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Committee for Medicinal Products for Human Use (CHMP)

Lumigan

bimatoprost

EMEA/H/C/000391/PSUV/0046

Period covered by the PSUR: 1 March 2010 – 28 February 2013

Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation

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Scientific conclusions

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

Cases of asthma (including serious cases) have been reported during the period of this PSUR. Previously reported reactions such as dyspnoea, hypoxia, wheezing and exacerbation of COPD could all fit into a larger category of acute obstructive pulmonary symptoms, where e.g. wheezing presents a milder case on the same scale as a severe asthma attack. Respiratory distress of any kind including new asthma, exacerbation of existing asthma, exacerbation of existing COPD or exacerbation of any other existing pulmonary illness, wheezing, hypoxia, dyspnoea, all constitute important adverse events. Given the multiple types of interconnected respiratory reactions presented, there is a need for further information on the total amount of any respiratory symptoms reported with the use of Lumigan.

The PRAC recommended that Section 4.4 of the SmPC should include new text to warn about reports of exacerbation of asthma, dyspnoea and COPD, as well as reports of asthma, in post marketing experience. Patients with COPD, asthma or compromised respiratory function due to other conditions should be treated with caution. In addition, Asthma, Asthma exacerbation, COPD exacerbation and dyspnoea should be added to section 4.8 of the SmPC.

The above-mentioned SmPC changes will need to be reflected in the PL.

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

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for Lumigan, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance bimatoprost is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation(s) should be varied.