



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 April 2025
EMA/240548/2025
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 / relatlimab

Procedure No. EMEA/H/C/PSUSA/00011018/202409

Period covered by the PSUR:
18/03/2024 To: 17/09/2024



Scientific conclusions

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

In view of available data on immune-mediated adverse reactions in patients with pre-existing autoimmune disease is at least a reasonable possibility from the literature, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between nivolumab / relatlimab and immune-mediated adverse reactions in patients with pre-existing autoimmune disease is at least a reasonable possibility. The PRAC concluded that the product information of products containing nivolumab / relatlimab should be amended accordingly.

In view of available data on myasthenia gravis from clinical trials, spontaneous reports, literature and in view of a plausible mechanism of action, the PRAC considers a causal relationship between nivolumab / relatlimab and myasthenia gravis is at least a reasonable possibility. The PRAC concluded that the product information of products containing nivolumab / relatlimab 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 / relatlimab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing nivolumab / relatlimab 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.