25 February 2021
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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/00010379/202007

Period covered by the PSUR: 03 July 2019 to 03 July 2020

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Scientific conclusions

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

In view of available data on the risk of "Lichen Sclerosus and Other Lichen Disorders" from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between nivolumab and "Lichen Sclerosus and Other Lichen Disorders" is established. Moreover, a further change to align the warnings on immuno-related adverse reactions to other product in the class has been introduced to capture warnings on "simultaneous immune-mediated disorders". The PRAC concluded that the product information of products containing nivolumab 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 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.