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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): pazopanib

Procedure No. EMEA/H/C/PSUSA/00002321/201910

Period covered by the PSUR: 19 October 2018 – 18 October 2019

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Scientific conclusions

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

In view of available data on Tumour lysis syndrome from published literature, the Novartis clinical database, the Novartis Global Safety Database, and global databases including four noteworthy cases with close temporal relationship and six cases where causality with pazopanib could not completely be ruled out and in view of a plausible mechanism of action, the PRAC considers a causal relationship between pazopanib and Tumour lysis syndrome is at least a reasonable possibility.

The PRAC concluded that the product information of products containing pazopanib 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 pazopanib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing pazopanib 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.