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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): rituximab

Procedure No. EMEA/H/C/PSUSA/00002652/202111

Period covered by the PSUR: 17 November 2020 to 17 November 2021

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Scientific conclusions

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

In view of available data on rituximab excretion into human breast milk, a review of safety data and a discussion of bioavailability of rituximab in breastfed infants provided by the MAHs, the PRAC considers that the product information of products containing rituximab should be amended accordingly.

Moreover, in view of available data on increased severity of COVID-19 in the autoimmune indications from the literature and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between rituximab and increased severity of COVID-19 is at least a reasonable possibility. The PRAC concluded that the product information of products containing rituximab 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 rituximab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing rituximab 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.