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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): ribociclib

Procedure No. PSUSA/00010633/202503

Period covered by the PSUR:
1 year to 12 March 2025

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**Scientific conclusions**

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

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