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/00000413/202103

Period covered by the PSUR: 08 March 2018 to 07 March 2021

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Scientific conclusions

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

In view of available data on prostaglandin analogue periorbitopathy from the literature and spontaneous reports, including in some cases a positive de-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between bimatoprost and prostaglandin analogue periorbitopathy established. The PRAC concluded that the product information of products containing bimatoprost should be amended accordingly.

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 unchanged subject to the proposed changes to the product information

The CHMP recommends that the terms of the marketing authorisation(s) should be varied.