Lemtrada

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 /	C.I HUMAN AND VETERINARY MEDICINAL	27/10/2025		SmPC, Annex	To update Sections 2 and 4.4 of the SmPC 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/0000304324	PRODUCTS - C.I.z Other variation - Accepted C.I.z (Type IB) – To update Sections 2 and 4.4 of the SmPC and section 2 of the PL to implement the recommendation of European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) regarding polysorbates excipients. In addition, the applicant took the opportunity to implement editorial updates by (1) updating the local representative's details in the PL by deleting UK(NI) in line with the QRD template, (2) updating the details of the local representative for IS, (3) updating Annex II Section A by deleting an irrelevant sentence, (4) deleting Annex IV, and (5) updating the translated PI for MT and EL in line with Member State comments received during PASS EMEA/H/C/PSR/S/0050 and 0051.			II and PL	section 2 of the PL to implement the recommendation of European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) regarding polysorbates excipients.
Variation type IA / EMA/VR/0000306412	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	16/10/2025	N/A		
Variation type IA / EMA/VR/0000287563	This was an application for a group of variations.	23/07/2025	N/A		

	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 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 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 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				
Variation type II / EMA/VR/0000259153	C.I.11 Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the risk management plan - C.I.11.b Implementation of change(s) which require to be further substantiated by new additional data to be submitted by the MAH where significant assessment by the competent authority is required* - Accepted	05/06/2025	N/A		n/a

	Submission of an updated RMP version 13.0 following the completion of the two non-interventional PASS category 1 Drug Utilization Study (dut0008) and Mortality study (csa0002). The risks table was updated with new DLP 12 September 2024 without new safety concerns.				