EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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/00001205/201609

Period covered by the PSUR: 1 October 2015 to 30 September 2016

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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:

There are currently educational materials for the first approved indication ITP in place. The review of the materials demonstrated that the product information contains the same messages related to the important identified and potential risks as the currently approved educational material. Therefore and taking also into account that the initial objectives to increase the awareness of the healthcare providers and patients of the relevant safety concerns have been met and the key elements to be included in the educational material reflected in Annex II are considered now part of the standard of care; that the safety profile of eltrombopag as is currently characterised is reflected in the product information; the PRAC recommends a variation to remove conditions or restrictions with regard to the safe and effective use of the medicinal product as detailed in Annex II.D and 127a.

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.