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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): etanercept (biosimilars)

Procedure No. EMEA/H/C/PSUSA/00010452/201901

Period covered by the PSUR: 15 July 2018 - 14 January 2019

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Scientific conclusions

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

Based on the review of the literature and spontaneous reporting presented in this PSUSA, covering the period from 15 July 2018 to 14 January 2019, as well as cumulative data since the European birth date, the PRAC considered that a causal relationship between inflammatory bowel disease and etanercept cannot be excluded and therefore recommends that the product information of medicinal products containing the active substance etanercept should be updated as follows: update of section 4.8 of the SmPC to add inflammatory bowel disease with a frequency uncommon. The package leaflet is updated 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 etanercept (biosimilars) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing etanercept (biosimilars) 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.