

Influenza Virus Vaccine Strain Selection – 2025 Southern Hemisphere

**Vaccines and Related Biological Products
Advisory Committee (10/10/2024)**

*Jerry P Weir, PhD, Director
Division of Viral Products/OVRR/CBER/FDA*

Purpose of Today's VRBPAC Committee Discussion

- Make recommendations for the strains of influenza A (H1N1 and H3N2) and B viruses to be included in the 2025 Southern Hemisphere formulation of influenza vaccine licensed in the United States
 - Since 2016, two U.S. vaccine manufacturers have been approved to produce Southern Hemisphere formulations of their influenza vaccine (Sanofi Fluzone and Seqirus Afluria)
 - Both vaccines are quadrivalent and produced in eggs
 - Strain recommendation and supplement approval for SH formulations follow the Northern Hemisphere process using the most recent WHO recommendations as a guide

Most Recent Recommendations for Northern Hemisphere Influenza Vaccines - 2024-2025



- February 23, 2024 – WHO recommendations
- March 5, 2024 – VRBPAC recommended only trivalent formulations for 2024-2025 influenza virus vaccines in the U.S. with the following strain compositions:
 - Influenza A (H1N1)
 - an A/Victoria/4897/2022 (H1N1)pdm09-like virus (Egg-based Vaccines)
 - an A/Wisconsin/67/2022 (H1N1)pdm09-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza A (H3N2)
 - an A/Thailand/8/2022 (H3N2)-like virus (Egg-based Vaccines)
 - an A/Massachusetts/18/2022 (H3N2)-like virus (Cell- or Recombinant-based Vaccines)
 - Influenza B
 - a B/Austria/1359417/2021-like virus (B/Victoria lineage)
- Because QIV is still distributed in other parts of the world, VRBPAC recommended inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine for U.S. licensed quadrivalent influenza vaccines intended for ex-U.S. distribution

WHO Recommendations for Southern Hemisphere Influenza Vaccines - 2025



- WHO recommendation – 9/27/2024
- Recommended that trivalent egg-based vaccines for use in the southern hemisphere influenza season contain:
 - An A/Victoria/4897/2022 (H1N1)pdm09-like virus;
 - An A/Croatia/10136RV/2023 (H3N2)-like virus; and
 - A B/Austria/1359417/2021 (B/Victoria lineage)-like virus
- “The recommendation for the B/Yamagata lineage component of quadrivalent influenza vaccines remains unchanged from previous recommendations:”
 - A B/Phuket/3073/2013 (B/Yamagata lineage)-like virus



Voting Question for the Committee

1. For the composition of egg-based trivalent 2025 SH formulations of influenza vaccines, does the committee recommend:
 - Inclusion of an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
 - Inclusion of an A/Croatia/10136RV/2023 (H3N2)-like virus; and
 - Inclusion of a B/Austria/1359417/2021 (B/Victoria lineage)-like virus

2. For quadrivalent 2025 SH formulations of influenza vaccines, does the committee recommend:
 - Inclusion of a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus as the 2nd influenza B strain in the vaccine



U.S. FOOD & DRUG
ADMINISTRATION