EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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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): bimatoprost

Procedure No. EMEA/H/C/PSUSA/00000413/201503

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Scientific conclusions

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

During the reporting period of this PSUR, a certain number of cases from routine pharmacovigilance activities were reported and indicated a causal relationship with the use of bimatoprost containing medicinal products. Based on the available data and analysis presented in this PSUR, the PRAC considered that the summary of product characteristics and package leaflet of bimatoprost (all formulations) containing medicinal products should be amended to reflect the following adverse drug reactions: hypersensitivity reaction including signs and symptoms of eye allergy and allergic dermatitis, asthma, asthma exacerbation, COPD exacerbation and dyspnea, with a frequency not known. The summary of product characteristics and package leaflet of bimatoprost (formulations 0.01%) should be amended to reflect the following adverse drug reactions: iris hyperpigmentation with a frequency uncommon, and macular oedema, blepharal pigmentation, periorbital and lid changes including deepening of the eyelid sulcus and dry eye with a frequency not known.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing bimatoprost were warranted.

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