COVID-19 Vaccine (inactivated, adjuvanted) Valneva

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/0006	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	22/11/2022	25/11/2022	SmPC and PL	The SmPC (Annex I) and the Package Leaflet (Annex IIIB) have been updated to reflect the change in shelf life to 18 months when stored at 5°C ± 3°C.
IB/0003	B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening	21/09/2022	27/09/2022	SmPC, Labelling and	Sections 6.3 and 6.6 of the SmPC (Annex I), section 9 of Labelling (Annex IIIA), and the Package Leaflet (Annex

[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).

	(supported by real time data)			PL	IIIB) have been updated to reflect the change in the in-use shelf life after first opening to "either up to 6 hours when stored below 25°C or up to 48 hours when stored at 2-8°C with a maximum time of 2.5 hours at room temperature (15–25°C)".
IB/0002/G	This was an application for a group of variations. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product B.I.a.1.a - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - The proposed manufacturer is part of the same pharmaceutical group as the currently approved manufacturer B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS B.II.g.5.c - Implementation of changes foreseen in an approved change management protocol - For a biological/immunological medicinal product	12/09/2022	27/09/2022	Annex II	Update in Section A of Annex II, adding a manufacturer of the biological active substance.

IB/0001/G	This was an application for a group of variations. B.II.f.1.z - Stability of FP - Change in the shelf-life or storage conditions of the finished product - Other variation 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	25/07/2022	28/07/2022	SmPC and PL	Section 6.3 of the SmPC and section 6 of the PL have been updated to reflect the extension of the shelf-life of the finished product from 12 months to 15 months when stored at 5°C ± 3°C. Furthermore, the PI has been updated to implement the official abbreviation "AgU" for Antigen Units.