20 September 2018
EMA/CHMP/652421/2018
Committee for Medicinal Products for Human Use (CHMP)

**Summary of opinion[1] (post authorisation)**

# Trelegy Ellipta

## fluticasone furoate / umeclidinium / vilanterol fluticasone

On 20 September 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 Trelegy Ellipta. The marketing authorisation holder for this medicinal product is GlaxoSmithKline Trading Services Limited.

The CHMP adopted an extension to the existing indication as follows[2]:

> "Trelegy Ellipta is indicated as a maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting β2-agonist **or a combination of a long-acting β2-agonist and a long-acting muscarinic antagonist** (for effects on symptom control **and prevention of exacerbations** see section 5.1)."

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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