Eydenzelt

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 /	B.I.a.2 Changes in the manufacturing	05/11/2025	N/A		

[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/0000297221	process of the active substance - B.I.a.2.z Other variation - Accepted				
Variation type II / EMA/VR/0000281997	This was an application for a group of variations. B.II.f.1 Change in the shelf-life or storage conditions of the finished product - B.II.f.1.c Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted B.II.f.1.b Extension of the shelf life of the finished product - B.II.f.1.b.5 Extension of the shelf-life of a biological/ immunological medicinal product in accordance with an approved stability protocol - Accepted 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	23/10/2025		SmPC and PL	The SmPC section 4.4, 6.3, 6.4 has been updated as follows: Editorial change and update of Shelf life (pre-filled syringe) and storage conditions (pre-filled syringe/vial). The PL has been updated accordingly and with editorial amendment.

Variation type II / EMA/VR/0000258093	This was an application for a group of variations. B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.a Secondary packaging site - 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 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 B.II.b.1 Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - B.II.b.1.c Site where any	09/10/2025	N/A		

	manufacturing operation(s) take place, except batch release, batch control, and secondary packaging, for biological/ immunological medicinal products, or for pharmaceutical forms manufactured by complex manufacturing processes - Accepted				
Variation type II / EMA/VR/0000268004	This was an application for a group of variations. B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.b Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product - Accepted B.I.d.1.a Re-test period/storage period - B.I.d.1.a.4 Extension or introduction of a re-test period/storage period supported by real time data - Accepted 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.z Other changes - Accepted	04/09/2025	N/A		Not applicable

Variation type IB / EMA/VR/0000272942	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 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with a frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data. The PL is updated accordingly. The change follows assessment of the same change to the reference product, Eylea. Additionally, the MAH took the opportunity to implement editorial changes to the PI in EN and DE to align with the reference product PI. The PI in DE was further updated to add a missing word, and to align user instructions in section 6.6 of the SmPC and the PL with the EN PI of Eydenzelt. Furthermore, the MAH took the opportunity to revise the term "plastic" to "COP" for the Immediate Packaging nomenclature in Annex A, as requested by EMA	06/06/2025		SmPC and PL	To update section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reactions (ADRs) with a frequency of '0.2 cases per 1 million injections' based on pharmacovigilance data. The PL is updated accordingly. The change follows assessment of the same change to the reference product, Eylea.
Variation type IB / EMA/VR/0000266692	C.I.2 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medicinal	16/05/2025		SmPC and PL	To update section 2 and 4.4 of the SmPC, to align the information on excipients with the reference product Eylea, after assessment of the same change

	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 2 and 4.4 of the SmPC, to align the information on excipients with the reference product Eylea, after assessment of the same change for the reference product. In addition, the MAH took the opportunity to update the local representative information for ES. Furthermore, the MAH took the opportunity to implement editorial changes to the DE SmPC and PL to align with the reference product and the QRD template.				for the reference product.