EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 March 2022
EMA/214293/2022
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. EMEA/H/C/PSUSA/00010730/202108

Period covered by the PSUR: 12/02/2021 To: 12/08/2021

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Scientific conclusions

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

There have been very serious reports of liver failure, transplantation and death in patients with CF and advanced liver disease whilst receiving the CFTR modulators ELX/TEZ/IVA (in combination with IVA) and LUM/IVA. Given the very serious nature of the events in question, in spite of a lack of specific data for TEZ/IVA it is considered that this information should be reflected in the product information of Symkevi in order to raise awareness of the potential for worsening of liver function so that patients can be monitored, and timely action taken to minimise the risk of serious outcomes.

The CHMP agrees with the scientific conclusions made by the PRAC.

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.