Pregabalin Viatris

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 /	E.4 Change in the name and/or address of	05/05/2026		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/0000325156	the marketing Term name: E.4 authorisation holder, ASMF holder, storage site of the master and/or working cell bank, manufacturing site for an active substance, intermediate or finished product, primary and/or secondary packaging site, manufacturer responsible for batch release, site where quality control takes place, and/or supplier of a packaging component, medical device (part), starting material, reagent and/or excipient (when mentioned in the dossier - E.4.b) The change in the name and/or address concerns a manufacturer(s)whose activities include batch release of the finished product - Accepted			PL	
Variation type IB / EMA/VR/0000327774	This was an application for a group of variations. Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted Q.II.e.4 Change in the specification attribute and/or acceptance criteria of the immediate packaging of the finished product - Q.II.e.4.c) Deletion of a non-significant or obsolete specification attribute - Accepted	25/02/2026			

Variation type IA / EMA/VR/0000320537	This was an application for a group of variations. B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.a Tightening of specification limits - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Accepted B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Refused B.II.e.2 Change in the specification parameters and/or limits of the immediate packaging of the finished product - B.II.e.2.c Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter) - Refused	07/01/2026			
Article 61(3) / EMA/N/0000319152	- Notification acc. Article 61(3) - Accepted	19/12/2025		PL	

	Update of the package leaflet with revised contact details of local representative.				
Variation type IA / EMA/VR/0000316987	This was an application for a group of variations. 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 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	12/12/2025			
Variation type IA / EMA/VR/0000293003	B.II.d.2 Change in test procedure for the finished product - B.II.d.2.a Minor changes to an approved test procedure - Accepted	25/08/2025			
Variation type IA / EMA/VR/0000288609	This was an application for a group of variations. 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 A.5 Change in the name and/or address of a manufacturer/importer of the finished	30/07/2025			

	product (including batch release or quality control testing sites) - A.5.b The activities for which the manufacturer/importer is responsible do not include batch release - Accepted				
Variation type IB / EMA/VR/0000268655	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.e) Container closure system - B.II.e.z Other variation - Accepted	10/07/2025			
Variation type IA_IN / EMA/VR/0000252315	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	06/03/2025		Annex II and PL	

	substance/starting material/reagent/ intermediate/or excipient - B.III.1.b.3 Updated certificate from an already approved manufacturer - Accepted A.5 Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing sites) - A.5.a The activities for which the manufacturer/importer is responsible include batch release - Accepted 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				
Variation type IB / EMA/VR/0000241422	This was an application for a group of variations. 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.h Addition or replacement (excluding biological or immunological substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue - Accepted	24/01/2025			

	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				
Variation type IB / EMA/VR/0000231406	This was an application for a group of variations. A. ADMINISTRATIVE CHANGES - A.6 Change in ATC Code / ATC Vet Code - Accepted 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 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 Holder has taken the opportunity to implement editorial changes in the following translations: MT, RO, SK, FI, CS, IS, SL and PT.	03/12/2024		SmPC	

Marketing Authorisation Transfer - H / EMA/T/0000177721	Transfer of Marketing Authorisation from Mylan Pharmaceuticals Limited to Viatris Limited.	31/05/2024	24/07/2024	SmPC, Labelling and PL	
Variation type IA_IN / EMA/VR/0000174634	A.2 Change in the (invented) name of the medicinal product - A.2.a) for Centrally Authorised products - Accepted	18/04/2024	19/07/2024	SmPC, Labelling and PL	
Variation type IB / EMA/VR/0000167464	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 and section 3 in the PIL with "suicidal ideation" as part of the observed withdrawal symptoms. In addition The MAH has taken this opportunity to amend the local representatives in Belgium, Luxembourg, Baltics, Greece, Spain, Italy, Croatia and Hungary. Also the DA, NL and LT have been corrected to be fully in line with the annexes of the reference product.	23/02/2024	19/07/2024	SmPC and PL	