EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 December 2010
EMA/CHMP/775689/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Libertek

roflumilast

On 16 December 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Libertek, 500 microgram, film-coated tablets intended for the maintenance treatment of severe chronic obstructive pulmonary disease (COPD).

The applicant for this medicinal product is Nycomed GmbH. 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.

The active substance of Libertek is roflumilast, a systemic drug for obstructive airway diseases (ATC Code: R03DX07). Roflumilast is an anti-inflammatory agent designed to target both the systemic and pulmonary inflammation associated with COPD. Roflumilast reduces the activity of phosphodiesterase 4 (PDE4), an enzyme found in body cells that is important to the pathogenesis of COPD.

The benefits with Libertek are its ability to reduce inflammation in the lungs, to reduce narrowing of airways and to ease breathing problems in adults with severe COPD.

The most common side effects are diarrhoea, weight decrease, nausea, stomach ache and headache. Diarrhoea, nausea, stomach ache and headache mainly occur within the first weeks of therapy and mostly resolve on continued treatment. After discontinuation of Libertek, the majority of patients regain body weight after 3 months.

A pharmacovigilance plan for Libertek will be implemented as part of the marketing authorisation.

The approved indication is:

"Libertek is indicated for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (FEV1 post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment."

[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.

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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 will be 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 for the reference product Daxas, considers there to be a favourable benefit to risk balance for Libertek and therefore recommends the granting of the marketing authorisation.