20 July 2017
EMA/677604/2017
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): indacaterol

Procedure No. EMEA/H/C/PSUSA/00001730/201611

Period covered by the PSUR: 01 December 2013 to 30 November 2016

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Scientific conclusions

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

Onbrez, Oslif and Hirobriz Breezhalers have been on the market since 2009 with information cards for Health Care Professionals (HCPs) underlining that the products are for adult use only for the treatment of COPD and not asthma, at a dose of 150 micrograms daily. European Post Authorisation Safety Study (PASS) study (QAB149B2431), performed 01-Mar-2010 to 31 Dec 2013, showed that the proportion of indacaterol initiators with a diagnosis of "pure" asthma was below 10%, whereas the proportion with pure asthma and mixed disease (i.e., patients with COPD and asthma without ICS therapy) was 7.4%. The results support that HCPs appear to be sufficiently aware that indacaterol must only be used in COPD.

Medication error regarding strength has not been reported.

No new safety information has arisen regarding incorrect indication use or dose for products containing indacaterol alone. As information in the educational materials for HCPs is sufficiently described in relevant sections of the SmPC, the PRAC agreed that the additional risk minimisation measures are no longer required.

Therefore, the RMP was updated to remove reference to additional risk minimisation measures throughout Parts V and VI. The Annex IID was 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 indacaterol the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing indacaterol 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.