

## COVID-19 vaccines – VRBPAC makes recommendations for new monovalent vaccine composition for 2025 – 2026

- On May 22, 2025, the FDA's <u>Vaccines and Related Biological Products Advisory Committee</u>
  (<u>VRBPAC</u>) unanimously voted for the 2025 2026 formula of COVID-19 vaccines in the U.S to include a vaccine composition of a monovalent JN.1-lineage.
  - For 2024 2025, Moderna's <u>Spikevax<sup>®</sup> (COVID-19 vaccine, mRNA)</u> and Pfizer's <u>Comirnaty<sup>®</sup> (COVID-19 vaccine, mRNA)</u> vaccines contained KP.2. Novavax/Sanofi's Nuvaxovid<sup>®</sup> (COVID-19 vaccine, adjuvanted) vaccine contained JN.1.
- Information was presented to the VRBPAC from the FDA, the Centers for Disease Control and Prevention (CDC), the World Health Organization and the COVID-19 vaccine manufacturers. SARS-CoV-2 was discussed, and several relevant points were made:
  - Genetic drift has slowed from last year to this year compared to major evolutionary changes in previous years. All currently circulating lineages are related to JN.1.
  - Currently, the most dominant strain is LP.8.1. Variants that become predominate usually dominate for a relatively short period of time (months).
  - The continued evolution and diversity of JN.1-lineage viruses complicates the specific strain selection decision.
  - SARS-CoV-2 continues to evolve without a well-defined seasonality and in an unpredictable manner. The timing for vaccine updating is not easily aligned with the emergence of virus variants.
- The VRBPAC discussed the selection of JN.1 and/or a specific JN.1-lineage strain for COVID-19 vaccine (2025 2026) to be used in the U.S.
  - Monovalent JN.1 or KP.2 remain appropriate COVID-19 vaccine antigens; monovalent LP.8.1 is a suitable alternative vaccine antigen.

## What's Next?

- The FDA will review VRBPAC's recommendations and approve final composition for the 2025 -2026 COVID-19 vaccines.
- The CDC's Advisory Committee on Immunization Practices (ACIP) will meet in <u>June 2025</u> to discuss and make recommendations on the FDA's approvals.
- The new vaccines are expected to be available in the Fall 2025 timeframe.



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