14 November 2024
EMA/18607/2025
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): belimumab

Procedure No. EMEA/H/C/PSUSA/00009075/202403

Period covered by the PSUR: 09 March 2021 to 08 March 2024

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Scientific conclusions

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

In view of available data, the PRAC considers a causal relationship between belimumab and serious cutaneous adverse reactions is at least a reasonable possibility. The PRAC concluded that the product information of products containing belimumab 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 belimumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing belimumab 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.