14 December 2023
EMA/130056/2024
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/00010644/202305

Period covered by the PSUR: 17/05/2022 To: 17/05/2023

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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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 immune-related adverse reactions in patients with pre-existing autoimmune disease treated with immune-checkpoint inhibitors from the literature, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between atezolizumab and increased risk of immune-related adverse reactions in patients with pre-existing autoimmune disease 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.