16 December 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): durvalumab

Procedure No. EMEA/H/C/PSUSA/00010723/202104

Period covered by the PSUR: 01 May 2020 To: 30 April 2021

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Scientific conclusions

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

In view of available data on pancreatitis, the PRAC considers a causal relationship between durvalumab and pancreatitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing durvalumab 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 durvalumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing durvalumab 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.