EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 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): alpelisib

Procedure No. EMEA/H/C/PSUSA/00010871/202111

Period covered by the PSUR: 24 May 2021 to 23 November 2021

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Scientific conclusions

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

In view of available data on colitis from spontaneous reports including in one case a close temporal relationship, the PRAC considers a causal relationship between alpelisib and colitis is at least a reasonable possibility. The PRAC concluded that the product information of products containing alpelisib should be amended accordingly.

In view of available data on angioedema from spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and re-challenge, and in view of a plausible mechanism of action, the PRAC considers a causal relationship between alpelisib and angioedema is at least a reasonable possibility. The PRAC concluded that the product information of products containing alpelisib 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 alpelisib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing alpelisib 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.