21 July 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): erlotinib

Procedure No. EMEA/H/C/PSUSA/00001255/202111

Period covered by the PSUR: 18 Novemer 2019 to 17 November 2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Scientific conclusions

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

Overall, based on the totality of the data presented in the current PSURs for erlotinib from the reporting interval and cumulative experience, no new risks or safety concerns with a significant impact on the already established safety and efficacy profile of erlotinib were identified. Consequently, the PRAC considers that the benefit-risk balance of erlotinib for the treatment of NSCLC and PC remains unchanged.

However, the PRAC considers that based on the data presented and the cases for which causality with erlotinib was deemed as a reasonable possibility, the events of hepatitis, acute hepatitis and pneumatosis intestinalis should be reflected in the product information. More specifically, the PRAC concluded as follows:

- In view of available data on hepatotoxicity from clinical trial(s), the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between erlotinib and hepatitis, acute hepatitis is at least a reasonable possibility.
- In view of available data on pneumatosis intestinalis from clinical trials, the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and/or re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between erlotinib and pneumatosis intestinalis is at least a reasonable possibility.

The PRAC concluded that the product information of products containing erlotinib 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 erlotinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing erlotinib 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.