# Fluad

## Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| Variation type II / | B.I.a.5 Changes to the active substance of a | 30/07/2025 | 09/07/2025 | SmPC, | B.I.a.5.a Replacement of the strain(s) in a seasonal, |

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| EMA/VR/0000272403 | seasonal, prepandemic or pandemic vaccine against human influenza - B.I.a.5.a Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza - Accepted<br><br>B.I.a.5.a (Type II): Seasonal update of the composition of the vaccine strains officially recommended by WHO and CHMP for the season Northern Hemisphere (NH) 2025/2026, which are the following: - A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238); - A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A); - B/Austria/1359417/2021 (B/Victoria lineage)-like strain (B/Austria/1359417/2021, BVR-26). The requested variation proposed amendments to the Summary of Product Characteristics, Labelling, Package Leaflet and Annex A. | | | Labelling and PL | prepandemic or a pandemic vaccine against human influenza |
| Variation type IB / EMA/VR/0000244302 | This was an application for a group of variations.<br><br>B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted<br><br>B.I.b.2 Change in test procedure for active substance or starting | 21/01/2025 | N/A | | |

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| | material/reagent/intermediate used in the manufacturing process of the active substance - B.I.b.2.a Minor changes to an approved test procedure - Accepted | | | | |