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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): tislelizumab

Procedure No. PSUSA/00000136/202412

Period covered by the PSUR:
6 months to 25 December 2024

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Scientific conclusions

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

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