Zoonotic Influenza Vaccine Seqirus

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
IB/0004	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	24/09/2024		SmPC	
IB/0005/G	This was an application for a group of variations.	28/08/2024	n/a		

[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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	B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation A.7 - Administrative change - Deletion of manufacturing sites A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
PSUSA/10008 /202310	Periodic Safety Update EU Single assessment - pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted), prepandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted)	16/05/2024	n/a		PRAC Recommendation - maintenance
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	21/03/2024	09/04/2024	SmPC, Labelling and PL	For more information, please refer to the Summary of Product Characteristics. The SmPC sections 1, 2, 3, 4.1,4.2, 4.3, 4.4, 4.5, 4.6, 4.8, 5.1, 5.3, 6.3 and 6.6, have been updated as follows: To include the updated vaccine strain: A/Astrakhan/3212/2020 (H5N8)-like strain (CBER-RG8A) (clade 2.3.4.4b) and to rationalise the text in relation to the updated H5N8 strain. Annex A, Labelling and PL have been updated accordingly.