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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): vandetanib

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Period covered by the PSUR: 7 October 2014 to 6 April 2015

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Scientific conclusions

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

The product information with regards to the treatment of severe skin reactions is being brought up to date with current clinical practice as systemic glucocorticosteroids should not be used for the treatment of these adverse drug reactions. The PRAC also considered the need to include information regarding the referral of patients experiencing these events to seek urgent medical specialist advice.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing vandetanib 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 VANDETANIB the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing VANDETANIB is favourable subject to the proposed changes to the product information

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.