LysaKare

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/0000335864	This was an application for a group of variations.	31/03/2026		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).

	Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted Q.II.b.2.c) Addition or replacement of a site responsible for batch release (QP certification) - Q.II.b.2.c.1 Not including batch control/testing - Accepted Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted				
Variation type II / EMA/VR/0000269283	This was an application for a group of variations. B.II.e.1.a Qualitative and quantitative composition - B.II.e.1.a.3 Sterile medicinal products and biological/ immunological medicinal products - Accepted B.II.d.1 Change in the specification parameters and/or limits of the finished product - B.II.d.1.d Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material) - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an	17/07/2025		SmPC and Labelling	

	intermediate used in the manufacture of the finished product - B.II.b.3.z Other changes - Accepted				
Article 61(3) / EMA/N/0000273490	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with the addition of contact details of local representatives.	20/05/2025		PL	