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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 authorisations

Active substances: empagliflozin, empagliflozin / metformin

Procedure No. EMEA/H/C/PSUSA/00010388/201510

Period covered by the PSUR: 27 May 2015 to 17 Oct 2015

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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:

A cumulative review was submitted with this PSUR regarding the important potential risk "Renal impairment". Initial decreases in eGFR have been found in empagliflozin treated patients in clinical trials. These decreases were generally transient during continous treatment or reversible after drug discontinuation. Besides the ADRs "blood creatinine increased" and "glomerular filtration rate decreased" are commonly reported in postmarketing experience. This led the rapporteur to propose an update of the product information to include these ADRs in section 4.8. of the SmPC under the System Organ Class "Investigations" and to modify package leaflet as well.

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

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 products containing empagliflozin, empagliflozin / metformin is unchanged subject to the proposed changes to the product information.

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