10 November 2022
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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

Procedure No. EMEA/H/C/PSUSA/00009327/202204

Period covered by the PSUR: 7 April 2021 – 6 April 2022

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Scientific conclusions

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

In view of available data on toxic epidermal necrolysis (TEN) from clinical trials, literature and spontaneous reports, including in 8 / 11 cases a suggestive/compatible temporal relationship, in one case a positive rechallenge and considering that Stevens-Johnson Syndrome is already listed as ADR for vandetanib, the PRAC Rapporteur considers that a causal relationship between vandetanib and TEN is at least a reasonable possibility. The PRAC Rapporteur concluded that the product information of products containing vandetanib should be amended accordingly.

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 unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.