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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): aflibercept (ophthalmological indication(s))

Procedure No. EMEA/H/C/PSUSA/00010020/201911

Period covered by the PSUR: Period Covered From: 01/12/2018 To: 30/11/2019

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Scientific conclusions

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

The PRAC considers a causal relationship between Eylea and the occurrence of retinal haemorrhage is at least a reasonable possibility. The SmPC of Eylea should be amended in order to add "retinal haemorrhage" in section 4.8, under Eye Disorders, at frequency "very common"."

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for aflibercept (ophthalmological indication(s)) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing aflibercept (ophthalmological indication(s)) 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.