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
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)

[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).

					(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.