14 April 2023
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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 2023/2024

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 2023/2024.

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 2023/2024 should be followed:

**Quadrivalent vaccines** should contain:

*Egg-based or Live attenuated Vaccines*

- an A/Victoria/4897/2022 (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/67/2022 (H1N1)pdm09-like virus;
- an A/Darwin/6/2021 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus

[1] This amended document includes a recommendation for a suitable A/Victoria/4897/2022 (H1N1)pdm09-like virus for seasonal live attenuated influenza vaccines. Annex I (Reagents for vaccine standardisation) has also been updated.

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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/4897/2022 (H1N1)pdm09-like virus:

- reassortant virus IVR-238, which is derived from A/Victoria/4897/2022

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/67/2022 (H1N1)pdm09-like virus;

- reassortant virus CVR-167 which is derived from A/Georgia/12/2022

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 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/4897/2022 (H1N1)pdm09-like virus[2]:

- Virus MEDI 369815, which is derived from A/Norway/31694/2022

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

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

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

- 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

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.

**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)

[2] Updated 14 April 2023

**ANNEX I**

# Reagents for vaccine standardisation[3]

***Available from MHRA (NIBSC), UK, TGA, Australia and CBER/FDA, USA.[4]***

**H1N1**

A/Victoria/4897/2022 (IVR-238) egg derived antigen is in progress (NIBSC 22/320, TGA 2023/143B and CBER/FDA H1-Ag-2303))

A/Victoria/4897/2022-like antiserum is in progress (NIBSC 23/100 and TGA AS451)

**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 and H3-Ab-2204)

**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 AS446-1 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, AS434 and AS434-1, and FDA/CBER B(y)-Ab-2215)

[3] Manufacturers may use reagents for standardisation prepared by MHRA, UK, 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.

[4] 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