25 April 2024
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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): abemaciclib

Procedure No. EMEA/H/C/PSUSA/00010724/202309

Period covered by the PSUR: 29/09/2022 To: 28/09/2023

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Scientific conclusions

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

In view of available data on photopsia from clinical trial(s), spontaneous reports including in some cases a positive re-challenge, the PRAC considers a causal relationship between abemaciclib and photopsia is at least a reasonable possibility. The PRAC concluded that the product information of products containing abemaciclib should be amended accordingly.

Having reviewed the PRAC recommendation, the CHMP agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for abemaciclib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing abemaciclib 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.