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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. PSUSA/00000403/202502

Period covered by the PSUR: 25 February 2022 to 25 February 2025

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Scientific conclusions

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

In view of available data on hyaline occlusive glomerular microangiopathy reported in the literature, including in some cases a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bevacizumab and hyaline occlusive glomerular microangiopathy is at least a reasonable possibility. The PRAC concluded that the product information of products containing bevacizumab should be amended accordingly.

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 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.