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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): belatacept

Procedure No. EMEA/H/C/PSUSA/00000311/201906

Period covered by the PSUR: from 15 June 2016 to 14 June 2019

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Scientific conclusions

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

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

A post-authorisation safety study was conducted to evaluate the effectiveness of the patient alert card (PAC), and indirectly the product label information, in four EU countries with relatively higher use of belatacept among eligible patients and renal physicians/nurses. The results of the patient survey revealed that only a minority of patients (26.6%) were aware of the PAC, and knowledge of its key messages was low and not statistically significantly better in those who had received it.

In the healthcare professional survey, awareness was moderate (69.2%). Knowledge of messages specific to the PAC was low while knowledge about information in the product label was generally high.

Based on the results of this study, and given the length of time belatacept has been on the market in the EU during which the existing safety concerns have been shown to be adequately managed by routine risk minimisation measures (SmPC/PL), as well as the fact that no new safety concerns have been identified that would warrant putting any additional risk minimisation measures in place, the PRAC considers that the PAC is no longer needed. Therefore, the annexes II, IIIA and IIIB of the product information are updated to remove reference to the PAC.

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 belatacept the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing belatacept 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.