22 September 2011
EMA/CHMP/754272/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Colobreathe

colistimethate sodium

On 22 September 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Colobreathe, 1,662,500 IU, inhalation powder, hard capsule intended for the the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF) aged 6 years and older. Colobreathe was designated as an orphan medicinal product on 19 February 2002. The applicant for this medicinal product is Forest Laboratories UK Ltd. 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 Colobreathe is colistimethate sodium, a cyclic polypeptide antibacterial agent belonging to the polymyxin group. Polymyxins work by damaging the cell membrane and the resulting physiological effects are lethal to the bacterium.

The benefits with Colobreathe are its ability to prevent deterioration of respiratory function in CF patients as shown in an open-label active comparator study comparing the efficacy of colistimethate sodium 1,662,500 IU dry powder for inhalation to tobramycin nebuliser solution for inhalation, 300 mg/5 mL, in 380 subjects aged 6 years and above with documented cystic fibrosis complicated by chronic pulmonary infection with *Pseudomonas aeruginosa*. The most common side effects are dyspnoea, cough, dysphonia, throat irritation and dysgeusia

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

The approved indication is: "Colobreathe is indicated for the management of chronic pulmonary infections due to *Pseudomonas aeruginosa* in patients with cystic fibrosis (CF) aged 6 years and older (see section 5.1).

Consideration should be given to official guidance on the appropriate use of antibacterial agents."

It is proposed that Colobreathe be subject to medical prescription.

[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 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 Colobreathe and therefore recommends the granting of the marketing authorisation.