25 January 2024
EMA/163179/2024
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): lumacaftor / ivacaftor

Procedure No. EMEA/H/C/PSUSA/00010455/202305

Period covered by the PSUR: 20/05/2022 To: 19/05/2023

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Scientific conclusions

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

In view of available data on the 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, and in the context of updates made to the product information for ELX/TEZ/IVA, IVA/TEZ and IVA mono-active the PRAC considers that a causal relationship between LUM/IVA and depression is at least a reasonable possibility.

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 lumacaftor/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 lumacaftor / ivacaftor the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing lumacaftor / 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.