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/00009200/202103

Period covered by the PSUR: 25 March 2020 to 24 March 2021

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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 myelitis from case reports including in some cases a close temporal relationship and improvement on steroid treatment, as well as a plausible mechanism of action, the PRAC considers a causal relationship between ipilimumab and myelitis is at least a reasonable possibility. The PRAC concluded that the product information of ipilimumab should be amended accordingly.

In view of available data on pneumonia associated with ipilimumab monotherapy from clinical trial(s), literature and spontaneous reports including in one literature case with a plausible TTO which improved with steroid treatment, as well as a plausible mechanism of action, the PRAC considers a causal relationship between ipilimumab monotherapy and pneumonia is at least a reasonable possibility. The PRAC concluded that the product information of ipilimumab should be amended to include pneumonia for monotherapy with frequency uncommon based on clinical trial data.

In view of available data on diabetes mellitus / diabetic ketoacidosis with ipilimumab monotherapy from post-marketing cases, reporting rates in clinical trials and a plausible mechanism of action, and given the importance of the risk and its prompt treatment, the PRAC concluded that the product information of ipilimumab should be amended accordingly.

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.