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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): cemiplimab

Procedure No. EMEA/H/C/PSUSA/00010780/202409

Period covered by the PSUR: 26 September 2022 to 26 September 2024

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Scientific conclusions

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

In view of the available data on the increased risk of immune-mediated adverse reactions (imAEs) in patients with pre-existing autoimmune disease from the literature, and in view of a plausible mechanism of action, the PRAC considers the relationship between cemiplimab and an increased risk of imAEs in patients with pre-existing autoimmune disease is at least a reasonable possibility. The PRAC concluded that the product information for cemiplimab 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 cemiplimab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cemiplimab 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.