22 March 2018

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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): ospemifene

Procedure No. EMEA/H/C/PSUSA/00010340/201708

Period covered by the PSUR: 27/02/2017 – 26/08/2017

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Scientific conclusions

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

The MAH conducted a review of headache cases and identified 167 individual case safety reports, of which there were reports of headache (n=147), migraine (n=15), sinus headache (n=2) and single reports for head discomfort, migraine with aura and exertional headache. There were 11 cases that included a positive dechallenge, with 5 of the cases also showing a positive rechallenge. A strong temporal relationship between ospemifene and headache was seen in many of the cases, which suggests a causal relationship between ospemifene and headache. The MAH has proposed to update Section 4.8 of the Summary of Product Characteristics and Section 4 of the Patient Information Leaflet to include headache as an adverse event for ospemifene, with a frequency of common which was agreed by the PRAC Committee.

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

Grounds for the variation to the terms of the marketing authorisation

On the basis of the scientific conclusions for ospemifene the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing ospemifene 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.