14 December 2023
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): durvalumab

Procedure No. EMEA/H/C/PSUSA/00010723/202304

Period covered by the PSUR:
01/05/2022 To: 30/04/2023

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Scientific conclusions

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

In view of available data on uveitis' and 'arthritis' from clinical trials, the literature, spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between durvalumab and 'uveitis' and 'arthritis' is at least a reasonable possibility. The PRAC concluded that the product information of products containing durvalumab should be amended accordingly.

In view of available data on immune-related adverse reactions in patients with pre-existing autoimmune disease treated with immune-checkpoint inhibitors from the literature, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between durvalumab and 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 durvalumab 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 durvalumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing durvalumab 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.