25 January 2018
EMA/CHMP/12287/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Relvar Ellipta

fluticasone furoate / vilanterol

On 25 January 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Relvar Ellipta. The marketing authorisation holder for this medicinal product is Glaxo Group Ltd.

The CHMP adopted an extension to one of the existing indications as follows[2]:

"Asthma

Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta$_2$-agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta$_2$-agonists.
- **patients already adequately controlled on both inhaled corticosteroid and long-acting beta$_2$-agonist.**

COPD (Chronic Obstructive Pulmonary Disease)

Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV$_1$<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy."

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in bold

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