Eylea

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.II.f.1.b Extension of the shelf life of the	25/09/2025		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/0000295095	finished product - B.II.f.1.b.1 As packaged for sale (supported by real time data) - Accepted				
Variation type II / EMA/VR/0000249440	C.I HUMAN AND VETERINARY MEDICINAL PRODUCTS - C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data - Accepted Update of sections 4.2, 4.8 and 5.1 of the SmPC in order to update the posology recommendations for indications nAMD and DME and update clinical information based on the final week 156 results from studies PULSAR and PHOTON. PULSAR (20968) was a pivotal Phase 3 study to investigate the efficacy and safety of high dose aflibercept in patients with neovascular age-related macular degeneration (nAMD). PHOTON (21091) was a pivotal Phase 2/3 study to investigate the efficacy and safety of high dose aflibercept in patients with Diabetic Macular Edema (DME). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce a minor editorial change to the PI.	22/05/2025	25/06/2025	SmPC and PL	C.I.4 Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet due to new quality, preclinical, clinical or pharmacovigilance data
Variation type II / EMA/VR/0000248781	B.I.a.1 Change in the manufacturer of a starting material/reagent/intermediate used	25/04/2025	N/A		

	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.e The change relates to a biological active substance or a starting material/reagent/intermediate used in the manufacture of a biological/immunological product - Accepted				