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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): umeclidinium bromide / vilanterol

Procedure No. EMEA/H/C/PSUSA/00010264/201506

Period covered by the PSUR: 18 December 2014 – 17 June 2015

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for umeclidinium bromide / vilanterol, the scientific conclusions of CHMP are as follows:

Scientific conclusions and grounds for variation to the terms of the marketing authorisations

Forty five case reports were identified cumulatively with umeclidinium bromide / vilanterol based on a signal evaluation of glaucoma (as per Standardised Medical Dictionary for Regulatory Activities (MedDRA) Query). In 9 cases a relationship with umeclidinium bromide / vilanterol could not be ruled out. Although based on the case description only one case of glaucoma has been specifically reported, it should be considered that intraocular pressure, reported in the other cases, is a sign of glaucoma that needs to be diagnosed in time in order to avoid serious complications of glaucoma. In addition, glaucoma is a known class effect of antimuscarinic drugs and it will be classified as an important identified risk in the Risk Management Plan.

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 umeclidinium bromide /vilanterol 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 umeclidinium bromide / vilanterol the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing umeclidinium bromide / vilanterol 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.