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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): trametinib

Procedure No. EMEA/H/C/PSUSA/00010262/201611

Period covered by the PSUR: 30th May 2016 to 29th November 2016

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Scientific conclusions

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

Following the assessment of the most recent dabrafenib (Tafinlar) PSUR (PSUSA/00010084/201608) which concluded in March 2017, the PRAC identified photosensitivity reaction as an adverse reaction of dabrafenib when used in combination with trametinib and recommended inclusion of this new adverse reaction in section 4.8 of the dabrafenib SmPC for the dabrafenib/trametinib combination with a frequency 'common'. This recommendation was endorsed by the CHMP on 23 March 2017. Therefore, the PRAC concluded that the SmPC for trametinib (Mekinist) should be updated accordingly to include this new adverse reaction for trametinib in combination with dabrafenib in section 4.8 of the SmPC with a frequency 'common'.

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

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