9 November 2023
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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): avelumab

Procedure No. EMEA/H/C/PSUSA/00010635/202303

Period covered by the PSUR: 23/03/2022 To: 22/03/2023

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Scientific conclusions

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

Patients with pre-existing autoimmune disease

In view of available data on immune-related adverse reactions in patients with pre-existing autoimmune disease from the literature, and in view of a plausible mechanism of action, the PRAC Rapporteur considers a causal relationship between avelumab and an increased risk of immune-related adverse reaction in patients with pre-existing autoimmune disease is at least a reasonable possibility. The PRAC concluded that the product information of products containing avelumab should be amended accordingly.

Sarcoidosis

In view of available data on sarcoidosis from clinical trials, the literature and spontaneous reports including in some cases a close temporal relationship, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between avelumab and sarcoidosis is at least a reasonable possibility. The PRAC concluded that the product information of products containing avelumab 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 avelumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing avelumab 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.