30 March 2023
EMA/252663/2023
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/00010544/202208

Period covered by the PSUR: 03 August 2021 to: 02 August 2022

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Scientific conclusions

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

In view of available data on venous thromboembolism from the literature, clinical trials, spontaneous reports including 531 cases with a close temporal relationship, and in view of a possible class effect for CDK4/6 inhibitors, the PRAC considers a causal relationship between palbociclib and venous tromboembolism is at least a reasonable possibility.

Furthermore, in view of available data on Palmar-plantar erythrodysaesthesia syndrome (PPES) 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 palbociclib and PPES is at least a reasonable possibility.

The PRAC concluded that the product information of products containing palbociclib 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 palbociclib the CHMP is of the opinion that the benefit-risk balance of the medicinal product 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.