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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): tadalafil

Procedure No. EMEA/H/C/PSUSA/00002841/201510

Period covered by the PSUR: 16 October 2014 – 15 October 2015

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Scientific conclusions

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

After the reanalysis of the integrated safety data from the Erectile Dysfunction (ED) on-demand indication, which was triggered during the reporting period by the recognition of a doubling (increase from 2319 subjects to 4769 subjects) of the placebo-controlled clinical trial database, the Marketing Authorisation Holder (MAH) has proposed the following changes in section 4.8 of the Summary of Product Characteristics (SmPC): to add as undesirable effects: nausea, fatigue, vomiting, and oedema peripheral; to update the frequency of the following adverse events: Gastro-oesophageal reflux, hyperhidrosis, Penile Haemorrhage and Haematospermia and Prolonged erections; to add data regarding Diarrhea in elderly patients, in subsection Other special population. Following the assessment of the integrated safety data from the clinical trial database, the PRAC agreed with the changes proposed.

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