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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): dapagliflozin

Procedure No. EMEA/H/C/PSUSA/00010029/202110

Period covered by the PSUR: 05/10/2020 To: 04/10/2021

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Scientific conclusions

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

In view of available data on two post-marketing cases of tubulointerstitial nephritis from spontaneous reports, and given that tubulointerstitial nephritis is already labelled for other SGLT2 inhibitor products, the PRAC considers a causal relationship between dapagliflozin and tubulointerstitial nephritis is at least a reasonable possibility. The PRAC concluded that the product information of products containing dapagliflozin should be amended accordingly.

In view of available data on mechanistic study and in view of a plausible mechanism of action, suggestive of a possible increase in lithium clearance by dapagliflozin, the PRAC considers a drug-drug interaction between dapagliflozin and lithium is at least a reasonable possibility. The PRAC concluded that the product information of products containing dapagliflozin 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 dapagliflozin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dapagliflozin 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.