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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): tocilizumab

Procedure No. EMEA/H/C/PSUSA/00002980/201804

Period covered by the PSUR: 11 April 2017 to 10 April 2018

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Scientific conclusions

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

The MAH provided a comprehensive cumulative review of cases of hypofibrinogenaemia and related terms, including data from the literature, clinical development and post-marketing, in association with tocilizumab. Based on this review, the PRAC considered that a causal relationship between tocilizumab and hypofibrinogenaemia is established warranting the addition of hypofibrinogenaemia as an adverse drug reaction in section 4.8 of the SmPC (frequency 'common'). The package leaflet should be updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for tocilizumab the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing tocilizumab is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.