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): ponatinib

Procedure No. EMEA/H/C/PSUSA/00010128/201612

Period covered by the PSUR: 14 June 2016 – 13 December 2016

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Scientific conclusions

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

The Iclusig SmPC was recently updated (variation EMEA/H/C/002695/II/32) to introduce dose reduction advice to 15 mg once daily for chronic phase - chronic myeloid leukaemia (CP-CML) patients who have achieved major cytogenetic response in order to mitigate the risk of arterial occlusive events and taking specific factors into account in the individual patient assessment. However, dose reduction recommendations for the management of toxicities had not been updated accordingly, resulting in a potential risk of misunderstanding regarding the dose reduction advice. Therefore, dose reduction recommendations for the management of toxicities should be further updated in patients who have already had their dose reduced. No changes to the package leaflet are required.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation

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.