30 January 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): atezolizumab

Procedure No. EMEA/H/C/PSUSA/00010644/202405

Period covered by the PSUR: 18/05/2023 To: 17/05/2024

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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 lichen disorders from clinical trials, the literature and spontaneous reports including in some cases a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between atezolizumab and lichen disorders is at least a reasonable possibility. The PRAC concluded that the product information of products containing atezolizumab should be amended accordingly.

In view of available data on colitis from clinical trial and in view of a plausible mechanism of action, the PRAC considers a causal relationship between atezolizumab (in combination therapy) and colitis 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.