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EMA/CHMP/BWP/134670/2020
Committee for Medicinal Products for Human Use (CHMP)

# BWP Ad hoc Influenza Working Group

## Amended[1] EU recommendations for the seasonal influenza vaccine composition for the season 2020/2021

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 2020/2021.

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 2020/2021 should be followed:

**Trivalent vaccines** should contain:

*Egg-based or Live attenuated Vaccines*

- an A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus;
- an A/Hong Kong/2671/2019 (H3N2)-like virus; and
- a B/Washington/02/2019 (B/Victoria lineage)-like virus;

*Cell- based Vaccines*

- an A/Hawaii/70/2019 (H1N1)pdm09-like virus;
- an A/Hong Kong/45/2019 (H3N2)-like virus; and
- a B/Washington/02/2019 (B/Victoria lineage)-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 virus in addition to the strains mentioned above is considered appropriate.

[1] Further to the EU recommendation dated 26 March 2020, this amended document includes a recommendation for a suitable A/Guangdong-Maonan/SWL1536/2019-like virus for seasonal live attenuated influenza vaccines. Annex I (Reagents for vaccine standardisation) has also been updated.

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

*Egg-derived vaccines*

As A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like viruses:

- reassortant virus CNIC-1909, which is derived from A/Guangdong-Maonan/SWL1536/2019
- reassortant virus IVR-207, which is derived from A/Victoria/2454/2019

As A/Hong Kong/2671/2019 (H3N2)-like viruses:

- reassortant virus IVR-208, which is derived from A/Hong Kong/2671/2019
- reassortant virus NIB-121, which is derived from A/Hong Kong/2671/2019

As B/Washington/02/2019-like viruses (B/Victoria/2/87 lineage):

- B/Washington/02/2019 (wild type)
- reassortant virus BVR-11, which is derived from B/Victoria/705/2018

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

- B/Phuket/3073/2013 (wild type)
- reassortant virus BVR-1B, which is derived from B/Phuket/3073/2013

*Cell-derived vaccines*

As an A/Hawaii/70/2019 (H1N1)pdm09-like virus:

- A/Nebraska/14/2019 (wild type)

As an A/Hong Kong/45/2019 (H3N2)-like virus:

- A/Delaware/39/2019 (wild type)

As a B/Washington/02/2019-like virus (B/Victoria/2/87 lineage):

- B/Darwin/7/2019 (wild type)

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

- B/Singapore/INFTT-16-0610/2016 (wild type)

*Live attenuated influenza vaccines*

As an A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus[2]:

- Virus MEDI 326775, which is derived from A/Hawaii/66/2019

As an A/Hong Kong/2671/2019 (H3N2)-like virus:

- Virus MEDI 325078, which is derived from A/Hong Kong/2671/2019

As a B/Washington/02/2019 -like virus (B/Victoria/2/87 lineage):

- Virus MEDI 323797, which is derived from B/Washington/02/2019

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

- Virus MEDI 306444, which is derived from B/Phuket/3073/2013

**Reagents** for vaccine standardisation may be obtained from WHO Essential Regulatory Laboratories (ERLs). It is anticipated that reagents are/ will be available from NIBSC (WHO ERL, UK) and TGA (WHO ERL, 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 2020.

**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.

It was agreed that although B lineage information is now included in EMA/WHO recommendation companies should adhere to existing labelling guidance (not to include the B lineage wording "B/Victoria/2/87 lineage" or "B/Yamagata/16/88 lineage") again this year. This would be reviewed when there would be an opportunity to review the relevant EMA (and CMDh) guidance on influenza vaccines (which includes labelling guidance). It was agreed that the prefixes NYMC and CNIC for respective strains for the 2020-21 recommendation would also be included in the labelling whereas no prefixes are required for the Seqirus-developed CVVs. This is generally in line with the WHO nomenclature. EMA would follow-up regarding specific requirements for labelling of the LAIV.

[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[5,6]

***Available from NIBSC, UK and TGA, Australia.***[7]

**H1N1**

A/Guangdong-Maonan/SWL1536/2019 (CNIC-1909) egg derived antigen is available (NIBSC 19/312)

A/Victoria/2454/2019 (IVR-207) egg derived antigen is available (NIBSC 19/306 and TGA 2020/132B)

A/Nebraska/14/2019 cell derived antigen will be available (CBER H1-Ag-2005)

A/Guangdong-Maonan/SWL1536/2019-like antiserum is available (NIBSC 19/314)

**H3N2**

A/Hong Kong/2671/2019 (IVR-208) egg derived antigen is available (NIBSC 19/310 and TGA 2020/133B)

A/Hong Kong/2671/2019 (NIB-121) egg derived antigen is available (NIBSC 20/108)

A/Delaware/39/2019 cell derived antigen is available (CBER H3-Ag-2006)

A/Hong Kong/2671/2019-like antiserum is available (NIBSC 19/316)

**B/Victoria/2/87 lineage**

B/Washington/02/2019 egg derived antigen is available (NIBSC 19/190 and NIBSC 19/238)

B/Victoria/705/2018 (BVR-11) egg derived antigen is available (NIBSC 19/208 and TGA 2019/130B)

B/Darwin/7/2019 cell-derived antigen is available (NIBSC 19/210)

B/Washington/02/2019-like antiserum is available (NIBSC 19/218 and TGA AS436)

**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 and TGA 2017/115B)

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

B/Singapore/INFTT-16-0610/2016 cell derived antigen is available (NIBSC 19/308)

B/Phuket/3073/2013-like antiserum is available (NIBSC 17/214 and TGA AS425 and AS426)

[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.

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[7] 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/