21 March 2024
EMA/107553/2024
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): palbociclib

Procedure No. EMEA/H/C/PSUSA/00010544/202308

Period covered by the PSUR: 02/08/2022 To: 02/08/2023

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Scientific conclusions

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

In view of available data on rhabdomyolysis following concomitant use of palbociclib and statins from the literature, spontaneous reports including in some cases a close temporal relationship, a positive de-challenge and in view of a plausible mechanism of action, and on available data on blood creatinine increased from clinical trials, the literature and spontaneous reports, the PRAC considers a causal relationship between palbociclib and rhabdomyolysis and blood creatinine increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing palbociclib 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 palbociclib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing palbociclib 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.