12 December 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): durvalumab

Procedure No. EMEA/H/C/PSUSA/00010723/202404

Period covered by the PSUR:
01/05/2023 To: 30/04/2024

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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 polymyalgia rheumatica from clinical trial, the literature and spontaneous reports, and in view of a plausible mechanism of action and class effect, the PRAC considers a causal relationship between durvalumab and polymyalgia rheumatica 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 myelitis transverse, the PRAC considers a causal relationship between tremelimumab in combination with durvalumab and myelitis transverse 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.