



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/455149/2020
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/00010644/202005

Period covered by the PSUR: 17 May 2019 To 17 May 2020



Scientific conclusions

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

Uveitis

Taking into account the available data on uveitis from clinical trials, the literature and spontaneous reports, and in view of a plausible mechanism of action, which is within the immune-related events already known for the class, the PRAC considers a causal relationship between atezolizumab when used in monotherapy and uveitis is established.

Psoriasis

A cumulative search of the company global safety database up to the DLP of this PSUR found 31 reports of psoriasis-related events in the clinical database and 55 case-reports in the safety database, which resulted from atezolizumab's use both in monotherapy and combination regimens. Despite in some cases the events could have been explained by the patient's clinical history, for a number of cases, no alternative explanation could be found and, in light of the mechanistic plausibility of the events and the fact that a number of products from the class of the immune checkpoint inhibitors already have psoriasis listed in their PIs, the PRAC considers the causal relationship is established.

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.