18 September 2025
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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): tezacaftor / ivacaftor

Procedure No. PSUSA/00010730/202502

Period covered by the PSUR: 12 February 2024 to 11 February 2025

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Scientific conclusions

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

In view of available data on cases of liver failure reported in patients both with and without pre-existing liver disease for elexacaftor / tezacaftor / ivacaftor (ELX/TEZ/IVA) and in the context of updates made to the product information for ELX/TEZ/IVA, given the very serious nature of the events in question, the PRAC considers that the product information of products containing tezacaftor / ivacaftor should be amended accordingly.

In view of available data on anxiety and insomnia from post-marketing reports including in some cases positive de-challenge, the PRAC considers a causal relationship between tezacaftor / ivacaftor and anxiety and insomnia is at least a reasonable possibility. The PRAC concluded that the product information of products containing tezacaftor / ivacaftor 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 tezacaftor / ivacaftor the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing tezacaftor / ivacaftor 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.