were authorised in the EU following positive opinions by EMA. Both vaccines incorporate the spike protein of the variant Omicron BA.1 and the SARS-CoV-2 original strain. As requested by the International Coalition of Medicines Regulatory Authorities clinical trials were conducted which showed that the new adapted vaccines provide a superior amount of antibodies able to neutralise the Omicron BA.1 variant compared to the current monovalent vaccines based on the original strain. In addition, the antibodies generated by these adapted vaccines seem to be able to neutralise other Omicron lineages and sub lineages, including BA.2, BA.2.75 and BA.5, more efficiently than current vaccines. To what extent these improvements in the immune response towards Omicron lineages will translate into increased protection is currently unknown. The data from clinical trials with Omicron adapted bivalent vaccines are showing a safety profile, measured by local and systemic reactogenicity, that is very similar compared to original monovalent vaccines.

Recommended population groups for booster doses

While the regulatory approval allows the use of these adapted vaccines from 12 years of age, the upcoming autumn/winter vaccination campaigns should prioritise the boosting of individuals that are at risk of progression to severe disease once infected because of risk factors, such as older adults (e.g. above 60 years of age), immunocompromised individuals and those with underlining medical conditions, and pregnant women. In addition, residents and staff in long term care facilities should also be considered a priority. Healthcare workers should also be considered for additional booster doses with these vaccines considering that it may have been a long time since their last dose (e.g. in some cases one year or more). The purpose of vaccinating healthcare workers would be to provide some protection against new infection, given their increased exposure, and to

maximise the ability of healthcare systems to operate in case of a significant new wave of SARS-CoV-2 later this year. Timely vaccination is more important than which booster vaccine is administered. Current monovalent vaccines based on the original strain are still providing protection from severe disease and should be considered in case adapted vaccines are not yet available.

Interval between doses

The regulatory approval supports the administration of additional booster doses with an interval as short as 3 months after the previous dose, if deemed needed. However, longer intervals may be considered in vaccination campaigns, based on real-world evidence of high level of protection against severe disease restored after the first booster dose and maintained for at least 4 months. Intervals longer than 4 months could be considered, based on the evidence of stronger immune response obtained with longer intervals between doses, but this needs to be balanced with waning protection and the local epidemiological situation. Priority for booster doses should be given to individuals from vulnerable groups who received their last vaccination more than 6 months ago. Synchronising booster vaccination just before or at the beginning of high viral circulation, as is normally expected with respiratory viruses at the start or during the cold season, would be highly desirable. Consideration should also be given to combining campaigns for vaccination against COVID-19 and influenza. Although it is still unknown how the virus will evolve in the coming months, it may be anticipated that in the longer-term, annual booster vaccination could be necessary at the beginning of the cold season similarly to influenza.

Vaccination of individuals with a recent SARS-CoV-2 infection

Studies looking at the combined effect of naturally acquired immunity and vaccine-induced immunity clearly point to an extra layer of protection for those with hybrid immunity. Evidence to-date also indicates that variant-specific protection against infection and severe disease conferred by hybrid immunity wanes more slowly than protection conferred by vaccine-induced or infection-induced immunity alone, although the strength and duration of the protection may depend on several factors such as type of vaccine, time since vaccination or infection, including which SARS-CoV-2 variant caused the infection, and host-specific factors. Recommending individuals with primary vaccination and a recent SARS-CoV-2 infection to wait at least 3 months or preferably even longer than 4 months after the infection before receiving a booster can therefore be considered.

Use of adapted vaccines for booster doses

The adapted vaccines are currently only approved for use as booster doses in individuals that completed at least a primary series, no matter which vaccines were used for the primary series. The use of these adapted vaccines should remain limited to booster use for the time being. Current monovalent vaccines incorporating the original strain are still to be used for an effective priming and for inducing sufficient initial protection in naïve individuals.

Additional vaccine options

Following the approval of bivalent Omicron BA.1/Original vaccines, other products incorporating either Omicron BA.4/5 and original strains or the Beta variant of concern, are being assessed for possible rapid approval, therefore offering a diversified portfolio of options for vaccination campaigns later this year. Due to the uncertainties around which variants will be circulating in the fall and winter period it is not possible to predict if any significant differences in protection across vaccines could emerge. Overall, the already approved adapted vaccines as well as the upcoming ones, if approved, are all expected to expand the immunity against variants of concern that recently emerged and circulated, especially Omicron and related lineages.

Importantly, as the clinical studies that supported the approval of these adapted vaccines were focused on collecting data related to safety and immunogenicity, real world evidence will be essential to measure the impact that these vaccines could have in preventing infection and disease.

More information available on the website: https://www.ema.europa.eu/en/news/ecdc-ema-

statement-booster-vaccination-omicron-adapted-bivalent-covid-19-vaccines [1]

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Links
[1] https://www.ema.europa.eu/en/news/ecdc-ema-statement-booster-vaccination-omicron-adapted-bivalent-covid-19-vaccines