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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): sarilumab

Procedure No. EMEA/H/C/PSUSA/00010609/202101

Period covered by the PSUR: 13 January 2020 to 12 January 2021

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Scientific conclusions

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

In view of available data on leukopenia and diverticulitis from clinical trials and spontaneous reports, including in some cases with a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between sarilumab and these adverse reactions can be established. The PRAC review concluded that the product information of products containing sarilumab 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 sarilumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing sarilumab 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.