FDA Briefing Document
Vaccines and Related Biological Products Advisory Committee
March 12, 2026

Recommendations for the Strain Composition of Influenza Virus Vaccines for Use in United States During the 2026-2027 Influenza Season

Meeting Objective

On March 12, 2026, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) will convene in open session to discuss and make recommendations on the virus strain compositions of influenza virus vaccines for use in the United States during the 2026-2027 influenza season.

Background

Influenza A and B viruses continue to evolve and diversify globally. Selecting the optimal vaccine strain composition requires careful review of multiple data sources, including recent virus surveillance and epidemiology data, genetic and antigenic characteristics of circulating virus isolates, serological responses and vaccine effectiveness estimates for current vaccines, and the availability of candidate vaccine viruses and reagents.

The World Health Organization (WHO) published comprehensive recommendations on February 27, 2026, based on data from the Global Influenza Surveillance and Response System (GISRS)—a network of 165 institutions across 135 countries, including U.S. institutions such as the Centers for Disease Control and Prevention (CDC) and FDA, which serve as WHO Collaborating Centres and WHO Essential Regulatory Laboratories. U.S. scientists contributed significantly to the surveillance data, antigenic characterization, and analysis presented in the global report.

Recent Influenza Activity and Circulating Strains

From September 2025 through January 2026, influenza activity was reported globally, with overall virus detections higher compared with the same period in 2024-2025. Influenza A viruses predominated, with activity peaking in December 2025. Among subtyped influenza A viruses, A(H3N2) viruses accounted for the majority of detections in most regions globally.

Influenza A(H1N1)pdm09: Since September 2025, A(H1N1)pdm09 viruses circulated globally but did not predominate in any region. Most of the recent H1N1pdm09 viruses had hemagglutinin (HA) genes belonging to clade 5a.2a.1, which has further diversified into subclades D.3.1 and D.3.1.1 (new nomenclature). Human serology studies showed that postvaccination antibody responses were significantly reduced for some recently circulating D.3.1 and D.3.1.1 subclade viruses when compared with responses against current vaccine strains.

Influenza A(H3N2): A(H3N2) viruses circulated and predominated globally. Most viruses had HA genes from subclade K (previously designated J.2.4.1), which now predominates in most regions. Critical findings show that subclade K viruses are poorly recognized by antibodies generated against current Northern Hemisphere (NH) 2025-2026 vaccine strains. Post-infection ferret antisera raised against subclade K viruses (A/Darwin/1454/2025 for egg-based vaccines and A/Darwin/1415/2025 for cell-based vaccines) showed improved

recognition of recently circulating K viruses compared with antisera raised against current vaccine strains. Human serology studies confirmed that postvaccination antibody responses against many recent subclade K viruses were significantly reduced compared with responses against current vaccine reference viruses.

Influenza B/Victoria Lineage: Influenza B virus detections remained low globally, though some countries reported increased detections in recent weeks. All characterized viruses belonged to the B/Victoria lineage with HA genes from clade 3a.2. Emerging subclades C.3 and C.3.1, which have the HA substitution D197N (adding a potential glycosylation site), are poorly recognized by antibodies against current vaccine strains. Post-infection ferret antisera raised against cell culture-propagated C.3.1 viruses (B/Pennsylvania/14/2025) recognized recently circulating viruses from C.3, C.3.1, and other 3a.2 subclades well. However, egg-propagated C.3.1 viruses (B/Tokyo/EIS13-175/2025) acquired egg-adaptive mutations that remove the glycosylation site, resulting in reduced recognition of circulating C.3 and C.3.1 viruses. Human serology studies showed significantly reduced antibody responses against C.3 and C.3.1 subclade viruses in most serum panels.

Global Recommendation for 2026-2027 North Hemisphere Vaccine Composition

Based on comprehensive global surveillance data and antigenic characterization, the globally recommended vaccine composition differs from previous seasons, with updates to all three components:

Egg-based vaccines:

- A/Missouri/11/2025 (H1N1)pdm09-like virus
- A/Darwin/1454/2025 (H3N2)-like virus
- B/Tokyo/EIS13-175/2025 (B/Victoria lineage)-like virus

Cell culture-, recombinant protein-, or nucleic acid-based vaccines:

- A/Missouri/11/2025 (H1N1)pdm09-like virus
- A/Darwin/1415/2025 (H3N2)-like virus
- B/Pennsylvania/14/2025 (B/Victoria lineage)-like virus

The different recommendations for egg-based versus cell culture/recombinant protein-based vaccines reflect viral adaptation that occurs during manufacturing in different production systems.

Scientific Rationale for Strain Updates

The global recommendation for strain updates addresses significant antigenic drift in circulating viruses, particularly for A(H3N2) and B/Victoria lineage components. The

emergence and global predominance of A(H3N2) subclade K viruses, along with increasing circulation of B/Victoria C.3 and C.3.1 viruses, necessitated the vaccine composition updates to maintain optimal vaccine effectiveness for the 2026-2027 season.

Regulatory Pathway

Following VRBPAC recommendations, FDA's Center for Biologics Evaluation and Research (CBER) will issue regulatory advice to manufacturers regarding strain composition for the 2026-2027 season. FDA anticipates manufacturers will develop vaccines using the recommended strains through established regulatory pathways (e.g., strain change supplements to existing biologics license applications).

Summary

A review and discussion of available surveillance, antigenic characterization, and human serology data are needed to inform strain composition updates for U.S.-licensed seasonal influenza vaccines. VRBPAC will meet in open session on March 12, 2026, to discuss and make recommendations on the strain composition of influenza virus vaccines for use in United States during the 2026-2027 influenza season

---

Reference: World Health Organization. Recommended composition of influenza virus vaccines for use in the 2026-2027 northern hemisphere influenza season. February 27, 2026. Available at: https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations