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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/00010662/201903

Period covered by the PSUR: 28 September 2018 to 27 March 2019

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Scientific conclusions

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

Considering the first report of hepatitis B reactivation published for ocrelizumab and described in the previous PSUR, the PRAC recommended a minor revision of the statements in section 4.4 of the SmPC on the risk of hepatitis B reactivation.

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.