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): nilotinib

Procedure No. EMEA/H/C/PSUSA/00002162/201901

Period covered by the PSUR: 1 February 2018 – 31 January 2019

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Scientific conclusions

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

Based on information from the 36-cycle interim analysis in an ongoing phase II study (CAMN107A2203) in paediatric patients with newly diagnosed Ph+ CML-CP, or imatinib or dasatinib-resistant/-intolerant CML-CP or -AP patients, the PRAC considers that new available objective data confirmed risk of growth retardation in the paediatric population and recommends changes to the product information to include 'growth retardation' with the frequency very common and recommend close monitoring of growth in paediatric patients. 'Growth retardation in paediatric population´ is also considered an important identified risk in future PSURs and in the risk management plan.

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