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SCIENCE MEDICINES HEALTH

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Emergency Task Force

EMA confirms its recommendation to update the antigenic composition of authorised COVID-19 vaccines for 2024-2025

In April 2024, the European Medicines Agency (EMA) issued a recommendation to change the antigenic composition of authorised COVID-19 vaccines for use during the 2024-2025 vaccination campaign¹.

The EMA Emergency Task Force (ETF) recommended to adapt vaccines to target the JN.1 family of Omicron subvariants to ensure cross-reactivity against the dominant strain (JN.1) and emerging strains and to increase the breadth of immunity against descendent lineages. Vaccine compositions targeting JN.1 subvariants could be considered if there was adequate justification. This position is in line with the WHO recommendation issued on 26 April 2024².

During its June plenary meeting, the CHMP recommended authorising an adapted Comirnaty vaccine targeting the JN.1 subvariant. The EC decision was expedited on 3 July 2024³. Spikevax, Nuvaxovid and Bimervax vaccines targeting JN.1 are under evaluation by the CHMP.

EMA was made aware of one potential regulatory submission to update the vaccine composition to target the KP.2 subvariant. KP.2 vaccines have been recommended by other jurisdictions, where feasible,⁴ and could therefore also become available for distribution where needed in the EU, subject to EMA approval.

JN.1 subvariant, differs in more than 30 mutations in the spike protein compared to XBB.1.5 which was used for the 2023-2024 updated COVID-19 vaccines. KP.2 variant, which is part of the SARS-CoV-2 variants sometimes called FLiRT variants, is a descendant of and closely related to the JN.1 variant, with both variants differing only by a handful of mutations in the spike protein (i.e. 3 mutations).

¹ [https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-jn1-variant#:~:text=EMA's%20Emergency%20Task%20Force%20\(ETF,the%202024%2F2025%20vaccination%20campaign](https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-jn1-variant#:~:text=EMA's%20Emergency%20Task%20Force%20(ETF,the%202024%2F2025%20vaccination%20campaign)

² <https://www.who.int/news/item/26-04-2024-statement-on-the-antigen-composition-of-covid-19-vaccines>

³ https://ec.europa.eu/health/documents/community-register/2024/20240703163286/dec_163286_en.pdf

⁴ <https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2024>

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The ETF considered that available animal data on cross-neutralisation are not sufficiently clear to indicate a greater benefit of a vaccine targeting KP.2 over the JN.1 variant, since the difference in immunogenicity between JN.1 and KP.2 vaccines remains uncertain at this stage and of minor relevance compared to the large differences in the immune response against currently circulating strains shown by JN.1 vaccines compared to XBB1.5 vaccines.

In this context, preliminary animal data with KP.2 adapted vaccines generated by Moderna and Pfizer/BioNTech showed differences in the immunogenicity profiles, especially with respect to neutralisation of KP.3, a further subvariant of JN.1⁵. Real world evidence from use of COVID-19 vaccines incorporating spike protein from very closely related variants did not identify significant differences in the level of protection achieved, especially for outcomes of severe disease such as hospitalisation and death⁶.

ETF also noted that KP.2 may no longer be the dominant variant in the weeks to come and in the autumn. Surveillance data indicates that KP3 continues to spread rapidly and is forecast to overcome KP2⁷. In the EU/EEA KP.3 detection is higher than KP.2 (25.9% vs. 7.4% in average)⁸, however the number of SARS-CoV2 sequences submitted to GISAID⁹ is limited. Other "FLIRT" mutants, such as LB.1, have also been detected¹⁰ (no increasing trends observed in the EU/EEA, but sequencing data are very limited).

The EMA/ETF strategy for COVID-19 vaccines is to make sure that updated vaccines can be manufactured and delivered in a timely manner and are able to retain adequate protection against the family of viruses that are dominant, acknowledging that matching exactly the viral strains that will circulate in the autumn is not possible.

Therefore, considering the available evidence, no change is currently warranted to the previously published ETF recommendation for COVID-19 vaccines update¹. Targeting JN.1 will facilitate timely vaccination campaigns in Europe after the summer to help reduce the burden of disease associated with COVID-19. All COVID-19 vaccines based on JN.1 or any subvariant of JN.1 such as KP2 will require marketing authorisation before they can be made available in the EU.

National authorities in the EU will ultimately make decisions about vaccination campaigns for 2024 and 2025, considering the situation in their country.

EMA will continue to follow the situation as it evolves and will communicate further as necessary.

⁵ <https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-5-2024-meeting-announcement#event-materials>

⁶ [Comparative effectiveness of bivalent BA.4-5 and BA.1 mRNA booster vaccines among adults aged ≥50 years in Nordic countries: nationwide cohort study | The BMJ](#)

⁷ [COVID-19 Variant Update \(idsociety.org\)](#)

⁸ <https://www.ecdc.europa.eu/en/covid-19/variants-concern>

⁹ <https://gisaid.org/>

¹⁰ https://www.idsociety.org/covid-19-real-time-learning-network/diagnostics/covid-19-variant-update/#/+0/publishedDate_na_dt/asc/