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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

Active substance: cabozantinib

Procedure No. EMEA/H/C/PSUSA/00010180/201603

Period covered by the PSUR: 22 September 2015 - 21 March 2016

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Scientific conclusions

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

A signal concerning a drug interaction with warfarin was raised based on well-documented literature case. In addition, 2 cases of drug interaction with warfarin were detected in the MAH's safety database, one of which is a possible interaction, the other one probable. Considering the cases identified from the literature and the MAH's safety database, the existing risk of haemorrhage for cabozantinib, the importance of a correct dosage of warfarin and the need for monitoring INR, the PRAC concluded that section 4.5 of the SmPC should be updated to include a new warning on the risk of drug-drug interaction between cabozantinib and warfarin and the need to monitor the INR with such combination.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing cabozantinib were warranted.

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 cabozantinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing cabozantinib is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisation should be varied.