25 January 2024
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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): encorafenib

Procedure No. EMEA/H/C/PSUSA/00010719/202306

Period covered by the PSUR: 26/06/2022 To: 26/06/2023

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Scientific conclusions

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

In view of available data on Tumour lysis syndrome from both clinical trial cases and spontaneous reports including in 3 cases a close temporal relationship and in view of a plausible mechanism of action, the PRAC considers a causal relationship between encorafenib and Tumour lysis syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing encorafenib should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for encorafenib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing encorafenib 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.