14 December 2023
EMA/CHMP/PRAC/108547/2024
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): tremelimumab

Procedure No. EMEA/H/C/PSUSA/00011038/202304

Period covered by the PSUR:
21 October 2022 To: 20 April 2023

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Scientific conclusions

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

In view of available data from clinical trials, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between tremelimumab in combination with durvalumab and "uveitis" and "arthritis" is at least a reasonable possibility. The PRAC concluded that the product information of products containing tremelimumab 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 tremelimumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tremelimumab 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.