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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/00010682/201806

Active substance: ertugliflozin

Period covered by the PSUR: 19 December 2017-18 June 2018

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Scientific conclusions

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

Interim results of an ongoing clinical trial of ertugliflozin on top of standard-of-care in type 2 diabetes patients with a history of established vascular disease, suggest an approximately 1.2-1.6-fold increased risk of lower limb amputation in patients treated with ertugliflozin. An increased risk of amputations with ertugliflozin is also supported by the broad pool safety data. The current information in the SmPC “an increase in cases of lower limb amputation (primarily of the toe) has been observed in long-term clinical studies with another SGLT2 inhibitor” is not adequate. It is therefore not accepted to wait until the final results of the MK-8835-004/B1521021 study are submitted in 2020. Section 4.4 on lower limb amputations should therefore be revised, and the package leaflet should be updated in line with the SmPC.

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 ertugliflozin the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ertugliflozin 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.