14 December 2023
EMA/100720/2024
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 / tezacaftor / elexacaftor

Procedure No. EMEA/H/C/PSUSA/00010868/202304

Period covered by the PSUR:
21/10/2022 To: 20/04/2023

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Scientific conclusions

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

At its November plenary meeting, PRAC has recommended to update the wording on breastfeeding in the PSUSA procedures for ivacaftor monocomponent and ivacaftor/tezacaftor combination in order to reflect the available data. As Kaftrio contains the above substances the same update applies to the triple combinations as well.

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