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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): obinutuzumab

Procedure No. EMEA/H/C/PSUSA/00010279/202310

Period covered by the PSUR:
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Scientific conclusions

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

In view of available data on hypogammaglobulinemia from clinical trials, and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between obinutuzumab and hypogammaglobulinemia is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing obinutuzumab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for obinutuzumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing obinutuzumab 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.