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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/00010307/201605

Period covered by the PSUR: 20 November 2015 to 19 May 2016

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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:

Based on the reasonable possibility of a link between formoterol and angina and given that angina is a recognised effect with formoterol and is listed in the SmPC for formoterol products, the proposal to add angina to section 4.8 of the SmPC for Duaklir/Brimica is considered appropriate. Therefore, the PRAC considered that changes to the product information of medicinal products containing aclidinium bromide – formoterol fumarate dihydrate were 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 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.