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): crizanlizumab

Procedure No. EMEA/H/C/PSUSA/00010888/202011

Period covered by the PSUR: 15 November 2019 To 14 November 2020

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Scientific conclusions

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

In view of available data on severe pain occurring in the context of an infusion-related reaction from the literature and spontaneous reports including in 22 cases a close temporal relationship, and in 4 cases a positive re-challenge, the PRAC considers a causal relationship between crizanlizumab and severe pain occurring in the context of an infusion-related reaction is established. The PRAC concluded that the product information of products containing crizanlizumab 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 crizanlizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing crizanlizumab 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.