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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): dabrafenib

Procedure No. EMEA/H/C/PSUSA/00010084/201808

Period covered by the PSUR: 27 August 2017 to 26 August 2018

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Scientific conclusions

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

The cumulative information on severe cutaneous adverse reactions (SCAR) is considered to present sufficient evidence to support a reasonable possibility for a causal association between SCARs and dabrafenib treatment. Information on these reactions should be added to the Product information.

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