

11 December 2025 EMADOC-1700519818-2706651 Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Eylea

aflibercept

On 11 December 2025, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending a change to the terms of the marketing authorisation for the medicinal product Eylea. The marketing authorisation holder for this medicinal product is Bayer AG.

The CHMP adopted a new indication for Eylea 114.3 mg/ml solution for injection, as follows:2

Eylea is indicated in adults for the treatment of

- neovascular (wet) age related macular degeneration (nAMD) (see section 5.1)
- visual impairment due to diabetic macular oedema (DME) (see section 5.1)
- visual impairment due to macular oedema secondary to retinal vein occlusion (branch, central and hemiretinal RVO) (see section 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.



¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold