



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Eyluxvi

### 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/<br>Notification<br><sup>1</sup> issued on | Commission<br>Decision<br>Issued <sup>2</sup> /<br>amended on | Product<br>Information<br>affected <sup>3</sup> | Summary   |
|----------------------------|------------------------------------|----------------------------------------------------|---------------------------------------------------------------|-------------------------------------------------|-----------|
| PSUR / EMA/PSUR/0000336116 | EURD: PSUSA/00010020/202511 Active | 23/07/2026                                         | 18/09/2026                                                    | SmPC and PL                                     | Variation |

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).



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|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--|--|--|
|                                          | <p>substance: aflibercept (ophthalmological indication(s)) Outcome: Variation</p> <p>In view of available data on retinal vasculitis with or without occlusion from clinical trials, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between aflibercept and retinal vasculitis with or without occlusion, is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing aflibercept (all formulation) should be amended accordingly.</p> |            |  |  |  |
| Variation type IB /<br>EMA/VR/0000350577 | <p>Outcome:<br/>This was an application for a group of variations.</p> <p>Q.II.b.2 Change to batch release arrangements and batch control testing of the finished product - Q.II.b.2.b) Addition or replacement of a batch control/testing site applying a biological/immunological/immunochemical analytical procedure for a biological finished product - Accepted</p> <p>Q.I.a.1 Change in the manufacturing site of a starting material/intermediate used in the manufacturing process of the active substance or change in the manufacturing</p>                                       | 14/07/2026 |  |  |  |

|                                          |                                                                                                                                                                                                                                                                                                                                                                                   |            |  |  |  |
|------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--|--|--|
|                                          | <p>site (including where relevant quality control testing sites) of the active substance -</p> <p>Q.I.a.1.i) Addition or replacement of a batch control/testing site of the active substance or starting material/intermediate used in the manufacturing of a biological active substance, applying a biological/immunological/immunochemical analytical procedure - Accepted</p> |            |  |  |  |
| Variation type IB /<br>EMA/VR/0000333279 | <p>Outcome:</p> <p>Q.I.b.2 Change to analytical procedure for active substance or starting material/reagent/intermediate used in the manufacturing process of the active substance - Q.I.b.2.d) Other change to an analytical procedure (including replacement or addition) for the active substance - Accepted</p>                                                               | 09/03/2026 |  |  |  |
| Variation type IB /<br>EMA/VR/0000320400 | <p>Outcome:</p> <p>This was an application for a group of variations.</p> <p>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</p>                                   | 28/01/2026 |  |  |  |

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|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
|  | <p>no Ph. Eur. Certificate of Suitability is part of the approved dossier - B.I.a.1.z Other variation - Accepted</p> <p>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</p> |  |  |  |  |
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