Skyclarys

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 /	Q.II.f.1.b) Extension of the shelf life of the	13/03/2026		SmPC	

[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/0000328186	finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IB / EMA/VR/0000326575	Q.II.c.1 Change in the specification attribute and/or acceptance criteria of an excipient - Q.II.c.1.b) Addition of a new specification attribute to the specification with its corresponding analytical procedure - Accepted	06/03/2026			
Variation type IA / EMA/VR/0000323217	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	19/01/2026			
Variation type II / EMA/VR/0000263377	B.I.b.1 Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - B.I.b.1.f Change outside the approved specifications limits range for the active substance - Accepted	04/12/2025			
Variation type IB / EMA/VR/0000292339	This was an application for a group of variations.	09/09/2025			

	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.a Up to 10-fold increase compared to the originally approved batch size - 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				
Variation type IA_IN / EMA/VR/0000294883	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	03/09/2025		Annex II and PL	
Variation type IB / EMA/VR/0000276345	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.z Other variation - Accepted	24/07/2025			
Variation type IA_IN / EMA/VR/0000275830	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	03/06/2025			
Variation type IA / EMA/VR/0000256186	A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Accepted	03/03/2025		SmPC	
PSUR / EMA/PSUR/0000274406					Maintenance

PSUR / EMA/PSUR/0000311117					maintenance