



# **Influenza Virus Vaccine Strain Selection – 2017 Southern Hemisphere**

**Vaccines and Related Biological Products  
Advisory Committee (10/13/2016)**

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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 2017 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
- Recently (2016), a U.S. manufacturer has been approved to produce Southern Hemisphere formulations of their influenza vaccine
  - Strain recommendation and supplement approval for SH formulations should 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 WHO Recommendations for Southern Hemisphere Influenza Vaccines - 2016

- WHO recommendation – 9/24/2015
- Recommended that the following viruses be used for trivalent influenza vaccines in the 2016 influenza season (SH winter):
  - an A/California/7/2009 (H1N1)pdm09-like virus
  - an A/Hong Kong/4801/2014 (H3N2)-like virus
  - a B/Brisbane/60/2008-like virus (B/Victoria lineage)
- It is 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 vaccine virus)

# Most Recent Recommendations for Northern Hemisphere Influenza Vaccines - 2016-2017

- WHO recommendation – 2/25/2016
- Recommended that the following viruses be used for trivalent influenza vaccines in the 2016-2017 influenza season (NH winter):
  - an A/California/7/2009 (H1N1)pdm09-like virus
    - *No change from 2015-2016 NH*
  - an A/Hong Kong/4801/2014 (H3N2)-like virus
    - *Change from 2015-2016 NH, but same as 2016 SH recommendation*
  - a B/Brisbane/60/2008-like virus (B/Victoria lineage)
    - *Change from 2015-2016 NH recommendation, previously recommended for quadrivalent vaccines*
- Recommended that quadrivalent vaccines containing two influenza B viruses contain the above 3 viruses and a B/Phuket/3073/2013-like virus (B/Yamagata)
  - *Previously recommended for trivalent vaccines*
- VRBPAC recommendation – 3/4/2016

# WHO Recommendations for Southern Hemisphere Influenza Vaccines - 2017

- WHO recommendation – 9/29/2016
- Recommended that trivalent vaccines for use in the 2017 southern hemisphere influenza season contain the following:
  - an A/Michigan/45/2015 (H1N1)pdm09-like virus
  - an A/Hong Kong/4801/2014 (H3N2)-like virus
  - a B/Brisbane/60/2008-like virus (B/Victoria lineage)
- It is 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 vaccine virus)

## Committee Discussion

- Which influenza strains should be recommended for the antigenic composition of 2017 Southern Hemisphere formulations of influenza virus vaccine produced by licensed U.S. manufacturers?



# Voting Questions for the Committee

1. For the composition of trivalent 2017 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/Hong Kong/4801/2014 (H3N2)-like virus
  - C. Inclusion of a B/Brisbane/60/2008-like virus (B/Victoria lineage)
  
2. For quadrivalent 2017 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