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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/00010379/201701

Period covered by the PSUR: 04 July 2016 to 03 January 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

7 seven cases of Vogt-Koyanagi-Harada (VKH) syndrome in patients who had been exposed to nivolumab have been reported. In two cases the patients were only exposed to nivolumab and, in the remaining 5 cases the patients had concomitant or previous/following exposure to either ipilimumab or vemurafenib. Following review of these cases, a causal association between nivolumab and VKH syndrome was considered to be a reasonable possibility. Based on this outcome, update of sections 4.4 and 4.8 of the Summary of Product Charateristics to add Vogt-Koyanagi-Harada-Syndrome is recommended.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC 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(s)

On the basis of the scientific conclusions for nivolumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nivolumab 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.