EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2017
EMA/465597/2017
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/00010029/201610

Period covered by the PSUR: 05 October 2015 to 04 October 2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSURs for dapagliflozin, the scientific conclusions of CHMP are as follows:

Based on Eudravigilance data, 17 cases of diabetic ketoacidosis have been spontaneously reported with fatal outcome for dapagliflozin. In line with other Sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated in the treatment of type 2 diabetes, the PRAC considered necessary to update the existing warning of diabetic ketoacidosis (DKA) on the occurrence of fatal cases.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing dapagliflozin were warranted.

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

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for dapagliflozin the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing dapagliflozin is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.