EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 October 2022
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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): bevacizumab

Procedure No. EMEA/H/C/PSUSA/00000403/202202

Period covered by the PSUR: 25 February 2021 – 25 February 2022

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Scientific conclusions

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

Anaphylactic and anaphylactoid-type reactions are included in SmPC section 4.8 under "Hypersensitivity reactions/infusion reactions". However, in view of available data on anaphylactic shock from the literature and spontaneous reports including a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bevacizumab and anaphylactic shock is at least a reasonable possibility.

The PRAC concluded that the product information of products containing bevacizumab should be amended accordingly.

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 bevacizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bevacizumab 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.