Opuviz

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 /	Outcome:	30/06/2026		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/0000350097	This was an application for a group of variations. Q.II.f.1 Change in the shelf life or storage - Q.II.f.1.e Change to an approved stability protocol of the finished product - Accepted Q.II.f.1.b) Extension of the shelf life of the finished product - Q.II.f.1.b.1 As packaged for sale (supported by real time data, fully in line with the stability protocol) - Accepted				
Variation type IA_IN / EMA/VR/0000350665	Outcome: Q.II.b.1 Change in the manufacturing site for part or all of the manufacturing process of the finished product (except for batch release and batch control testing sites) - Q.II.b.1.a) Addition or replacement of a site responsible for secondary packaging - Accepted	08/06/2026			
Variation type IB / EMA/VR/0000323748	Outcome: 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.z Other variation - 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	13/02/2026			

	testing sites) of the active substance, where no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.k New storage site of Master Cell Bank and/or Working Cell Banks - Accepted				
Variation type IB / EMA/VR/0000306620	Outcome: This was an application for a group of variations. 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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.z Other variation - 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.b Tightening of specification limits - 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	02/12/2025			

	substance - B.I.b.2.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.a Minor change in the manufacturing process of the active substance - Accepted				
Variation type II / EMA/VR/0000280586	Outcome: 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.d Site which requires an initial or product specific inspection - Accepted B.II.b.3 Change in the manufacturing process of the finished product, including an intermediate used in the manufacture of the finished product - B.II.b.3.z Minor change in the manufacturing process of a sterile finished product after the primary packaging step - Accepted B.II.e.1.b Change in type of container or addition of a new container - B.II.e.1.b.2 Sterile medicinal products and biological/ immunological medicinal products - Accepted	27/11/2025		SmPC, Labelling and PL	

Variation type IB / EMA/VR/0000301944	Outcome: 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 no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted	20/10/2025			
Variation type IA / EMA/VR/0000302007	Outcome: B.II.c.2 Change in test procedure for an excipient - B.II.c.2.a Minor changes to an approved test procedure - Accepted	17/10/2025			
Variation type IB / EMA/VR/0000281508	Outcome: 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.e Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/intermediate - Accepted	14/08/2025			
Article 61(3) / EMA/N/0000281956	Outcome: - Notification acc. Article 61(3) - Accepted Update of the package leaflet to delete the list of contact details of local representatives	16/07/2025		PL	

Variation type IB / EMA/VR/0000265733	Outcome: 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 reaction (ADRs) with frequency of '0.2 cases per 1 milion injections' based on pharmacovigilance data, following assessment of the same change for the reference product Eylea. The PL is updated accordingly. Additionally, the MAH took the opportunity to update the SmPC and PL to add warnings for polysorbate 20 in line with the EC Excipient Guideline.	14/05/2025		SmPC and PL	To update section 4.8 of the SmPC in order to add 'scleritis' to the list of adverse drug reaction (ADRs), following assessment of the same change for the reference product Eylea. The PL is updated accordingly. Additionally, the MAH took the opportunity to update the SmPC and PL to add warnings for polysorbate 20 in line with the EC Excipient Guideline.
Variation type II / EMA/VR/0000254853	Outcome: B.I.a.2 Changes in the manufacturing process of the active substance - B.I.a.2.c The change refers to a biological / immunological substance or use of a different chemically derived substance in the manufacture of a biological/immunological substance, which may have a significant impact on the quality, safety and efficacy of the medicinal product and is not related to a protocol - Accepted	08/05/2025			
