EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): ipilimumab

Procedure No. EMEA/H/C/PSUSA/00009200/202003

Period covered by the PSUR: 24 March 2019 to 24 March 2020

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Scientific conclusions

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

In view of available data on solid organ transplant rejection and haemophagocytic lymphohistiocytosis from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between ipilimumab and solid organ transplant rejection and also between ipilimumab and haemophagocytic lymphohistiocytosis is at least a reasonable possibility. The PRAC concluded that the product information of products containing ipilimumab should be amended accordingly.

The updated information is aligned with the SmPCs of other check point inhibitors.

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 ipilimumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ipilimumab 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.