30 April 2024
European Medicines Agency
Emergency Task Force

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

The European Medicines Agency (EMA) is providing a recommendation to change the antigenic composition of authorised COVID-19 vaccines for use during the 2024-2025 vaccination campaign.

The composition of vaccines against COVID-19 has changed three times since first approval in 2020. SARS-CoV-2, like any RNA virus that infects humans, is prone to rapid evolution due to accumulating mutations in its genome during replication in the human host. In addition, new SARS-CoV-2 variants can arise through recombination between co-circulating virus strains.

Authorised COVID-19 vaccines remain effective at preventing severe disease and death caused by variants that have become dominant in the community over time; however, protection decreases over time and as the circulating virus evolves into more antigenically distant variants with respect to vaccine composition. Furthermore, studies have shown that matching the content of vaccines to the circulating viruses improves protection against the disease. For these reasons, COVID-19 vaccine composition has been updated in the last 3 years.

A new SARS-CoV-2 variant, JN.1, globally overtook the previously circulating XBB family of variants between December 2023 and January 2024. JN.1 belongs to the BA.2.86 family of Omicron subvariants, which is antigenically distant from the XBB family and from previously circulating variants. Currently, JN.1 is differentiating and evolving into a new family of drifting variants.

The EMA's Emergency Task Force (ETF) has consulted with the World Health Organization (WHO) expert group TAG-CO-VAC, international regulators and marketing authorisation holders for COVID-19 vaccines. In the course of these consultations, the following evidence was evaluated:

- real world evidence on the effectiveness of vaccines targeting XBB.1.5
- data on virus variant epidemiology and evolution
- animal and human studies on cross-neutralisation elicited by XBB vaccines against emerging variants
- animal studies of JN.1-adapted vaccine candidates.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Overall, these data have provided insight into the protection afforded by the approved XBB.1 vaccines and newer candidate vaccines against variants belonging to the BA.2.86 ad JN.1 strains.

Recommendations and considerations to Marketing Authorisation Holders regarding updates to vaccine composition

The ETF is of the opinion that:

- Adapting vaccines to target the JN.1 family of Omicron subvariants is adequate to ensure cross-reactivity against current dominant and emerging strains. JN.1 itself is also considered a reasonable choice to increase the breadth of immunity against descendent lineages. Vaccine compositions targeting other JN.1 strains could be considered if there is adequate justification;
- Approvals can be based on manufacturing/quality and non-clinical data, provided that data with prior vaccines of different composition support predictability of clinical immunogenicity and reactogenicity.

This ETF position is intended to provide guidance to marketing authorisation holders (MAHs) of EU-authorised COVID-19 vaccines on the next steps to update vaccine composition for the upcoming winter season. 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 marketing authorisation and amending the vaccine composition before marketing in the EU.

Post-authorisation collection of effectiveness and clinical immunogenicity data will be needed to support future decisions on vaccine updates and vaccination campaigns strategies.

Revision of product information for the strain change variation

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 Committee for Medicinal Products for Human Use (CHMP) will reach a final decision on the variation and changes to the product information on conclusion of the assessment of the data submitted.