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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/00010662/201809

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

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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:

In previous PSUR the MAH was requested to provide a cumulative review of all available data regarding the association between hypogammaglobulinemia and serious infections.

During the reporting interval, a cumulative review was prepared that analysed the incidence, nature, severity and outcome of serious infections occurring in patients treated with ocrelizumab.

At the time of initial Marketing Authorisation approval the exposure from clinical trials was very limited and no define conclusion could be drawn. With the data provided by the MAH in this reporting interval the PRAC concluded that there is an association between low Immunoglobulins level and risk of serious infections, which can be further supported by biological plausibility.

Therefore, the PRAC recommended to update section 4.8 of the SmPC to reflect the association between treatment with ocrelizumab, decreased level of immunoglobulins and risk of serious infections.

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.