24 March 2022
EMA/CHMP/BWP/116744/2022
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 2022/2023

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 2022/2023.

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 2022/2023 should be followed:

Quadrivalent vaccines should contain:

Egg-based or Live attenuated Vaccines

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- an A/Darwin/9/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

Cell- culture vaccines

- an A/Wisconsin/588/2019 (H1N1)pdm09-like virus;
- an A/Darwin/6/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and

[1] this amended document includes a recommendation for a suitable A/Darwin/9/2021 (H3N2)-like virus and B/Austria/1359417/2021 (B/Victoria lineage)-like virus for seasonal live attenuated influenza vaccines. Annex I (Reagents for vaccine standardisation) has also been updated.

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- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus

For vaccine manufacturers considering the use of one B lineage vaccine virus only in **trivalent vaccines**, B/Austria/1359417/2021 (B/Victoria lineage)-like virus is considered appropriate for inclusion. Therefore, a B/Yamagata lineage virus is not recommended for inclusion in trivalent vaccines.

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/Darwin/9/2021 (H3N2)-like virus:

- reassortant virus IVR-227, which is derived from A/Darwin/6/2021
- reassortant virus IVR-228, which is derived from A/Darwin/9/2021
- reassortant virus SAN-010, which is derived from A/Darwin/9/2021

As a B/Austria/1359417/2021 (B/Victoria lineage)-like virus:

- B/Michigan/01/2021 (wild type)
- reassortant virus BVR-26, which is derived from B/Austria/1359417/2021

As a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus, 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)
- reassortant virus CVR-45, which is derived from A/Delaware/55/2019

As an A/Darwin/6/2021 (H3N2)-like virus:

- A/Darwin/11/2021 (wild type)

As a B/Austria/1359417/2021 (B/Victoria lineage)-like virus:

- B/Singapore/WUH4618/2021 (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:

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

As an A/Darwin/9/2021 (H3N2)-like virus[2]:

- Virus MEDI 355293, which is derived from A/Norway/16606/2021

As a B/Austria/1359417/2021 (B/Victoria lineage)-like virus[2]:

- Virus MEDI 355292, which is derived from B/Austria/1359417/2021

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

- 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[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 (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.

[2] Updated 29 March 2022

[3] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-influenza-vaccines-submission-procedural-requirements-rev1_en.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, TGA, Australia and CBER/FDA, USA.[6]

H1N1

A/Victoria/2570/2019 (IVR-215) egg derived antigen is available (NIBSC 20/232, TGA 2021/137B, 2022/140B and CBER/FDA H1-Ag-2118)

A/Washington/19/2020 cell derived antigen is available (CBER/FDA H1-Ag-2106)

A/Delaware/55/2019 CVR-45 cell derived antigen is in preparation (CBER/FDA H1-Ag-2203)

A/Victoria/2570/2019-like antiserum is available (NIBSC 21/120, TGA AS443 and AS443-1, and CBER/FDA H1-Ab-2109)

H3N2

A/ Darwin/9/2021 (IVR-228) egg derived antigen is available (NIBSC 21/318).

A/ Darwin/9/2021 (SAN-010) egg derived antigen is available (NIBSC 21/320 and CBER/FDA H3-Ag-2116)

A/ Darwin/6/2021 (IVR-227) egg derived antigen is available (NIBSC 21/314 and TGA 2021/138B).

A/ Darwin/11/2021 cell derived antigen is available (CBER/FDA H3-Ag-2114)

A/ Darwin/9/2021-like antiserum is available (NIBSC 21/324, TGA AS445 and CBER/FDA H3-Ab-2120)

B/Victoria/2/87 lineage

B/Michigan/01/2021 egg derived antigen is available (NIBSC 21/330 and CBER/FDA B(v)-Ag-2117)

B/Austria/1359417/2021 (BVR-26) egg derived antigen is available (NIBSC 21/316 and TGA 2021/139B)

B/Singapore/WUH4618/2021 cell derived antigen is available (CBER/FDA B(v)-Ag-2115)

B/Austria/1359417/2021-like antiserum is available (NIBSC 21/326, TGA AS446 and CBER/FDA B(v)-Ab-2119 and B(v)-Ab-2202).

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

B/Phuket/3073/2013 egg derived antigen is available (NIBSC 21/136, TGA 2017/115B and FDA/CBER B(y)-Ag-2112).

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

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

B/Phuket/3073/2013-like antiserum is available (NIBSC 19/322, TGA AS425, AS426 and AS434, and FDA/CBER B(y)-Ab-1808)

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