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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 /	B.I.e.5 Implementation of changes foreseen	23/07/2025		Annex II	

[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).

EMA/VR/0000275018	in an approved change management protocol - B.I.e.5.c Implementation of a change for a biological/immunological medicinal product - Accepted				
Variation type IB / EMA/VR/0000279285	B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted	16/07/2025		SmPC and PL	
Variation type IA_IN / EMA/VR/0000279769	B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - Accepted	17/06/2025	N/A		
Variation type IB / EMA/VR/0000264282	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.z Other variation - Accepted	04/06/2025	N/A		
Variation type II / EMA/VR/0000254901	B.II.g) Design Space and post approval change management protocol - B.II.g.2	08/05/2025	N/A		

	Introduction of a post approval change management protocol related to the finished product - Accepted				
Variation type IB / EMA/VR/0000262726	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.f Changes to quality control testing arrangements for the active substance-replacement or addition of a site where batch control/testing takes place - Accepted	28/04/2025	N/A		
Variation type IB / EMA/VR/0000263912	B.II.c.2 Change in test procedure for an excipient - B.II.c.2.d Other changes to a test procedure (including replacement or addition) - Accepted	28/04/2025	N/A		
Variation type IB / EMA/VR/0000263394	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be	24/04/2025		SmPC and PL	To update section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with a frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data. The Package Leaflet is updated accordingly. The MAH also took the opportunity to add warnings for polysorbate into the SmPC and the Package Leaflet

	submitted by the MAH - Accepted C.I.2.a - To update section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with a frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data, following the same change of the reference product. The Package Leaflet is updated accordingly. The MAH also took the opportunity to add warnings for polysorbate into the SmPC and the Package Leaflet in line with the instructions in the most recent updates to the Appendix of the EC Excipient Guideline, and made an editorial correction to section 4.8 of the SmPC in ES language to include a previously missing table 1 description, in alignment with the reference product. In addition, the MAH took the opportunity to update the contact information of the local representative of Italy.				in line with the instructions in the most recent updates to the Appendix of the EC Excipient Guideline, and made an editorial correction to section 4.8 of the SmPC in ES language to include a previously missing table 1 description, in alignment with the reference product.
Variation type IB / EMA/VR/0000262014	B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted	14/04/2025	N/A		
Variation type IA / EMA/VR/0000255758	B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Refused	21/03/2025	N/A		

Variation type IA / EMA/VR/0000256533	B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.z Minor change of an analytical procedure for an in-process control - Accepted	05/03/2025	N/A		