12 October 2023
EMA/97030/2024
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): ivacaftor

Procedure No. EMEA/H/C/PSUSA/00009204/202301

Period covered by the PSUR:
24/01/2020 To: 23/01/2023

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Scientific conclusions

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

In view of available data on risk of occurrence of depression and related events from spontaneous reports in post-marketing surveillance, including in some cases a close temporal relationship and a positive de-challenge and re-challenge, the PRAC considers a causal relationship between Ivacaftor and depression is at least a reasonable possibility, mainly when used in a combination treatment with TEZ/IVA or IVA/TEZ/ELX. The PRAC concluded that the product information of medicinal products containing Ivacaftor should be amended accordingly.

In view of available data on breast-feeding from the literature, update of section 4.6 of the SmPC is warranted regarding breast-feeding. The PRAC concluded that the product information of products containing 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 ivacaftor the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing 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.