Pregabalin Sandoz

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 IA_IN /	B.II.b.2.c Replacement or addition of a	18/02/2025		Annex II and	

[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/0000252648	manufacturer responsible for importation and/or batch release - B.II.b.2.c.1 Not including batch control/testing - Accepted			PL	
Variation type IA / EMA/VR/0000245431	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.2 Updated certificate from an already approved manufacturer - Accepted	21/01/2025			
Variation type IB / EMA/VR/0000231572	This was an application for a group of variations. C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Accepted C.I.2.a - To update section 4.4 of the SmPC in order to add information on potential abuse in recreational drug users, following assessment of the same change in the reference product. A.6 – To change the ATC code from N03AX16 to N02BF02. Furthermore, the Marketing Authorisation	21/11/2024		SmPC and PL	

	Holder has taken the opportunity to update the local representative details for Romania and Slovakia.				
Article 61(3) / EMA/N/0000224521	- Notification acc. Article 61(3) - 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.	04/09/2024		PL	
Variation type IA / EMA/VR/0000174983	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	24/04/2024	N/A		
Variation type IB / EMA/VR/0000168879	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal products following assessment of the same change for the reference product - C.I.2.a Implementation of change(s) for which no new additional data is required to be submitted by the MAH - Accepted To update the SmPC sections 4.4 and 4.8	07/03/2024	29/05/2024	SmPC and PL	

	and section 3 in the PIL with "suicidal ideation" as part of the observed withdrawal symptoms.				
Variation type IA_IN / EMA/VR/0000168275	B.III.1.a European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - B.III.1.a.3 New certificate from a new manufacturer (replacement or addition) - Accepted	20/02/2024	N/A		