EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Fluenz

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification [1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
II/0002	Update of sections 4.2 and 4.4 of the SmPC to restrict the 2-dose schedule to children from 2 to 8 years of age who have not been vaccinated before, instead of children from 2 to 17 years of age who have not been vaccinated before, and to include a warning regarding the postponement of vaccinations	27/02/2025	28/03/2025	SmPC, Labelling and PL	

[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).

	in individuals with symptoms of an acute infection and in case of nasal blockage. In addition, the MAH took the opportunity to implement changes in sections 1, 2, 3, 4.1, 4.3, 4.4, 4.5, 4.6, 4.8, 4.9, 5.1, 6.1, 6.3, 6.5, 6.6 and 8 of the SmPC. The labelling and Package Leaflet are updated accordingly. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
WS/2796	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product B.I.a.1.e - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The change relates to a biological AS or a starting material [-] used in the manufacture of a biological/immunological product	30/01/2025	n/a		
IG/1811/G	This was an application for a group of variations. B.II.f.1.e - Stability of FP - Change to an approved stability protocol	18/12/2024	n/a		

	B.II.e.5.b - Change in pack size of the finished product - Deletion of a pack size(s)				
IB/0004	C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation	18/11/2024	28/03/2025	Annex II	
II/0001	B.I.a.5.a - Changes to the AS of a seasonal, prepandemic or pandemic vaccine against human influenza - Replacement of the strain(s) in a seasonal, prepandemic or a pandemic vaccine against human influenza	11/07/2024	17/07/2024	SmPC, Labelling and PL	As a result of this variation, Section 2 of the SmPC (qualitative and quantitative composition) has been updated to reflect the changes in influenza strains included in the 2024-2025 formulation. The SmPC section 2 has been updated as follows: A/Victoria/4897/2022 (H1N1)pdm09 - like strain (A/Norway/31694/2022, MEDI 369815) A/Thailand/8/2022 (H3N2) - like strain (A/Thailand/8/2022, MEDI 370626) B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021, MEDI 355292) The Labelling, Package leaflet and Annex A have been updated accordingly.