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Committee for Medicinal Products for Human use

BWP Ad-hoc Influenza Working Group

EU recommendations for the seasonal influenza vaccine composition for the season 2016/2017

The meeting of the Ad hoc Influenza Working Group of the Biologics Working Party (BWP) was convened in order to recommend the virus strains for the manufacture of seasonal influenza vaccine for 2016/2017.

Having considered the information on international surveillance by WHO presented by the representative of the WHO Collaborating Centre, The Worldwide Influenza Centre at the Francis Crick Institute (UK), the CHMP BWP Ad hoc Influenza Working Group, consisting of experts on influenza from the Member States, considered that the WHO recommendation on the composition of vaccines for 2016/2017 should be followed:

Trivalent vaccines should contain:

– 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.

For vaccine manufacturers considering the use of a B/Yamagata/16/88 virus lineage vaccine virus in **quadrivalent vaccines** containing two influenza B viruses, a B/Phuket/3073/2013-like in addition to the strains mentioned above is considered appropriate.

The above recommendation is applicable also for live attenuated influenza vaccines.

On the basis of cross reactivity and growth in eggs, the group agreed that for the purpose of **vaccine manufacture**, the following **strains** be accepted:

As A/California/7/2009 (H1N1) pdm09-like viruses:

- reassortant virus NYMC X-179A, which is derived from A/California/7/2009
- reassortant virus NYMC X-181, which is derived from A/California/7/2009
- reassortant virus NIB-74, which is derived from A/Christchurch/16/2010
- reassortant virus NIB-74xp, which is derived from A/Christchurch/16/2010
- A/Brisbane/10/2010 (wild type)

30 Churchill Place ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

As A/Hong Kong/4801/2014 (H3N2)-like viruses:

- reassortant virus X-263B, which is derived from A/Hong Kong/4801/2014
- reassortant virus X-257A, which is derived from A/New Caledonia/71/2014

As B/Brisbane/60/2008-like viruses:

- B/Brisbane/60/2008 (wild type)
- reassortant virus NYMC BX-35, which is derived from B/Brisbane/60/2008
- reassortant virus NYMC BX-31B, which is derived from B/Brisbane/60/2008

As B/Phuket/3073/2013-like viruses (for quadrivalent vaccines including two influenza B viruses):

- B/Phuket/3073/2013 (wild type)
- B/Brisbane/9/2014 (wild type)
- B/Utah/9/2014 (wild type)

Furthermore, for manufacture of **live attenuated influenza vaccines**, the group agreed that the following strains be accepted.

- A/Bolivia/559/2013 (H1N1)pdm09
- A/Hong Kong/4801/2014 (H3N2) or A/New Caledonia/71/2014 (H3N2)
- B/Brisbane/60/2008

  B/Phuket/3073/2013

Reagents for vaccine standardisation are available and will be supplied by NIBSC, UK and TGA, Australia (see Annex I).

Submission time of variation in accordance with Article 18 of Commission Regulation (EC) No 1234/2008

CHMP informs the Marketing Authorisation holders of centrally approved seasonal influenza vaccines of the recommended deadline for submission of the annual strain change variation[1]: 13 June 2016

Note on labelling requirements

NCAs and manufacturers are requested to follow the labelling examples given in this document, which updates the advice given in the 'Explanatory note on the withdrawal of the Note for guidance on harmonisation of requirements for influenza Vaccines and of the core SmPC/PL for inactivated seasonal influenza vaccines,[2]' The examples in Annex II of this strain recommendation describe the strain nomenclature to be used in the SmPC, small immediate packaging, outer/immediate packaging and the package leaflet. The translation of the word '-like' should be one word/ a succinct translation. The term '-derived strain' should not be used in place of '-like strain'.

[1] See: EMA fast track procedure for community human influenza inactivated vaccines annual strain(s) update according to art. 18 of Commission regulation (EC) no 1234/2008 (EMEA/CHMP/BWP/99698/2007Rev. 2)

[2] http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2014/02/WC500161022.pdf

ANNEX I

Reagents for vaccine standardisation[3]

Available from NIBSC, UK and TGA, Australia.[4]

H1N1

A/California/7/2009 (NYMC X-179A) egg derived antigen is available (NIBSC 13/164)
A/California/7/2009 (NYMC X-181) egg derived antigen is available (NIBSC 12/168) [limited availability, replacement will be prepared].
A/Christchurch/16/2010 (NIB-74) egg derived antigen is available (NIBSC 10/258), acceptable for use also with NIB-74xp
A/California/7/2009-like antiserum is available (NIBSC 14/310) [limited availability, replacement will be prepared].

H3N2

A/Hong Kong/4801/2014 (NYMC X-263B) egg derived antigen is available (NIBSC 15/230)
A/New Caledonia/71/2014 (NYMC X-257A) egg derived antigen is available (NIBSC 15/238)
A/Hong Kong/4801/2014-like antiserum will be available (NIBSC, replacement will be prepared).

B/Victoria/2/87 lineage

B/Brisbane/60/2008 egg derived antigen is available (NIBSC 13/234)
B/Brisbane/60/2008 (NYMC BX-35) egg derived antigen will be prepared
B/Brisbane/60/2008-like antiserum is available (NIBSC 13/254) [limited availability, replacement will be prepared].

B/Yamagata/16/88 lineage (for quadrivalent vaccines including two influenza B strains)

B/Phuket/3073/2013 egg derived antigen is available (NIBSC 14/252) [limited availability, replacement will be prepared].
B/Brisbane/9/2014 egg derived antigen is available (NIBSC 14/274) [limited availability, replacement will be prepared].
B/Phuket/3073/2013-like antiserum is available (NIBSC 14/248) [limited availability, replacement will be prepared].

[3] Manufacturers may use reagents for standardisation prepared by TGA, Australia and CBER, USA following discussion and agreement with the concerned OMCL and provided the same reagents are used for the entire production campaign.
[4] For availability and progress in development of reagents, consult the following websites:
http://www.nibsc.org/science_and_research/virology/influenza_resource_/full_reagent_update.aspx
http://www.who.int/influenza/vaccines/virus/en/

ANNEX II

Labelling

Information on the SmPC, small immediate packaging, outer/immediate packaging and package leaflet should comply with Directive 2001/83/EC and should also contain:

Small immediate packaging (section 1)	• season of use displayed as: "{year/year} season"
Outer/immediate packaging (section 2)	• WHO/EU recommended strains, e.g.: • A/Victoria/361/2011 (H3N2) - like strain • B/Brisbane/60/2008 – like strain • B/Phuket/3073/2013 – like strain • A/California/7/2009 (H1N1)pdm09 – like strain • season of use displayed as: "{year/year} season"
Package leaflet	• WHO/EU recommended strains followed by actual strains, e.g.: • A/Victoria/361/2011 (H3N2) - like strain (A/Victoria/361/2011, IVR-165) [5] • B/Brisbane/60/2008 – like strain (B-Brisbane/60/2008, wild type)[6] • B/Phuket/3073/2013 – like strain, (B/Utah/9/2014, wild type)[7] • A/California/7/2009 (H1N1)pdm09 – like strain (A/Christchurch/16/2010, NIB-74)[8] • The statement "This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the {year/year} season." should be stated in Section 6.

[5] Example describes the case whereby the reassortant is derived from the recommended wild-type
[6] Example describes the case whereby the wild-type is used as the vaccine strain
[7] Example describes the case whereby the vaccine strain is derived from a wild-type antigenically like the recommended strain
[8] Example describes the case whereby the reassortant is derived from a wild-type antigenically like the recommended strain

SmPC	• WHO/EU recommended strains followed by actual strains, e.g.: • A/Victoria/361/2011 (H3N2) - like strain (A/Victoria/361/2011, IVR-165) [9] • B/Brisbane/60/2008 – like strain (B-Brisbane/60/2008, wild type)[10] • B/Phuket/3073/2013 – like strain, (B/Utah/9/2014, wild type)[11] • A/California/7/2009 (H1N1)pdm09 – like strain (A/Christchurch/16/2010, NIB-74)[12] • The statement "This vaccine complies with the World Health Organisation (WHO) recommendation (northern hemisphere) and EU recommendation for the {year/year} season." should be stated in Section 2.

[9] Example describes the case whereby the reassortant is derived from the recommended wild-type
[10] Example describes the case whereby the wild-type is used as the vaccine strain
[11] Example describes the case whereby the vaccine strain is derived from a wild-type antigenically like the recommended strain
[12] Example describes the case whereby the reassortant is derived from a wild-type antigenically like the recommended strain