ELAHERE

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 IA_IN / EMA/VR/0000323227	This was an application for a group of variations.	22/01/2026		Annex II and PL	

[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).

	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 B.II.b.2.c Replacement or addition of a manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted				
Variation type II / EMA/VR/0000297255	B.I.a.3 Change in batch size (including batch size ranges) of active substance or intermediate used in the manufacturing process of the active substance - B.I.a.3.c The change requires assessment of the comparability of a biological/immunological active substance - Accepted	04/12/2025	N/A		
Variation type IB / EMA/VR/0000286590	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted C.I.z. - to propose changes in sections 1, 2, 3, 4, 5 and 6 of the Package Leaflet following an assessment carried out on target patient groups. The MAH took the opportunity to make some editorial changes in the SmPC and additional editing amendments have been carried out in FI, DE, NO, PL, SL, ES and LT annexes. In addition, Annex II has been amended by reporting the correct	20/08/2025		SmPC, Annex II and PL	

	manufacturer of the biological active substance: Bsp Pharmaceuticals S.p.A, Via Appia Km 65561, Latina Scalo, LT 04013 Italy. Finally, an editorial correction has been performed in the contact details of the Icelandic local representative in section 6 of the PL.				
Variation type IA / EMA/VR/0000290386	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.z Other changes - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted 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 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	13/08/2025	N/A		

	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				
Variation type II / EMA/VR/0000249246	This was an application for a group of variations. B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted B.II.d.2 Change in test procedure for the finished product - B.II.d.2.c Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol - Accepted	25/04/2025			B.II.d.2.a Minor changes to an approved test procedure. B.II.d.2.c Substantial change to, or replacement of, a biological/ immunological/ immunochemical test method or a method using a biological reagent or replacement of a biological reference preparation not covered by an approved protocol
PSUR / EMA/PSUR/0000288269	- -				Maintenance