

### **Questions and Answers**

Recommended composition of influenza virus vaccines for use in the southern hemisphere 2015 influenza season and development of candidate vaccine viruses for pandemic preparedness

### September 2014

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- 2. What is the purpose of the WHO recommendations on the composition of influenza virus vaccines?
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#### 1. What is the WHO Global Influenza Surveillance and Response System(GISRS)?

GISRS is a global public health laboratory network coordinated by WHO, currently consisting of 141 National Influenza Centres (NICs) in 111 Member States, 6 WHO Collaborating Centers for Influenza (CCs), 4 WHO Essential Regulatory Laboratories (ERLs) and 12 WHO H5 Reference Laboratories.

This network conducts numerous public health activities including warning and assessment of influenza viruses of concern, such as viruses with pandemic potential. NICs collect and test clinical specimens from patients and share representative influenza viruses with the WHO CCs for detailed analysis, and for making recommendations for vaccine composition. This network also provides guidance to countries and support for activities such as training, outbreak response, development of diagnostic tests, testing for antiviral drug resistance and scientific interpretation of important findings.

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### 2. What is the purpose of the WHO recommendations on the composition of influenza virus vaccines?

These WHO recommendations provide a guide to national public health authorities and vaccine manufacturers for the development and production of influenza vaccines for the next influenza season. In contrast to many other vaccines, the viruses in influenza vaccines have to be updated frequently because circulating influenza viruses continuously evolve. As it takes approximately 6-8 months to produce influenza vaccines, recommendations are made in September for the following influenza season in the southern hemisphere and in February for the following influenza season in the northern hemisphere.

# 3. What viruses are recommended by WHO to be included in influenza vaccines for use in the 2015 southern hemisphere influenza season?

WHO recommends that influenza vaccines for use in the 2015 southern hemisphere influenza season contain the following viruses:

- an A/California/7/2009 (H1N1)pdm09-like virus
- an A/Switzerland/9715293/2013 (H3N2)-like virus
- a B/Phuket/3073/2013-like virus.

It is recommended that quadrivalent vaccines containing two influenza B viruses contain the above three viruses and a B/Brisbane/60/2008-like virus.

## 4. Are the vaccine viruses in this recommendation different from those used following previous recommendations?

The vaccine viruses recommended for the 2015 southern hemisphere influenza season are different from those used for the 2014 southern hemisphere and those recommended for the northern hemisphere 2014-2015 influenza seasons.

#### 5. Could a B/Victoria lineage virus still be considered for use as a vaccine component?

For those considering the use of both a B/Yamagata and a B/Victoria lineage vaccine virus for quadrivalent vaccines, B/Brisbane/60/2008-like viruses continue to be the most appropriate 4<sup>th</sup> component. In addition, countries or regions of the world that expect B/Victoria lineage viruses to predominate in 2015 may choose to use a B/Brisbane/60/2008-like virus in their trivalent influenza vaccines.

Approval of the composition and formulation of vaccines that will be used in each country is the responsibility of national or regional authorities.

## 6. Have the antigenic characteristics of the circulating seasonal influenza viruses changed since the last recommendation?

Yes, increasing proportions of the recently circulating A(H3N2) and influenza B Yamagatalineage viruses have undergone antigenic drift since the last vaccine recommendation.

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#### 7. How are egg- and cell- propagated viruses different?

Influenza viruses from humans are grown or propagated in both mammalian cell lines and hens' eggs. When human influenza viruses are grown in eggs they may undergo changes, which may alter the antigenic properties of these viruses. In contrast when influenza viruses are grown in cells, fewer such changes occur. Currently most inactivated influenza vaccines utilize egg-isolated viruses and so it is important to monitor these changes and minimize their impact.

#### 8. What candidate vaccine viruses are available for use in influenza vaccines?

The WHO recommended candidate vaccine viruses for vaccine development and production for the 2015 southern hemisphere influenza season are listed at: http://www.who.int/influenza/vaccines/virus/candidates\_reagents/2015\_south

The availability of high-growth reassortants by type/subtype, including A(H7N9) and A(H5N1) viruses, and corresponding potency test reagents is posted and updated on the WHO GISRS web site:  $\frac{\text{http://www.who.int/influenza/vaccines/virus/en/}}{\text{http://www.who.int/influenza/vaccines/virus/en/}}.$ 

## 9. How was the WHO recommendation made for the composition of influenza virus vaccines for the 2015 southern hemisphere influenza season?

The recommendation was made based on continuous surveillance conducted by the WHO GISRS and the virus characterization data generated in WHO CCs and WHO ERLs along with surveillance information from NICs and antigenic cartography analysis by the University of Cambridge.

From 22-24 September 2014 a WHO Consultation took place with 9 Advisers from WHO CCs and WHO ERLs. The Consultation was observed by 23 other experts from WHO CCs, WHO ERLs, WHO H5 Reference Laboratories, NICs, the University of Cambridge and the OIE/FAO Network of expertise on animal influenza (OFFLU)<sup>1</sup>.

The consultation was conducted to discuss analyses of the characterization of seasonal influenza viruses that have been shared with WHO through GISRS, complemented by results from vaccine serological studies and available epidemiological and clinical information, as well as vaccine effectiveness estimates. In addition the consultation covered zoonotic influenza viruses, including A(H5N1), A(H7N9), A(H9N2) and A(H3N2)v viruses. Based on thorough analysis and considerations, the Advisers provided a recommendation to WHO.

# 10. Why does GISRS continue to update the list of available candidate vaccine viruses for pandemic preparedness?

Influenza viruses evolve in animals and may transmit sporadically to humans resulting in zoonotic infections. As part of influenza pandemic preparedness programme, the WHO

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<sup>1</sup> www.offlu.net

GISRS in collaboration with animal health partners analyses a range of zoonotic and potentially pandemic influenza viruses as they emerge, and develops relevant candidate vaccine viruses as a first step in the production of influenza vaccines. The selection and development of a zoonotic candidate vaccine virus is done for the purposes of having a bank of potential viruses suitable for the immediate development of vaccines, for example during a pandemic, and also to assist those who may want to make pilot lots of vaccines, conduct clinical trials, or perform other pandemic preparedness tasks. The decision to use these materials for vaccine development should be based on an assessment of the public health risk and needs in consultation with national regulatory and public health authorities.

For more information, please contact gisrs-whohq@who.int.

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