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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): ranibizumab

Procedure No. PSUSA/00002609/202510

Period covered by the PSUR:

3 years to 05 October 2025

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ranibizumab, the scientific conclusions of PRAC are as follows:

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 ranibizumab and retinal vasculitis with or without occlusion, at least a reasonable possibility.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for ranibizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ranibizumab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.