25 April 2025
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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): pembrolizumab

Procedure No. EMEA/H/C/PSUSA/00010403/202409

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for pembrolizumab, the scientific conclusions of PRAC are as follows:

In view of available data on the risk for immune-mediated adverse reactions in patients with pre-existing autoimmune disease from the literature, the PRAC considers a relationship between pembrolizumab 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 pembrolizumab 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

On the basis of the scientific conclusions for pembrolizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing pembrolizumab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.