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Committee for Medicinal Products for Human Use (CHMP)

Eylea

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: Aflibercept

Procedure No. EMEA/H/C/002392/PSUV/0011

Period covered by the PSUR: 01.06.2013 to 30.11.2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for Eylea, the scientific conclusions of PRAC are as follows:

Following a signal for “blindness” and “visual acuity (VA) reduced” identified in August 2013 a cumulative review was submitted by the Marketing Authorisation Holder. The assessment of this signal has confirmed a causal relationship with aflibercept for intravitreal injection. The PRAC therefore considers that “blindness” and “visual acuity reduced” should be added in the section 4.8 of the SmPC.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Eylea, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance AFLIBERCEPT is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.