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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): vemurafenib

Procedure No. EMEA/H/C/PSUSA/00009329/202208

Period covered by the PSUR: 17 August 2019 – 16 August 2022

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Scientific conclusions

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

In view of available data on thrombocytopenia from clinical trial(s), the literature, and spontaneous reports including in some cases with a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, at least in combination with a MEK inhibitor, the PRAC considers a causal relationship between vemurafenib and thrombocytopenia is at least a reasonable possibility. The PRAC concluded that the product information of products containing vemurafenib should be amended accordingly. The frequency should be Common, based on data from two MAH-sponsored clinical trials.

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