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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): aclidinium bromide / formoterol fumarate dihydrate

Procedure No. EMEA/H/C/PSUSA/00010307/201811

Period covered by the PSUR: 20/11/2017 - 19/11/2018

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Scientific conclusions

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

During the reporting period of the PSUR, study D6560C00002 was completed and showed that the proportion of patients with an adverse event of 'peripheral oedema' was numerically lower in the aclidinium group than in the placebo group. Similarly, in pooled clinical studies with Duaklir Genuair/Brimica Genuair and its mono-component, 'peripheral oedema' was numerically less common on the active treatment than on placebo. Moreover, post-marketing reports of 'peripheral oedema' did not show positive re-challenge. Based on the above mentioned data, the PRAC considered that 'peripheral oedema' should be removed from the list of adverse drug reactions in section 4.8 of the SmPC and 'Swelling of hands, ankles or feet' should be deleted in section 4 of the Package Leaflet.

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 aclidinium bromide / formoterol fumarate dihydrate the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing aclidinium bromide / formoterol fumarate dihydrate 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.