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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): cemiplimab

Procedure No. EMEA/H/C/PSUSA/00010780/202103

Period covered by the PSUR: 27 March 2020 to: 27 March 2021

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Scientific conclusions

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

The risk of diabetic ketoacidosis is listed in the SmPC (section 4.4 and footnotes of table of ADRs in section 4.8) linked to type 1 diabetes mellitus (uncommon). In order to inform the patients, section 2 and 4 of PIL of cemiplimab should be updated to include risk of diabetic ketoacidosis, including the symptoms.

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