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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): budesonide / formoterol

Procedure No. EMEA/H/C/PSUSA/00010585/201908

Period covered by the PSUR: 24/08/2016 To: 24/08/2019

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Scientific conclusions

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

In view of available data on 'dysphonia' from clinical trials, the literature and cases reports presented, the PRAC considers that a causal relationship between budesonide/formoterol and dysphonia is established. The current product information lists 'hoarseness' as an undesirable effect in section 4.8 of the SmPC with a 'common' frequency. the PRAC agreed that 'hoarseness' is a term that might be reported in practice, however other terms might be reported as well. 'Hoarseness' is considered a sub-element of 'dysphonia' and the two terms cannot be used interchangeably. Therefore, the preferred term (PT) 'dysphonia' should be included in the product information. However, to indicate that 'hoarseness' is the most frequently reported lowest level terms (LLT) under the PT 'dysphonia' it is proposed to update the product information with 'dysphonia including hoarseness'. The PRAC concluded that the product information of products containing budesonide/formoterol 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 budesonide / formoterol the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing budesonide / formoterol 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.