



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 January 2026
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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): atezolizumab

Procedure No. PSUSA/00010644/202505

Period covered by the PSUR:
1 year to 17 May 2025



ANNEX IV

**SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE VARIATION TO THE TERMS
OF THE MARKETING AUTHORISATION(S)**

Scientific conclusions

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

In view of available data on autoimmune haemolytic anaemia from spontaneous reports and in view of a plausible mechanism of action, the PRAC considers that a causal relationship between atezolizumab and autoimmune haemolytic anaemia is at least a reasonable possibility, given the potential class-effect. The PRAC concluded that the product information of products containing atezolizumab should be amended accordingly.

In view of available data on neutropenia from clinical trial, postmarketing and the literature, the PRAC considers a causal relationship between atezolizumab (in monotherapy) and neutropenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing atezolizumab 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 atezolizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing atezolizumab 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.