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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)

Procedure no.: EMEA/H/C/PSUSA/00010077/201903

Active substance(s): canagliflozin, canagliflozin / metformin

Period covered by the PSUR: 29 March 2018 to 28 March 2019

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Scientific conclusions

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

Based on the imbalance observed with regard to photosensitivity cases in the CANVAS trial and post-marketing cases of photosensitivity reported in the PSUR reporting period, the PRAC considers that "photosensitivity" should be added as an ADR to the product information of medicines containing canagliflozin and canagliflozin/metformin with a frequency: "uncommon".

Based on cases of serious urinary tract infections reported as part of spontaneous reports and clinical trials, in the PSUR reporting period, the PRAC considers that these ADRs, which are already labelled in the product information of canagliflozin and canagliflozin/metformin should be allocated to the correct SOC "infections and infestations" and that the Package Leaflet should be updated to include the signs and symptoms of these ADRs.

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