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COVID-19: recommendations on use of adapted vaccines

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

The EU has recently extended its arsenal with two new updated vaccines, Comirnaty Original/Omicron BA.1 and Spikevax Bivalent Original/Omicron BA.1. As the virus SARS-CoV-2 continues to evolve, the existing vaccines are being adapted to ensure optimal protection of EU citizens against COVID-19.

The two bivalent formulations for use as a booster dose recently recommended for approval by EMA expand the immunity versus variants of concern, especially Omicron and related sub lineages. Exposing the immune system to contemporary versions of the virus so that it learns and recognizes subsequent variants is key for building up a broader immune response.

Recommended use of adapted boosters

Although these first two 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 advise 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. This includes people aged 60 years and above, the immunocompromised, and other vulnerable persons (from 12 years of age) with underlying conditions putting them at higher risk of severe COVID-19, and pregnant women. In addition, residents and staff in long-term care homes should be prioritised. Healthcare workers may also be considered due to their increased exposure in case of future new waves of SARS-CoV-2 and their key role for well-functioning healthcare systems.

'The authorisation of the first two adapted vaccines is an important step in our ongoing fight against the pandemic' said EMA's Executive Director, Emer **Cooke**.

'We have a virus that evolves quickly and unpredictably. It is important for the EU to have a broad range of vaccines that are updated with respect to their composition, so Member States have more options to meet their needs when designing their vaccination strategies'.

She added that 'Health authorities in the EU were doing their utmost for people to be vaccinated.'

The Director of ECDC, Dr Andrea **Ammon**, stressed the importance of vaccines in the fight against the COVID-19 pandemic.

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‘With the newly authorized adapted COVID-19 vaccines, Member States will now have a wider range of choices to roll out autumn/winter COVID-19 immunisation campaigns aimed at protecting most vulnerable groups and boost their immunity against most recent emerging variants’, Dr. Ammon said.

‘As these new vaccines are currently approved for use as booster doses only, the original ones remain essential to increase the vaccination coverage with a primary series among unvaccinated individuals to close the immunisation gaps’.

Autumn vaccination schedule

Timely vaccination and deployment of boosters ahead of a potential autumn and winter surge of COVID-19 cases is essential for protecting people and stopping health systems from being overwhelmed. Eligible people who still have had no COVID-19 vaccination or who have not had any booster dose are advised to come forward for vaccination as recommended in their countries.

The adapted vaccines recently authorised are only approved for use as booster doses in individuals that completed at least a primary series (initial vaccination), no matter which vaccines were used then.

The original COVID-19 vaccines continue to provide protection against severe disease, hospitalisation, and death, and should be used for primary vaccinations and be considered for booster doses when newer adapted vaccines are not yet available.

Future adapted vaccines

Further adaptations of COVID-19 vaccines’ composition are inevitable to address existing and future circulating variants. Preliminary data indicate that the immune response induced by the approved BA.1 adapted vaccines goes beyond the selected strains and covers other Omicron subvariants such as BA.2, BA.2.75 and BA.5.

In addition to the two authorised adapted vaccines targeting the Omicron BA.1 subvariant and the original strain of SARS-CoV-2, EMA is evaluating one adapted vaccine matching the original strain and Omicron BA.4 and BA.5 subvariants. There are also reviews ongoing for vaccines including the beta strain of the virus. If authorised, these vaccines will further extend options for vaccinations.

Factors to be considered in vaccination campaigns

National authorities in the EU make final decisions on the roll-out of vaccines, including booster doses and type of vaccines, considering factors such as the spread of infection, the impact of COVID-19 in different populations and the emergence of new variants. These elements will determine which vaccines people receive and when, based on their level of risk and the epidemiological situation.

ECDC and EMA will continue to closely evaluate emerging vaccines’ effectiveness and epidemiological data and will update their recommendations accordingly.