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): ocrelizumab

Procedure No. EMEA/H/C/PSUSA/00010662/202003

Period covered by the PSUR: 27/03/2019 To: 27/03/2020

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Scientific conclusions

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

In view of available data on the risk of late onset of neutropenia from the literature and spontaneous reports, and in view of a plausible class effect in therapeutic CD20 antibodies, the PRAC considers a causal relationship between ocrelizumab and late onset of neutropenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing ocrelizumab 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 ocrelizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ocrelizumab 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.