EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: ipilimumab

Procedure No. EMEA/H/C/PSUSA/00009200/201409

Period covered by the PSUR: 25 March 2014 – 24 September 2014

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Scientific conclusions

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

A cumulative review on Toxic Epidermal Necrolysis (TEN) from clinical trials and post-marketing setting for ipilimumab has resulted in a total of 8 cases, including fatal cases. One fatal case was thought to be related to sequential therapy of nivolumab and ipilimumab. Therefore, in view of available data, the PRAC agreed that changes to the product information are warranted to include a new warning against introducing a patient on ipilimumab who had previously experienced a severe or life-threatening skin adverse reaction on a prior cancer immune stimulatory therapy.

In addition, during the reporting period, 4 cases of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) associated with ipilimumab have been identified. Therefore this adverse reaction and a corresponding warning should be included in the product information.

Therefore, in view of available data regarding ipilimumab, the PRAC considered that changes to the product information were warranted.The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

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

The CHMP recommends that the terms of the Marketing Authorisations should be varied.