25 July 2019
EMA/467304/2019
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/00010263/201812

Period covered by the PSUR: 18/12/2017 - 17/12/2018

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Scientific conclusions

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

Following a post-approval regulatory request in the last PSUR (EMEA/H/C/PSUSA/00010263/201712), the MAH provided a review of the adverse drug reaction 'dizziness'. The MAH retrieved 73 cases of 'dizziness' in the umeclidinium database, all from spontaneous source. Fifteen cases were serious, and five were due to a serious event of dizziness. In two cases, positive dechallenge was reported describing events that reoccurred the same day after each dose. The evidence presented suggests a possible causal association between umeclidinium and the event of dizziness. Based on the above and also taking into account that serious cases have been reported, the PRAC considered that a product information update with regard to the undesirable effect dizziness is warranted. Update of section 4.8 of the SmPC to add 'dizziness' with a frequency not known is recommended. The package leaflet should be updated accordingly.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the marketing authorisations

On the basis of the scientific conclusions for umeclidinium the CHMP is of the opinion that the benefit-risk balance of the medicinal products containing umeclidinium is unchanged subject to the proposed changes to the product information.

The CHMP recommends that the terms of the marketing authorisations should be varied.