EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human use

BWP Ad-hoc Influenza Working Group

Amended[1] EU recommendations for the seasonal influenza vaccine composition for the season 2015/2016

The meeting of the Ad hoc Influenza Working Group of the BWP was convened in order to recommend the virus strains for the manufacture of seasonal influenza vaccine for 2015/2016.

Having considered the information on international surveillance by WHO presented by the representative of the WHO Collaborating Centre, NIMR (Mill Hill, 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 2015/2016 should be followed:

Trivalent vaccine containing:

– an A/California/7/2009 (H1N1)pdm09-like virus

– an A/Switzerland/9715293/2013 (H3N2)-like virus

– a B/Phuket/3073/2013-like virus.

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

For vaccine manufacturers considering the use of a B/Victoria/2/87 lineage vaccine virus in **quadrivalent vaccines** containing two influenza B viruses, a B/Brisbane/60/2008-like virus in addition to the strains mentioned above is considered appropriate.

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

[1] Further to the recommendation dated 26 March 2015, this amended document includes a recommendation for a suitable A/California/7/2009-like candidate vaccine virus for live attenuated influenza vaccines.

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- A/Brisbane/10/2010 (wild type)

As A/Switzerland/9715293/2013 (H3N2)-like viruses:

- reassortant virus NIB-88, which is derived from A/Switzerland/ 9715293/2013
- reassortant virus IVR-175, which is derived from A/South Australia/55/2014
- A/South Australia/55/2014 wild-type

As B/Phuket/3073/2013-like viruses:

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

As B/Brisbane/60/2008-like viruses (for quadrivalent vaccines including two influenza B 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

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

- A/Bolivia/559/2013 (H1N1)pdm09[2]
- A/Switzerland/9715293/2013 (H3N2)
- B/Phuket/3073/2013
- B/Brisbane/60/2008 (for quadrivalent formulation)

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[3]: 15 June 2015.

Note on labelling requirements

NCAs and manufacturers are requested to follow the labelling examples given in the document, '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,[4]' This

[2] Updated.
[3] 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)

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

document describes the strain nomenclature to be used on 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,' (see Annex II for examples).

ANNEX I

Reagents for vaccine standardisation[5]

Available from NIBSC, UK and TGA, Australia.[6]

H1N1

A/California/7/2009 (NYMC X-179A) egg derived antigen is available (NIBSC 13/164)
A/California/7/2009 (NYMC X-179A) cell derived antigen is available (NIBSC 09/174)
A/California/7/2009 (NYMC X-181) egg derived antigen is available (NIBSC 12/168)
A/Christchurch/16/2010 (NIB-74) egg derived antigen is available (NIBSC 10/258), acceptable for use also with NIB-74xp
A/Brisbane/10/2010 cell derived antigen is available (NIBSC 11/134)
A/California/7/2009-like antiserum is available (NIBSC 14/310)

H3N2

A/Switzerland/9715293/2013 (NIB-88) egg derived antigen is available (NIBSC 14/254)
A/South Australia/55/2014 (IVR-175) egg derived antigen is available from TGA
A/Switzerland/9715293/2013-like antiserum is available (NIBSC 14/272)

B/Yamagata/16/88 lineage

B/Phuket/3073/2013 egg derived antigen is available (NIBSC 14/252)
B/Brisbane/9/2014 egg derived antigen is available (NIBSC 14/274)
B/Phuket/3073/2013-like antiserum is available (NIBSC 14/248)

B/Victoria/2/87 lineage (for quadrivalent vaccines including two influenza B strains)

B/Brisbane/60/2008 egg derived antigen is available (NIBSC 13/234)
B/Brisbane/60/2008 (NYMC BX-35) cell derived antigen is available (NIBSC 14/146)
B/Brisbane/60/2008-like antiserum is available (NIBSC 13/254)

[5] Manufactures 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.
[6] For availability and progress in development of reagents, consult the following websites:
http://www.nibsc.org/Influenza/Reagents.aspx
http://www.who.int/influenza/vaccines/virus/en/
https://www.tga.gov.au/aivc-recommendations-composition-influenza-vaccine-australia-2015

ANNEX II

Labelling

Information on small immediate packaging, outer/immediate packaging and package leaflet should comply with Directive 2001/83/EC and should also contain[7]:

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 • 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)) • 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.

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