15 September 2022
EMA/896677/2022
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/00010264/202112

Period covered by the PSUR: 18 December 2018 – 17 December 2021

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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 the CHMP are as follows:

1) In view of available data on risk of muscle spasm from spontaneous reports in post-marketing surveillance, including in some cases a positive de-challenge and re-challenge, and in view of the known relation between muscle spasm/cramps and other LABAs, the PRAC considers a causal causality between umeclidinium bromide / vilanterol and muscle spasm is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing umeclidinium bromide / vilanterol should be amended accordingly.
Update of section 4.8 of the SmPC to add the adverse reaction Muscle spasm under the SOC "Musculoskeletal and connective tissue disorders" is deemed necessary, with the frequency uncommon. The Package leaflet is updated accordingly.

2) In view of available data on risk of eye pain from spontaneous reports in post-marketing surveillance, including in some cases a time to onset (TTO) plausible with a drug effect and a positive de-challenge and re-challenge, and in view of the known relation between ocular effects and other LAMAs, the PRAC considers a causal causality between umeclidinium bromide / vilanterol and eye pain is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing umeclidinium bromide / vilanterol should be amended accordingly.
Update of section 4.8 of the SmPC to add the adverse reaction Eye pain under the SOC "Eye disorders" is deemed necessary, with the frequency rare. The Package leaflet is updated 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 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.