EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Temodal

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
Article 61(3) /	- Notification acc. Article 61(3) - Accepted	06/11/2025		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).

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EMA/N/0000309483	Update of the package leaflet with revised contact details of local representatives.				
Variation type IA / EMA/VR/0000280114	This was an application for a group of variations. B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted B.III.1.b European Pharmacopoeial TSE Certificate of suitability for an active substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.4 Deletion of certificates (in case multiple certificates exist per material) - Accepted	04/07/2025	N/A		
Variation type IA / EMA/VR/0000278708	B.II.b.5 Change to in-process tests or limits applied during the manufacture of the finished product - B.II.b.5.b Addition of a new test(s) and limits - Accepted	11/06/2025	N/A		

Variation type IA / EMA/VR/0000267522	A. ADMINISTRATIVE CHANGES - A.7 Deletion of manufacturing sites for an active substance, intermediate or finished product, packaging site, manufacturer responsible for batch release, site where batch control takes place, or supplier of a starting material, reagent or excipient (when mentioned in the dossier)* - Accepted	28/04/2025	N/A		
Article 61(3) / EMA/N/0000264275	- Notification acc. Article 61(3) - Accepted Update of the package leaflet with revised contact details of local representatives and deletion of 'United Kingdom (Northern Ireland)' from the list of local representatives in line with the QRD template v10.4.	22/04/2025		PL	