



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Xermelo

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 /	This was an application for a group of	05/12/2025		SmPC, 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).



EMA/VR/0000314461	<p>variations.</p> <p>A.1 Change in the name and/or address of the marketing authorisation holder - Accepted</p> <p>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</p>			II, Labelling and PL	
Variation type IA_IN / EMA/VR/0000310903	<p>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</p>	21/11/2025		Annex II and PL	
Variation type IA_IN / EMA/VR/0000263801	<p>This was an application for a group of variations.</p> <p>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</p> <p>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.b Primary packaging site - Accepted</p> <p>B.II.b.2 Change to importer, batch release</p>	10/04/2025		Annex II and PL	

	<p>arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted</p> <p>B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted</p> <p>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</p> <p>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</p>				
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