17 October 2024
EMA/531182/2024
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/00011018/202403

Period covered by the PSUR:
18/09/2023 To: 17/03/2024

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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 serositis and pleural effusion from clinical trials and spontaneous reports, the PRAC considers a causal relationship between nivolumab+relatlimab and serositis and/or pleural effusion 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.