21 March 2024
EMA/60123/2024
Committee for Medicinal Products for Human Use (CHMP)

BWP Ad hoc Influenza Working Group

EU recommendations for the seasonal influenza vaccine composition for the season 2024/2025

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 2024/2025.

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 2024/2025 should be followed:

Trivalent vaccines should contain:

Egg-based or Live attenuated Vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Thailand/8/2022 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and

Cell-derived vaccines

- an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- an A/Massachusetts/18/2022 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and

For vaccine manufacturers considering the use of a B/Yamagata/16/88 lineage vaccine virus in egg-based or cell-derived inactivated **quadrivalent vaccines** containing two influenza B viruses:

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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

in addition to the strains mentioned above is considered appropriate.

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/Thailand/8/2022 (H3N2)-like virus:

- reassortant virus IVR-237, which is derived from A/Thailand/8/2022
- reassortant virus SAN-022, which is derived from A/California/122/2022

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/Massachusetts/18/2022 (H3N2)-like virus:

- A/California/45/2023 (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)

These will be confirmed at a later date.

Reagents for vaccine standardisation may be obtained from WHO Essential Regulatory Laboratories (ERLs). It is anticipated that reagents are/ will be available from MHRA (WHO ERL, UK) and other ERLs (see Annex I)

ANNEX I

Reagents for vaccine standardisation[1]

Available from MHRA (NIBSC), UK, TGA, Australia and CBER/FDA, USA.[2]

H1N1

A/Victoria/4897/2022 (IVR-238) egg derived antigens are available (NIBSC 22/320, TGA 2023/143B + 2023/146B and CBER/FDA H1-Ag-2303))

A/Georgia/12/2022 (CVR-167) cell derived antigen (CBER/FDA H1-Ag-2307)

A/Victoria/4897/2022-like antisera are available (NIBSC 23/100, TGA AS451-1 and AS454 and CBER/FDA H1-Ab-2316)

A/Sydney/5/2021 antiserum (CBER/FDA H1-Ab-2214, used with CBER reference antigens only)

H3N2

A/Thailand/8/2022 (IVR-237) egg derived antigens are available (NIBSC 23/220 and TGA 2023/145B)

A/ California/122/2022 (SAN-022) egg derived antigens are available (NIBSC 23/226 and CBER/FDA H3-Ag-2314)

A/California/45/2023 cell derived antigen is in progress

A/Thailand/8/2022-like antisera are available (NIBSC 23/222, TGA AS450 and CBER/FDA H3-Ab-2315)

B/Victoria/2/87 lineage

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

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

B/Singapore/WUH4618/2021 cell derived antigens are available (NIBSC 23/268 and CBER/FDA B(v)-Ag-2115)

B/Austria/1359417/2021-like antisera are available (NIBSC 22/228, TGA AS446-1 and AS452 and CBER/FDA B(v)-Ab-2202 and B(v)-Ab-2308).

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

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

B/Phuket/3073/2013 (BVR-1B) egg derived antigens are available (TGA 2020/136B and 2023/142B)

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

[1] 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.

[2] For availability and progress in development of reagents, consult the following websites:
NIBSC - Full reagent update
Global Influenza Programme (who.int)

B/Phuket/3073/2013-like antisera are available (NIBSC 22/132, TGA AS425, AS426 and AS449, and FDA/CBER B(y)-Ab-2215)