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): bosutinib

Procedure No. EMEA/H/C/PSUSA/00010073/201603

Period covered by the PSUR: 4 March 2015 to 3 March 2016

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Scientific conclusions

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

Based on data from post-marketing reporting, a causal relationship between bosutinib and occurrence of Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) cannot be excluded. The MAH therefore agreed with the PRAC's recommendation to update the product information by adding these side effects.

In addition, following a review of cases of Tumour Lysis Syndrome (TLS) and taking into consideration that this is a known adverse reaction of similar agents, the PRAC considered the cases likely related to bosutinib treatment; consequently, the product information was updated.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing bosutinib 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 bosutinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing bosutinib 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.