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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): ponatinib

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Period covered by the PSUR: 14 December 2014 to 13 June 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for ponatinib, the scientific conclusions of CHMP are as follows:

Cases of hypothyroidism have been reported in both clinical trials and from post-market sources. Twenty-five cases of hypothyroidism were identified in sponsored clinical trials, 8 of which were assessed as related to ponatinib. Seven cases of hypothyroidism have been reported from post market sources, 5 of which are derived from a single literature article. All cases of hypothyroidism were non-serious.

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