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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): apremilast

Procedure No. EMEA/H/C/PSUSA/00010338/201509

Period covered by the PSUR: 21 March 2015 to 20 September 2015

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Scientific conclusions

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

Based on the analysis of cases of gastrointestinal haemorrhages reported in the post-marketing setting and in clinical trials, there is evidence to suggest a causal association with the use of apremilast. This relationship is supported after reviewing the cases in Eudravigilance by the following: compatible temporal association; positive dechallenge in all cases with spontaneous recovery after withdrawal of apremilast and lack of confounding factors (concomitant medication, medical conditions). Moreover, during the placebo-controlled period a higher number of gastrointestinal bleeding was experienced by patients treated with apremilast than with placebo; even when the absolute numbers were low.

Therefore, in view of available data regarding gastrointestinal haemorrhages with the use of apremilast, the PRAC considered that changes to the product information were warranted.

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