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European Medicines Agency
Emergency Task Force

EMA recommendation to update the antigenic composition of authorised COVID-19 vaccines for 2026-2027

The European Medicines Agency (EMA) is providing through its Emergency Task Force a recommendation with respect to the antigenic composition of authorised COVID-19 vaccines for use during the 2026-2027 vaccination campaign in the EU/EEA region.

The composition of vaccines against COVID-19 has changed five times since first approval in 2020. SARS-CoV-2, like any RNA virus that infects humans, is prone to accumulating mutations in its genome during replication in the human host. The selective pressure to evade host immunity while preserving replicative fitness leads to the emergence of new SARS-CoV-2 variants from the viral quasispecies inhabiting a human host. These new variants can, depending on their inherent characteristics, co-circulate with several other variants at the same time or replace them and become dominant.

A large body of evidence is now available to anticipate that, even if recently updated COVID-19 vaccines remain effective at preventing severe disease and death caused by new emerging variants, protection tends to decrease as the virus evolves into more antigenically distant variants. Studies have shown that adjusting the content of vaccines to the circulating viruses improves protection against the disease, even if perfect matching is not achieved. For these reasons, COVID-19 vaccine composition has been updated since the virus established itself in humans.

For the 2025-2026 vaccination campaign, LP.8.1 was recommended by the EMA Emergency Task Force (ETF) as the preferred option within the JN.1 family for vaccine update, but other JN.1 descendants would have been acceptable too. Of the 4 EMA authorised COVID-19 vaccines that are on the EU market[1], three included the spike protein from the LP.8.1 SARS-CoV-2 variant (Bimervax, Comirnaty, Spikevax) and one retained the JN.1 spike protein (Nuvaxovid).

[1] mNexpsike was authorised in February 2026 and not yet updated or marketed. Kostaive was authorised in February 2025 and not yet updated or marketed. mCombriax is a combined vaccine containing both influenza and SARS-CoV-2 antigens for which Commission Decision for marketing authorization in the EU was only recently issued (20 April 2026).

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To assess the situation for 2026 and 2027, the EMA's ETF has consulted with Marketing Authorisation Holders (MAHs) for COVID-19 vaccines, international regulators and the WHO. In the course of these consultations, the following evidence was evaluated:

- surveillance data on virus epidemiology and evolution;
- real world evidence on the effectiveness of vaccines containing JN.1/KP.2 and LP.8.1;
- animal and human studies on cross-neutralisation elicited by LP.8.1 vaccines against emerging variants, including antigenic cartography;
- animal studies of LP.8.1, XFG and BA.3.2.2-adapted vaccine candidates, including both primary and boosting settings.

In the course of 2025, surveillance data showed that other omicron variants have emerged globally, and some have been categorised as variants under monitoring by WHO: KP.3.1.1, NB.1.8.1, XFG and BA.3.2. In 2026, the latter three variants have been those most commonly identified globally as well as in the EU, with no consistent pattern of dominance among them:

- Variant NB.1.8.1[2] is derived from the recombinant variant XDV.1.5.1 and has 6 additional mutations compared to LP.8.1. These mutations have been shown to enhance binding affinity to the human receptor ACE2, which could increase the variant's transmissibility vs. LP.8.1 and other emerging variants except for XFG. Immune escape vs. LP.8.1 is very limited (1.3-fold lower post-vaccination neutralization titres in humans[3]).
- Variant XFG[4], a recombinant of the lineages LF.7 and LP.8.1.2, shows a different mutational profile vs. JN.1 as compared to NB.1.8.1, but some mutations are shared. Since June 2025, XFG started to increase globally as compared to NB.1.8.1, due to its highest relative growth advantage, peaking at 74% of sequences globally in October 2025, even if not consistently across regions. Immune escape vs. LP.8.1 remains relatively limited but is more pronounced compared to NB.1.8.1 (3.5-fold lower post-vaccination neutralization titres in humans[3]).
- Variant BA.3.2 is a descendent lineage of the Omicron variant BA.3 (detected until early 2022[5]), which is genetically distinct from the JN.1 lineage including LP.8.1 and XFG, from which it differs by 70-75 mutations (55 located in the spike protein). BA.3.2 shows limited growth advantage, reduced intrinsic infectivity (inefficient hACE2 binding due to closed Receptor-Binding Domain conformation) but marked immune evasion relative to co-circulating JN.1-descendant variants (6.7-fold lower post-vaccination neutralization titres vs. LP.8.1 in humans[3]) due to the genetic differences. Fold drop in neutralization titre for BA.3.2 vs. LP.8.1 can be higher depending on the immunization background as predicted by mathematical modelling[6]. Despite having spread globally, BA.3.2 has not managed to become dominant in any part of the world like other saltation variants did before (e.g. BA.1, BA.2 and JN.1).

Currently XFG, NB.1.8.1 and BA.3.2 are cocirculating in Europe, in different amounts by country; other variants are also detected, albeit at a much lower frequency. However, the interpretation of surveillance data is hampered by the limited number of cases, hospitalisations and deaths reported in

[2] 23052025_nb.1.8.1_ire.pdf
[3] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(25)00690-5/fulltext
[4] 25062025_xfg_ire.pdf
[5] Ancestor BA.3 appeared briefly between 2021 and 2022 and has since disappeared. BA.3.2 is a heavily mutated form of BA.3 (53 aminoacids difference between spikes), which indicates a saltation event in evolutionary terms, thought to occur during long and undetected replication and evolution possibly in a chronically infected immunocompromised person. Its sudden reappearance in late 2024 earned BA.3.2 the nickname of *cicada* variant.
[6] https://www.medrxiv.org/content/10.64898/2026.02.24.26346954v1.full.pdf

the EU, gaps and delays in reporting as well as low sequencing efforts. Globally, 80% of the circulating variants belong to the JN1 lineage (XFG remains prevalent), and BA.3.2 show an increasing trend in countries where sequencing continues.

Data in naïve animals and antigenic cartography data based on animals as well as human sera show that JN.1 sublineages continue to remain antigenically similar, whilst BA.3.2.2 is antigenically very distant from the JN.1 family cluster.

Early estimates of vaccine effectiveness data show that an mRNA vaccine containing LP.8.1 protects against COVID-19 as expected based on results from previous years (57% and 54% protection against emergency department visits and outpatient visits)[7].

Immunogenicity data in animals and in humans shared confidentially by vaccine developers indicate that the current vaccines containing the LP.8.1 variant are broadly able to cross-neutralise emerging JN.1-related variants such as XFG and NB.1.8.1, however lower titres are induced against them. Updating vaccines against XFG, which show robust immunogenicity, is expected to improve protection at least against future newer subvariants that are already differentiating especially within the XFG subfamily. Furthermore, the LP.8.1 variant is no longer circulating.

Data in primed mice have also shown that updating vaccines to BA.3.2.2 increased titres against BA.3.2.2 variants, as expected. However, titres against LP.8.1, XFG and NB.1.8.1 variants are very low with minimal boosting effect, if any, indicating BA.3.2.2 minimal cross-reactivity to the JN.1 lineage. Moreover, higher levels of baseline immunity to BA.3.2 have been reported[8] as compared to currently circulating JN.1 variants, reasonably due to antigenic similarity to omicron ancestor variants that were circulating between 2021 and 2022 and to which most people may have developed immune responses. These baseline titres have been shown to be boosted by JN.1 vaccines, suggesting that vaccines adapted to JN.1 descendants such as XFG should be able to confer protection against BA.3.2.2 as well.

Recommendations to MAHs regarding updates of vaccine composition

The EMA ETF is of the opinion that:

- Within the JN.1 family of Omicron subvariants, the XFG variant would be the preferred choice. Other JN.1 recent descendant viruses including LP.8.1 could also be considered.
- XFG vaccines are expected to provide protection against BA3.2. However, due to the uncertain but growing circulation of BA.3.2, its immune evasion phenotype and its potential further evolution, it cannot be excluded that the current recommendation may need to be updated in case the epidemiological situation changes substantially in the future.

Post-authorisation collection of effectiveness and clinical immunogenicity data is needed to support decisions on vaccine updates and vaccination campaign strategies. MAHs for EU-authorised vaccines are expected to provide such data during the consultation phase with the Agency and its Emergency Task Force. Particularly, it is critical when conducting clinical trials with updated vaccines to store blood samples for retesting vaccine cross-reactivity against new emerging variants.

[7] https://www.medrxiv.org/content/10.64898/2026.01.22.26344618v1
[8] Kaku Y, Fet al. The Lancet Infectious Diseases. 2026;26(3):e142-e143.
Happle C, et al. The Lancet Infectious Diseases. 2026;26(1):e3-e5.

Regulatory requirements for the strain change variation

This EMA ETF recommendation is intended to provide guidance to MAHs of EU-authorised COVID-19 vaccines on the next steps to update vaccine composition for the upcoming winter season. Authorisation of updated vaccines can be based on manufacturing/quality and non-clinical data submitted via type II variation, provided that data generated with prior vaccines of different composition support predictability of clinical immunogenicity and reactogenicity as agreed with the Committee for Medicinal Products for Human Use (CHMP).

For investigational vaccines with compositions that do not meet the most recent recommendations regarding antigen content, applicants should discuss with EMA the strategy for obtaining initial marketing authorisation and for amending the vaccine composition.

Marketing authorisation holders of authorised COVID-19 vaccines should discuss revision of the product information with the EMA. Changes should be kept to a minimum to ensure a rapid assessment timetable and should focus on the antigenic composition and any important editorial improvements.

The CHMP will reach a final decision on the variation and changes to the product information on conclusion of the assessment of the data submitted.