15 May 2019
EMA/CHMP/BWP/266098/2019
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 2019/2020

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 2019/2020.

Having considered the information on international surveillance by WHO presented by the representative of the WHO Collaborating Centre for Reference and Research on Influenza 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 2019/2020 should be followed:

Trivalent vaccines should contain:

- an A/Brisbane/02/2018 (H1N1)pdm09-like virus;

- an A/Kansas/14/2017 (H3N2)-like virus;

– a B/Colorado/06/2017-like virus (B/Victoria/2/87 lineage).

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 virus in addition to the strains mentioned above is considered appropriate.

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

The group agreed that for the purpose of **vaccine manufacture**, the following **strains** be accepted:

As A/Brisbane/02/2018 (H1N1)pdm09-like viruses:

- egg-propagated reassortant virus IVR-190, which is derived from A/Brisbane/02/2018
- cell-culture propagated A/Idaho/07/2018 (wild type)

[1] Further to the EU recommendation dated 10 April 2019, this amended document includes a recommendation for suitable A/Brisbane/02/2018 (H1N1)pdm09-like and A/Kansas/14/2017 (H3N2)-like viruses for seasonal live attenuated influenza vaccines. Annex I (Reagents for vaccine standardisation) has also been updated.

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As A/Kansas/14/2017 (H3N2)-like virus:

- egg-propagated reassortant virus NYMC X-327, which is derived from A/Kansas/14/2017
- cell-culture propagated A/Indiana/08/2018 (wild type)

As B/Colorado/06/2017-like viruses (B/Victoria/2/87 lineage):

- egg-propagated B/Maryland/15/2016 (wild type)
- egg-propagated reassortant virus NYMC BX-69A, which is derived from B/Maryland/15/2016
- cell-culture propagated B/Iowa/06/2017 (wild type)

As B/Phuket/3073/2013-like viruses (B/Yamagata/16/88 lineage, for quadrivalent vaccines including two influenza B viruses):

- egg-propagated B/Phuket/3073/2013 (wild type)
- egg-propagated B/Brisbane/9/2014 (wild type)
- egg-propagated B/Utah/9/2014 (wild type)
- egg-propagated reassortant virus BVR-1B, which is derived from B/Phuket/3073/2013
- cell-culture propagated B/Singapore/INFTT-16-0610/2016 (wild type)

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

As A/Brisbane/02/2018 (H1N1)pdm09-like virus[2]:

- Virus MEDI307134, which is derived from A/Switzerland/3330/2017

As A/Kansas/14/2017 (H3N2)-like virus[2]:

- Virus MEDI308763, which is derived from A/Kansas/14/2017

As /Colorado/06/2017-like virus (B/Victoria/2/87 lineage):

- Virus MEDI293454, which is derived from B/Colorado/06/2017

As B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage):

- Virus MEDI254977, which is derived from B/Phuket/3073/2013

[2] Updated 15 May 2019

Reagents for vaccine standardisation may be obtained from any WHO Essential Regulatory Laboratory (ERL). It is anticipated that reagents are/ will be available from 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]: 17 June 2019.

Note on labelling requirements

NCAs and manufacturers are requested to follow the labelling examples (strain descriptions) given in the updated Guideline on influenza vaccines – submission and procedural requirements, which applies to centrally-approved influenza vaccines[3]. Equivalent labelling guidance for influenza vaccines authorised by other routes in the EU[4] should be followed to harmonise the product information of all EU authorised influenza vaccines. Please note that in line with these documents and as discussed at the Ad hoc Influenza WG meeting, B-lineage information should continue to be omitted after the B-strains' descriptions in the labelling.

[3] See: Guideline on influenza vaccines – submission and procedural requirements Regulatory and procedural requirements module
http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2017/03/WC500223481.pdf

[4] http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Variations/CMDh_290_2013_Rev02_2017_03_clean.pdf

ANNEX I

Reagents for vaccine standardisation[5]

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

H1N1

A/Brisbane/02/2018 (IVR-190) egg derived antigen is available (NIBSC 18/238)

A/Brisbane/02/2018-like antiserum is available (NIBSC 19/102)

H3N2

A/Kansas/14/2017 (NYMC X-327) egg derived antigen is available (NIBSC 19/104)

A/Kansas/14/2017-like antiserum is available (NIBSC 19/110)

B/Victoria/2/87 lineage

B/Maryland/15/2016 egg derived antigen is available (NIBSC 18/100)

B/Maryland/15/2016 (BX-69A) egg derived antigen is available (NIBSC 18/104)

B/Colorado/06/2017-like antiserum is available (NIBSC 18/170)

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

B/Phuket/3073/2013 egg derived antigen is available (NIBSC 16/158)

B/Brisbane/9/2014 egg derived antigen is available (NIBSC 14/274) [limited availability, replacement not planned]

B/Phuket/3073/2013 (BVR-1B) egg derived antigen is available (TGA 2017/117B)

B/Utah/9/2014 cell derived antigen is available (NIBSC 15/100) [limited availability, replacement not planned]

B/Phuket/3073/2013-like antiserum is available (NIBSC 15/150)

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[5] 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.

[6] 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/