Tevimbra

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, please 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.II.f.1.b Extension of the shelf life of the	02/06/2025		SmPC 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).

EMA/VR/0000269138	finished product - B.II.f.1.b.3 After dilution or reconstitution (supported by real time data) - Accepted				
Variation type IB / EMA/VR/0000266115	This was an application for a group of variations. B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted B.I.d.1 Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier - B.I.d.1.z Other variation - Accepted	28/05/2025	N/A		
Variation type IA_IN / EMA/VR/0000271889	A. ADMINISTRATIVE CHANGES - A.1 Change in the name and/or address of the marketing authorisation holder - Accepted	13/05/2025		SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000255439	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	19/03/2025	N/A		