



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): toripalimab

Procedure No. PSUSA/00011094/202506

Period covered by the PSUR: 17 December 2025 to 16 June 2025

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Scientific conclusions

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

In view of the available data on the increased risk of immune-mediated adverse reactions in patients with pre-existing autoimmune disease (AID) from the literature and spontaneous reports, and in view of a plausible mechanism of action, the PRAC considers the relationship between toripalimab and an increased risk of Immune-mediated adverse reactions in patients with pre-existing AID is at least a reasonable possibility. The PRAC concluded that the product information for toripalimab 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 toripalimab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing toripalimab 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.