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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): empagliflozin, empagliflozin / metformin

Procedure No. EMEA/H/C/PSUSA/00010388/202104

Period covered by the PSUR: 17/04/2019 To: 17/04/2021

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SCIENTIFIC CONCLUSIONS AND GROUNDS FOR THE VARIATION TO THE TERMS OF THE MARKETING AUTHORISATION(S)

Scientific conclusions

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

In view of available data on tubulointerstitial nephritis from the literature and spontaneous reports highly suggestive of causality association including a close temporal relationship and a positive dechallenge, the PRAC considers a causal relationship between empagliflozin, empagliflozin/metformin and tubulointerstitial nephritis is at least a reasonable possibility. The PRAC concluded that the product information of products containing empagliflozin, empagliflozin/metformin should be amended accordingly.

In view of available data on the drug-drug interaction between empagliflozin and lithium from clinical trials and the literature suggestive for causal association, including in some cases a close temporal relationship and positive dechallenge/rechallenge and in view of a plausible mechanism of interaction, the PRAC considers a causal relationship between empagliflozin, empagliflozin/metformin and drug-drug interaction with lithium is at least a reasonable possibility. The PRAC concluded that the product information of products containing empagliflozin, empagliflozin/metformin should be amended accordingly.

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 empagliflozin, empagliflozin/metformin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing empagliflozin, empagliflozin/metformin 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.