09 September 2016
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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/00010264/201512

Period covered by the PSUR: 18/06/2015-17/12/2015

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
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Scientific conclusions

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

A total of 30 spontaneous cases were received describing 31 adverse events according to the pre-defined preferred terms for urinary adverse events associated with umeclidinium bromide / vilanterol (UMEC/VI).

From those, a total of 12 spontaneous case reports were considered detailed enough to perform a full evaluation, and they comprised 13 urinary adverse events: 8 serious events of urinary retention, 2 serious events of urinary tract obstruction reported, 2 non-serious cases of urine flow decreased and 1 micturition frequency decreased. A close latency to onset (≤ 2 weeks) following start of treatment with UMEC/VI was reported in 7/12 evaluable cases. In 8 cases, there was evidence of positive dechallenge following discontinuation of UMEC/VI.

“Urinary retention” is a known class effect of anticholinergic drugs (Halpin, 2015 Stephenson, 2011; Afonso, 2011) and a warning is already included in the SmPC recommending the use of UMEC/VI with caution in patients with urinary retention.

Based on the results of the cumulative evaluations and considering the pharmacological plausibility of anticholinergic effect on urinary function, there is sufficiently robust evidence to warrant an update of the Product Information with ‘urinary retention, bladder outlet obstruction and dysuria" as ADRs associated to UMEC/VI.

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 /vilanterol 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 / 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.

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