EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2017
EMA/472868/2017
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

Procedure No. EMEA/H/C/PSUSA/00010263/201610

Period covered by the PSUR: 16 April 2016 to 15 October 2016

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Scientific conclusions

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

- 1 serious ADR of “ocular hypertension” with positive de-challenge and 2 non-serious “intraocular pressure increased” have been reported cumulatively with Umeclidinium bromide therapy;
- “Ocular hypertension” or “intraocular pressure increased” are known class effect of antimuscarinic that could lead to glaucoma;
- The Product information of Umeclidinium bromide/Vilanterol has been recently updated to include the undesirable effect “intraocular pressure increased”;

Based on the above, the PRAC concluded that the product information of Umeclidinium bromide should be updated to reflect the undesirable effects “intraocular pressure increased” under the SOC “eye disorders” with frequency “not known”.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considers that changes to the product information of medicinal products containing umeclidinium bromide are 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 the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing umeclidinium bromide 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.