EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2021
EMA/CHMP/BWP/80561/2021
Committee for Medicinal Products for Human Use (CHMP)

Amended[1] BWP Ad hoc Influenza Working Group

EU recommendations for the seasonal influenza vaccine composition for the season 2021/2022

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 2021/2022.

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 2021/2022 should be followed:

Trivalent vaccines should contain:

Egg-based or Live attenuated Vaccines

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- an A/Cambodia/e0826360/2020 (H3N2)-like virus;
- a B/Washington/02/2019 (B/Victoria lineage)-like virus

Cell- based Vaccines

- an A/Wisconsin/588/2019 (H1N1)pdm09-like virus;
- an A/Cambodia/e0826360/2020 (H3N2)-like virus;
- 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 25 March 2021, this amended document includes a recommendation for a suitable A/Victoria/2570/2019 (H1N1)pdm09-like virus and A/Cambodia/e0826360/2020-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 an A/Victoria/2570/2019 (H1N1)pdm09-like virus:

- reassortant virus IVR-215, which is derived from A/Victoria/2570/2019

As an A/Cambodia/e0826360/2020 (H3N2)-like virus:

- reassortant virus IVR-224, which is derived from A/Cambodia/e0826360/2020
- reassortant virus IVR-221, which is derived from A/Tasmania/503/2020

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

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

As a B/Phuket/3073/2013-like virus (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/Wisconsin/588/2019 (H1N1)pdm09-like virus:

- A/Washington/19/2020 (wild type)

As an A/Cambodia/e0826360/2020 (H3N2)-like virus:

- A/Tasmania/503/2020 (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 (LAIV)

As an A/Victoria/2570/2019 (H1N1)pdm09-like virus[2]:

- Virus MEDI 340505, which is derived from A/Victoria/1/2020

As an A/Cambodia/e0826360/2020 (H3N2)-like virus[2]:

[2] Updated 24 June 2021

- Virus MEDI 339018, which is derived from A/Tasmania/503/2020

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

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

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 other ERLs (see Annex I)

Note on labelling requirements

NCAs and manufacturers are requested to follow the labelling examples (strain descriptions) given in the Guideline on influenza vaccines – submission and procedural requirements, which applies to centrally-approved influenza vaccines**Error! Bookmark not defined.**. Equivalent labelling guidance for influenza vaccines authorised by other routes in the EU[3] 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 (e.g. NYMC, Seqirus) for respective strains for future EU influenza recommendations would not be included in the labelling. This is generally in line with the WHO nomenclature.

[3] 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[4]

Available from NIBSC, UK, TGA, Australia and CBER/FDA, USA.[5]

H1N1

A/Victoria/2570/2019 (IVR-215) egg derived antigen is available (NIBSC 20/232, TGA 2020/134B, 2021/137B and CBER/FDA H1-Ag-2016)

A/Washington/19/2019 cell derived antigen is available (CBER/FDA H1-Ag-2106)

A/Victoria/2570/2019-like antiserum is available (NIBSC 20/234, TGA AS443 and CBER/FDA H1-Ab-2101, and H1-Ab-2109)

H3N2

A/Tasmania/503/2020 (IVR-221) egg derived antigen is available (NIBSC 21/116 and CBER/FDA H3-Ag-2104).

A/Cambodia/e0826360/2020 (IVR-224) egg derived antigen is available (NIBSC 21/100)

A/Tasmania/503/2020 cell derived antigen is available (CBER/FDA H3-Ag-2107)

A/Cambodia/e0826360/2020-like antiserum is available (NIBSC 21/118, TGA AS444 and CBER/FDA H3-Ab-2110)

B/Victoria/2/87 lineage

B/Washington/02/2019 egg derived antigen is available (NIBSC 19/238 and CBER/FDA B(v)-Ag-1912)

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, CBER/FDA B(v)-Ag-2002 and B(v)-Ag-2108)

B/Washington/02/2019-like antiserum is available (NIBSC 19/318, TGA AS436 and AS436-1, and CBER/FDA B(v)-Ab-1914 and B(v)-Ab-2014).

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 21/136, TGA 2017/115B and FDA/CBER #80).

B/Phuket/3073/2013 (BVR-1B) egg derived antigen is available (TGA 2017/117B and 2020/136B)

B/Singapore/INFTT-16-0610/2016 cell derived antigen is available (NIBSC 19/308 and CBER/FDA B(y)-Ag-1709, B(y)-Ag-1817 and B(y)-Ag-2103)

B/Phuket/3073/2013-like antiserum is available (NIBSC 19/322, TGA AS425 and AS434, and FDA/CBER B(y)-Ab-1808)

B/Wisconsin/1/2010 (BX41A)-like antiserum is available (TGA AS426)

[4] 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.

[5] 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
https://www.who.int/teams/global-influenza-programme/vaccines/who-recommendations/candidate-vaccine-viruses