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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): avelumab

Procedure No. EMEA/H/C/PSUSA/00010635/202103

Period covered by the PSUR: 23 September 2020 to 22 March 2021

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Scientific conclusions

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

In view of new available data on immunogenicity from clinical trials, the PRAC concluded that the product information of products containing avelumab should be amended accordingly.

Additionally, based on a review of the product information with regards to diabetic ketoacidosis, the PRAC concluded that the package leaflet should be amended in order to inform patients of the risk and symptoms of diabetic ketoacidosis.

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 avelumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing avelumab 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.