Vyepti

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 II / EMA/VR/0000324932	Outcome: C. Safety, efficacy, pharmacovigilance changes - C.4 Change(s) in the summary of	10/04/2026		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).

	product characteristics, labelling or package leaflet due to new quality, preclinical, clinical or pharmacovigilance data. – Accepted Update of sections 4.4 and 4.8 of the SmPC in order to update the safety information based on final results from phase 3 studies 19140A and 19140B, as well as post-marketing data. The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to implement editorial changes to the PI and to update the list of local representatives in the Package Leaflet.				
Variation type II / EMA/VR/0000258913	Outcome: This was an application for a group of variations. 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 B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used in the manufacturing process of the active substance or change in the manufacturer (including where relevant quality control testing sites) of the active substance, where	17/07/2025			N/A

	no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.j Changes to quality control testing arrangements for a biological active substance: replacement or addition of a site where batch control/testing including a biological / immunological / immunochemical method takes place - Accepted B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.b Replacement or addition of a site where batch control/testing takes place for a biological/immunological product and any of the test methods performed at the site is a biological/immunological method - Accepted				
Variation type IB / EMA/VR/0000261075	Outcome: B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.e Change to an approved stability protocol - Accepted	16/04/2025			
PSUR/EMA/PSUR/0000274456	EURD: PSUSA/00010966/202502 Active substance: eptinezumab Outcome: Maintenance	02/10/2025			Maintenance