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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/00010609/202001

Period covered by the PSUR: from 13 July 2019 to 12 January 2020

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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 gastrointestinal perforation from clinical trials and spontaneous reports including in some cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between sarilumab and gastrointestinal perforation is established. The PRAC concluded that the existing warning on gastrointestinal perforation in the Section 4.4 of the SmPC should be updated to reflect that gastrointestinal perforation has been reported in association with Kevzara in patients with and without diverticulitis. In addition, the following adverse reaction should be added in the Section 4.8 of the SmPC under the SOC "Gastrointestinal disorders" with a frequency "rare": Gastrointestinal perforation. The package leaflet should be updated accordingly. The PRAC 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.