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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 IB / EMA/VR/0000334680	Q.I.b.3 Change to an in-house reference standard/preparation for a biological active substance - Q.I.b.3.b) Replacement of an in-	20/03/2026			

[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).

	house reference standard/preparation not covered by an approved qualification protocol, where comparability test results using current and proposed reference standard/preparation material are available - Accepted				
Variation type II / EMA/VR/0000302084	This was an application for a group of variations. B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted B.II.b.1 Replacement or addition of a	05/03/2026		Annex II	Annex II of the Product Information is updated with the information of an additional active substance manufacturing site: Valneva Scotland Ltd, 1 Oakbank Park Place, Livingston, West Lothian, EH53 0TN, United Kingdom.

	manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted				
Variation type IA / EMA/VR/0000332202	This was an application for a group of variations. Q.III.1.b) European Pharmacopoeial TSE certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Q.III.1.b.3 Update of an approved TSE certificate - Accepted Q.III.1.b) European Pharmacopoeial TSE certificate of suitability for an active substance/starting material/reagent/intermediate/or excipient - Q.III.1.b.3 Update of an approved TSE certificate - Accepted	16/02/2026			
Variation type IA / EMA/VR/0000280033	B.III.2 Change to comply with Ph. Eur. or with a national pharmacopoeia of a Member State - B.III.2.b Change to comply with an update of the relevant monograph of the Ph. Eur. or national pharmacopoeia of a Member	19/06/2025			

	State - Accepted				
Variation type IB / EMA/VR/0000263527	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	01/05/2025			
Variation type IB / EMA/VR/0000249332	B.I.b.2 Change in test procedure for active substance or starting 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	13/03/2025			