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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): pembrolizumab

Procedure No. EMEA/H/C/PSUSA/00010403/202109

Period covered by the PSUR: 3 September 2020 to 3 September 2021

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Scientific conclusions

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

Diabetic ketoacidosis (DKA) is a known risk listed in the Summary of Product Characteristics. To ensure that patients are fully informed of what DKA is and of the particular signs to be aware of, the risk of DKA and relevant symptoms, should be reflected in the Package Leaflet.

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