EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 May 2021
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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): teriflunomide

Procedure No. EMEA/H/C/PSUSA/00010135/202009

Period covered by the PSUR: 12 September 2017 To: 12 September 2020

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Scientific conclusions

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

In view of the available data on colitis from clinical trial(s), the literature, and spontaneous reports, including in some cases a close temporal relationship and in view of the data on pulmonary hypertension from spontaneous reports and the literature and taking into account the already established association of these two adverse events with the parent compound leflunomide, the PRAC considers a causal relationship between teriflunomide and colitis as well as pulmonary hypertension is at least a reasonable possibility. The PRAC concluded that the product information of products containing teriflunomide 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 teriflunomide the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing teriflunomide 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.