22 April 2022
EMA/246133/2022
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): crizotinib

Procedure No. EMEA/H/C/PSUSA/00010042/202108

Period covered by the PSUR: 26 August 2019 to 25 August 2021

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Scientific conclusions

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

In view of available data on photosensitivity from an in vitro phototoxicity study (which demonstrated that crizotinib may have phototoxic potential), clinical trials, literature, spontaneous reports, including three cases with a close temporal relationship, positive dechallenge and rechallenge, two cases with positive dechallenge either at full dose or reduced dose and two cases highlighting that with appropriate prophylactic sun protective measures, crizotinib may be continued without dose modification in some patients , the PRAC considers a causal relationship between crizotinib and photosensitivity is at least a reasonable possibility. The PRAC concluded that the product information of products containing crizotinib should be amended accordingly.

In view of available data on blood creatine phosphokinase increased from spontaneous reports including five cases with a close temporal relationship and a positive rechallenge, and in view of a possible class effect, the PRAC considers a causal relationship between crizotinib and blood creatine phosphokinase increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing crizotinib should be amended accordingly.

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