



Influenza Virus Vaccine Strain Selection – 2019 Southern Hemisphere

**Vaccines and Related Biological Products
Advisory Committee (10/03/2018)**

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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 2019 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 - 2018

- WHO recommendation – 9/27/2017
- Recommended that the following viruses be used for trivalent influenza vaccines in the 2018 influenza season (SH winter):
 - an A/Michigan/45/2015 (H1N1)pdm09-like virus
 - an A/Singapore/INFIMH-16-0019/2016 (H3N2)-like virus
 - a B/Phuket/3073/2013-like virus (B/Yamagata lineage)
- Recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Brisbane/60/2008-like virus (B/Victoria lineage)
- VRBPAC recommendation for U.S. manufacturers of SH formulations same as WHO – 10/4/2017

Most Recent Recommendations for Northern Hemisphere Influenza Vaccines - 2018-2019

- WHO recommendation – 2/22/2018
- Recommended that the following viruses be used for trivalent influenza vaccines in the 2018-2019 influenza season (NH winter):
 - an A/Michigan/45/2015 (H1N1)pdm09-like virus
 - an A/Singapore/INFIMH-16-0019/2016 (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 – 3/1/2018

WHO Recommendations for Southern Hemisphere Influenza Vaccines - 2019

- WHO recommendation – 9/27/2018
- Recommended that egg-based trivalent vaccines for use in the 2019 southern hemisphere influenza season contain the following:
 - 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 virus)
- 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 2019 Southern Hemisphere formulations of influenza virus vaccine produced by licensed U.S. manufacturers?

Voting Questions for the Committee

1. For the composition of trivalent 2019 SH formulations of influenza vaccines, does the committee recommend:
 - A. Inclusion of an A/Michigan/45/2015 (H1N1)pdm09-like virus
 - B. Inclusion of an A/Switzerland/8060/2017 (H3N2)-like virus
 - C. Inclusion of a B/Colorado/06/2017-like virus (B/Victoria lineage)

2. For quadrivalent 2019 SH formulations influenza vaccines, does the committee recommend:
 - A. Inclusion of a B/Phuket/3073/2013-like virus (B/Yamagata lineage) as the 2nd influenza B strain in the vaccine