



# **Influenza Virus Vaccine Strain Selection – 2020 Southern Hemisphere**

**Vaccines and Related Biological Products  
Advisory Committee (10/09/2019)**

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# 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 2020 Southern Hemisphere formulation of influenza vaccine licensed in the United States

# Background for Today's VRBPAC Committee Discussion

- The World Health Organization makes recommendations for the virus strains to be included in influenza vaccines
  - Recommendations for Northern Hemisphere – February/March
  - Recommendations for Southern Hemisphere – September
- National regulatory authorities approve the composition and formulation of vaccines in each country
  - VRBPAC provides the recommendations for U.S. licensed vaccines – February/March for vaccines to be used in Northern Hemisphere influenza season
  - FDA/CBER approves license supplements for U.S. manufacturers to incorporate updated strain recommendations – June/July
- In 2016, a U.S. vaccine manufacturer was approved to produce Southern Hemisphere formulations of their influenza vaccine (egg-based)
  - Strain recommendation and supplement approval for SH formulations follow the Northern Hemisphere process

## Data and Types of Analyses to be Presented

- Epidemiology of circulating strains (*CDC*)
  - Surveillance data from U.S. and around the world (summarized from most recent WHO SH strain selection consultation)
  
- Antigenic relationships among contemporary viruses and candidate vaccine strains (*CDC*)
  - Hemagglutination inhibition (HI) and virus neutralization (VN) tests using post-infection ferret sera
  - HI and VN tests using panels of sera from humans receiving recent inactivated influenza vaccines
  - Antigenic cartography
  - Phylogenetic analyses of HA and NA genes

# Previous Recommendations for Southern Hemisphere Influenza Vaccines - 2019

- WHO recommendation – 9/27/2018
- Recommended that the following viruses be used for trivalent influenza vaccines in the 2019 influenza season (SH winter):
  - an A/Michigan/45/2015 (H1N1)pdm09-like virus
  - an A/Switzerland/8060/2017 (H3N2)-like virus
  - a B/Colorado/06/2017-like virus (B/Victoria lineage)
- Recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Phuket/3073/2013-like virus (B/Yamagata lineage)
- VRBPAC recommendation for U.S. manufacturers of SH formulations same as WHO – 10/03/2018

# Most Recent Recommendations for Northern Hemisphere Influenza Vaccines - 2019-2020

- WHO recommendation – 2/21/2019 and 3/21/2019
- Recommended that the following viruses be used for trivalent influenza vaccines in the 2019-2020 influenza season (NH winter):
  - an A/Brisbane/02/2018 (H1N1)pdm09-like virus
  - an A/Kansas/14/2017 (H3N2)-like virus
  - a B/Colorado/06/2017-like virus (B/Victoria lineage)
- Recommended that quadrivalent vaccines containing two influenza B viruses contain the above 3 viruses and a B/Phuket/3073/2013-like virus (B/Yamagata lineage)
- VRBPAC recommendation – 3/6/2019 and 3/22/2019

# WHO Recommendations for Southern Hemisphere Influenza Vaccines - 2020

- WHO recommendation – 9/27/2019
- Recommended that egg-based trivalent vaccines for use in the 2020 southern hemisphere influenza season contain the following:
  - an A/Brisbane/02/2018 (H1N1)pdm09-like virus
  - an A/South Australia/34/2019 (H3N2)-like virus
  - a B/Washington/02/2019-like virus (B/Victoria lineage)
- Recommended that egg-based quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Phuket/3073/2013-like virus (B/Yamagata lineage virus)

## Committee Discussion

- Which influenza strains should be recommended for the antigenic composition of 2020 Southern Hemisphere formulations of influenza virus vaccine produced by licensed U.S. manufacturers?



# Voting Questions for the Committee

1. For the composition of trivalent 2020 SH formulations of influenza vaccines, does the committee recommend:
  - A. Inclusion of an A/Brisbane/02/2018 (H1N1)pdm09-like virus
  - B. Inclusion of an A/South Australia/34/2019 (H3N2)-like virus
  - C. Inclusion of a B/Washington/02/2019-like virus (B/Victoria lineage)
  
2. For quadrivalent 2020 SH formulations influenza vaccines, does the committee recommend:
  - A. Inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2<sup>nd</sup> influenza B strain in the vaccine