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): nivolumab

Procedure No. EMEA/H/C/PSUSA/00010379/201607

Period covered by the PSUR: 04 January 2016 - 03 July 2016

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Scientific conclusions

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

28 serious cases of encephalitis were retrieved from various sources including spontaneous reports, literature reports and cases from clinical trials receiving either nivolumab monotherapy (19 cases) or combination therapy (9 cases) of whom 24 were assessed as related to nivolumab. Based on this outcome, update of sections 4.4 and 4.8 of the Summary of product characteristic to include encephalitis is recommended.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC Rapporteur considered that changes to the product information of medicinal products containing nivolumab were warranted.

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 nivolumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing nivolumab is unchanged subject to the proposed changes to the product information

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