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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/00010780/202209

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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:

Based on the possibility of a class effect, one literature case (with causality assessed as probable related) and three suggestive cases, the PRAC concluded that the product information should be amended accordingly to include the risk of haemophagocytic lymphohistiocytosis.

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.