08 April 2025
EMADOC-628903358-119194 Corr.1[1]
Committee for Medicinal Products for Human Use (CHMP)

Amended[2] BWP Vaccines Quality Operational Expert Group (BV-OEG) Influenza Meeting

EU recommendations for the seasonal influenza vaccine composition for the season 2025/2026

The meeting of the Biologics Working Party (BWP) vaccines quality operational expert group (BV-OEG) influenza meeting was convened in order to recommend the virus strains for the manufacture of seasonal influenza vaccine for 2025/2026.

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 BV-OEG influenza meeting, consisting of experts on influenza from the Member States, considered that the WHO recommendation on the composition of vaccines for 2025/2026 should be followed:

Trivalent vaccines should contain:

Egg-based or Live attenuated Vaccines

- an A/Victoria/4897/2022 (H1N1)pdm09-like virus;
- an A/Croatia/10136RV/2023 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus;

[1] The second paragraph of the document has been updated to correct the correct influenza season i.e. 2025/2026.
[2] This amended document includes a recommendation for a suitable A/Croatia/10136RV/2023 (H3N2)-like virus for seasonal live attenuated influenza vaccines. Annex I (Reagents for vaccine standardisation) has also been updated.

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Cell-derived vaccines

- an A/Wisconsin/67/2022 (H1N1)pdm09-like virus;
- an A/District of Columbia/27/2023 (H3N2)-like virus;
- a B/Austria/1359417/2021 (B/Victoria lineage)-like virus;

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:

- 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/Croatia/10136RV/2023 (H3N2)-like virus:

- reassortant virus X-425A, which is derived from A/Croatia/10136RV/2023

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/District of Columbia/27/2023 (H3N2)-like virus:

- reassortant virus CVR-289, which is derived from A/ Victoria/800/2024

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:

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

As an A/Croatia/10136RV/2023 (H3N2)-like virus[3]:

- Virus MEDI 392611, which is derived from A/Perth/722/2024

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

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

Reagents It is anticipated that reagents for vaccine standardisation are/ will be available from WHO Essential Regulatory Laboratories such as MHRA and other laboratories (see Annex I).

[3] Updated 08 April 2025

ANNEX I

Reagents for vaccine standardisation[4]

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

H1N1

H1N1

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

A/Georgia/12/2022 (CVR-167) cell derived antigen (MHRA 24/198, CBER/FDA H1-Ag-2307)

A/Victoria/4897/2022-like antisera are available (MHRA 23/100 and 23/278, TGA 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/Croatia/10136RV/2023 (X-425A) egg derived antigens are available (MHRA 24/174, TGA 2024/148B and CBER/FDA H3-Ag-2411)

A/Victoria/800/2024 (CVR-289) cell derived antigen is in preparation (TGA 2025/150B)

A/Croatia/10136RV/2023-like antisera are available (MHRA 24/176, TGA AS460 and CBER/FDA H3-Ab-2412)

B/Victoria/2/87 lineage

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

B/Austria/1359417/2021 (BVR-26) egg derived antigens are available (MHRA 21/316 + 24/180 and TGA 2025/149B)

B/Singapore/WUH4618/2021 cell derived antigens are available (MHRA 23/268 and CBER/FDA B(v)-Ag-2402)

B/Austria/1359417/2021-like antisera are available (MHRA 22/228 + 24/118, TGA AS446-1 + AS452 and CBER/FDA B(v)-Ab-2202 + 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 (MHRA 21/136 + 24/182, TGA 2017/115B and CBER/FDA B(y)-Ag-2112).

[4] 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.

[5] 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 (BVR-1B) egg derived antigens are available (TGA 2023/142B)

B/Singapore/INFTT-16-0610/2016 cell derived antigens are available (MHRA 19/308 and CBER/FDA B(y)-Ag-2403)

B/Phuket/3073/2013-like antisera are available (MHRA 22/132, TGA AS425 + AS449 + AS449-1 (in preparation), and CBER/FDA B(y)-Ab-2215)