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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/00010644/201811

Period covered by the PSUR: 17 May 2018 to 17 November 2018

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Scientific conclusions

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

A cumulative review of cases of anaphylactic reaction with atezolizumab revealed a number of cases for which the role of Tecentriq cannot be excluded and two cases when the reaction occurred during the first infusion of atezolizumab. Both patients were receiving atezolizumab in combination with chemotherapy and both discontinued treatment with atezolizumab permanently as a consequence and completely recovered following standard treatment with corticoids and/or epinephrine. Despite the lack of diagnostic tests, the medical review of these cases leads to the consideration of these events as anaphylaxis and an update to the Product Information is considered warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.