EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): lorlatinib

Procedure No. PSUSA/00010760/202509

Period covered by the PSUR: 1 year to 20 September 2025

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Scientific conclusions

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

In view of available data on increased transaminases from clinical trials, the literature, and spontaneous reports, including cases with a close temporal relationship, and in view of known non-clinical data on repeat-dose toxicity that show increases in liver enzymes, the PRAC considers a causal relationship between lorlatinib and alanine aminotransferase increased/aspartate aminotransferase increased is at least a reasonable possibility. The PRAC concluded that the product information of products containing lorlatinib 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 lorlatinib the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lorlatinib 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.