27 January 2022

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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): ravulizumab

Procedure No. EMEA/H/C/PSUSA/00010787/202106

Period covered by the PSUR: 1 January 2021 To: 30 June 2021

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Scientific conclusions

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

In view of available data on urticaria from spontaneous reports including in some cases with a close temporal relationship, a positive re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between ravulizumab and urticaria is established. The PRAC concluded that the product information of products containing ravulizumab 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 ravulizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ravulizumab 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.