EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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 (indicated for wet macular degeneration and CRVO)

Procedure No. EMEA/H/C/PSUSA/00010020/201511

Period covered by the PSUR: 01 December 2014 to 30 November 2015

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## Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for aflibercept (indicated for wet macular degeneration and CRVO), the scientific conclusions of CHMP are as follows:

During the post-marketing period, reports of hypersensitivity reactions included rash, pruritus, urticaria, and isolated cases of severe anaphylactic/anaphylactoid reactions. Cases described included positive rechallenged, close temporal relationship to the administration of aflibercept and lack of alternative explanations. The PRAC considered that based on evidence during post-marketing period that there is a confirmed causal association between aflibercept and the above mentioned hypersensitivity reactions. Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing aflibercept were warranted.

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 (indicated for wet macular degeneration and CRVO) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing aflibercept (indicated for wet macular degeneration and CRVO) 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.