PAVBLU

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 /	Q.II.f.1.b) Extension of the shelf life of the	14/04/2026		SmPC	

[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/0000339035	finished product - Q.II.f.1.b.5 Extension of the shelf life of the finished product based on extrapolation of stability data in accordance with relevant stability guidelines - Accepted				
Variation type IB / EMA/VR/0000338196	Q.II.b.4 Change in the batch size (including batch size ranges) of the finished product - Q.II.b.4.b) Downscaling down to 10-fold - Accepted	08/04/2026			
Variation type IA_IN / EMA/VR/0000312713	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	17/11/2025			
Variation type IB / EMA/VR/0000307161	B.II.b.2 Change to importer, batch release arrangements and quality control testing of the finished product - B.II.b.2.a Replacement or addition of a site where batch control/testing takes place - Accepted	28/10/2025			
Variation type IA / EMA/VR/0000296458	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.b The activities for which the manufacturer/importer is responsible do not include batch release - Refused	22/09/2025			

Variation type IB / EMA/VR/0000276431	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 (IB) - To update section 4.8 of the SmPC and PL in order to add `scleritis' to the list of adverse drug reactions (ADRs) with frequency of `0.2 cases per 1 million injections' based on pharmacovigilance data. The change follows assessment of the same change to the reference product, Eylea. Additionally, the MAH took the opportunity to add a warning for polysorbate in the SmPC and the PL in line with the EC Excipient Guideline. Furthermore, the MAH took the opportunity to implement editorial changes to align the PFS blister pack heading in the Labelling with the QRD template, to update the Vial Instructions for use, and to update the pre-filled syringe PL to ensure consistency with the corresponding section on `children and adolescents' in the SmPC.	26/06/2025		SmPC, Labelling and PL	To update section 4.8 of the SmPC and PL in order to add `scleritis' to the list of adverse drug reactions (ADRs) with frequency of `0.2 cases per 1 million injections' based on pharmacovigilance data. The change follows assessment of the same change to the reference product, Eylea. Additionally, the MAH took the opportunity to add a warning for polysorbate in the SmPC and the PL in line with the EC Excipient Guideline.
Variation type IB / EMA/VR/0000273946	B.II.g.5 Implementation of changes foreseen in an approved change management	26/06/2025			

	protocol - B.II.g.5.c Implementation of a change for a biological/immunological medicinal product - Accepted				