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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/00002652/202211

Period covered by the PSUR:
17/11/2021 To: 17/11/2022

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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 enteroviral meningoencephalitis from the literature and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between rituximab and enteroviral meningoencephalitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing rituximab should be amended accordingly.

In view of available data on false negative serologic testing of infections from the literature and spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between rituximab and false negative serologic testing 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.