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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): eltrombopag

Procedure No. EMEA/H/C/PSUSA/00001205/201709

Period covered by the PSUR: 1 Oct 2016 – 30 Sep 2017

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Scientific conclusions

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

The review of the signal of laboratory test interference following on from several publications indicated the potential for interference between eltrombopag and laboratory tests including false negative bilirubin and false positive creatinine results. Therefore the update to the section 4.4 of the SmPC is recommended.

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