27 February 2025
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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/00010379/202407

Period covered by the PSUR:
04/07/2021 To: 03/07/2024

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Scientific conclusions

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

In view of available data on optic neuritis from clinical trials, spontaneous reports, the literature, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between nivolumab and optic neuritis is at least a reasonable possibility. In addition, in view of available data on immune-related adverse reactions in patients with pre-existing autoimmune disease from the literature and in view of a plausible mechanism of action, the PRAC considers the addition of a warning regarding the risk of immune-related adverse reactions in patients with pre-existing autoimmune disease to be appropriate. The PRAC concluded that the product information of products containing nivolumab should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

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.