



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

19 September 2013  
EMA/CHMP/476694/2013  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (initial authorisation)

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### Relvar Ellipta Fluticasone furoate/vilanterol

On 19 September 2013, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Relvar Ellipta, 184 µg/22 µg and 92 µg/22 µg, inhalation powder, pre-dispensed intended for the regular treatment of asthma and Relvar Ellipta, 92 µg/22 µg, inhalation powder, pre-dispensed for the symptomatic treatment of chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Glaxo Group Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

Relvar Ellipta (ATC code: R03AK10, Drugs for obstructive airways diseases, Adrenergics and other drugs for obstructive airway disease) is a fixed-dose combination of the active substance fluticasone furoate, a synthetic corticosteroid with potent anti-inflammatory activity, and the active substance vilanterol, a selective long-acting beta<sub>2</sub>-receptor agonist. Beta<sub>2</sub>-receptor agonists stimulate intracellular adenylate cyclase which converts ATP into cyclic AMP. Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.

The benefits with Relvar Ellipta in the symptomatic treatment of COPD are its ability to improve the weighted mean FEV<sub>1</sub> 0-4 hours at day in 6 months studies versus placebo and to improve the annual rate of moderate and severe exacerbations in one year clinical studies versus vilanterol 25 µg.

The benefits with Relvar Ellipta in the regular treatment of asthma are its ability to improve trough FEV<sub>1</sub> in a 24 weeks study comparing the 184/22 µg strength versus placebo, fluticasone furoate 200 µg and fluticasone propionate 1000 µg and to reduce the number of severe exacerbations in a 24 weeks study comparing the 92/22 µg strength versus fluticasone furoate 100 µg.

The most common side effects are headache and nasopharyngitis and upper respiratory tract infections. Cases of pneumonia have been reported in patients taking Relvar Ellipta in both indications.

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<sup>1</sup> Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.



Pneumonia has been included as an important identified risk in the Risk Management Plan and the applicant will conduct two post-authorisation safety studies to further investigate this risk.

A Pharmacovigilance plan for Relvar Ellipta will be implemented as part of the marketing authorisation.

The approved indications are:

#### "Asthma

Relvar Ellipta is indicated for the regular treatment of asthma in adults and adolescents aged 12 years old and older where use of a combination medicinal product (long-acting beta<sub>2</sub>-agonist and inhaled corticosteroid) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short acting beta<sub>2</sub>-agonists.

#### COPD (Chronic Obstructive Pulmonary Disease)

Relvar Ellipta is indicated for the symptomatic treatment of adults with COPD with a FEV<sub>1</sub> < 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 summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Relvar Ellipta and therefore recommends the granting of the marketing authorisation.