15 December 2022
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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/00010644/202205

Period covered by the PSUR: 17/05/2021 To: 17/05/2022

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Scientific conclusions

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

In view of available data on haemophagocytic lymphohistiocytosis from clinical trials, the literature, spontaneous reports and in view of a plausible mechanism of action, the PRAC considers a causal relationship between atezolizumab and haemophagocytic lymphohistiocytosis is at least a reasonable possibility. The PRAC concluded that the product information of products containing atezolizumab should be amended accordingly.

Although in view of the available data on gastrointestinal perforation a definitive causal relationship between atezolizumab and gastrointestinal perforation could not be established, colitis is reported as a common ADR for atezolizumab and immune checkpoint inhibitor–associated colitis may result in perforation. Gastrointestinal perforation is reported as an ADR in the Product Information of ipilimumab, pembrolizumab and nivolumab. Even though gastrointestinal perforation is a rare complication of colitis, the PRAC concluded that the existing warning regarding immune-related colitis should be updated to include gastrointestinal perforation.

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

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for atezolizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing atezolizumab is unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation should be varied.