15 September 2022
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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

Procedure No. EMEA/H/C/PSUSA/00010263/202112

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 for umeclidinium bromide, the scientific conclusions of the CHMP are as follows:

In view of available data on risk of occurrence of anaphylactic reaction from spontaneous reports in post-marketing surveillance, including in some cases a close temporal causality and a positive de-challenge and re-challenge, the PRAC considers a causality between umeclidinium bromide and Anaphylaxis is at least a reasonable possibility. The PRAC concluded that the product information of medicinal products containing umeclidinium bromide should be amended 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 the CHMP is of the opinion that the benefit-risk balance of the medicinal products 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.