21 June 2012
EMA/CHMP/422793/2012 corr *
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion† (initial authorisation)

Tovanor Breezhaler

glycopyrronium bromide

On 21 June 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Tovanor Breezhaler 44 micrograms inhalation powder, hard capsules intended for the maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). The applicant for this medicinal product is Novartis Europharm 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.

The active substance of Tovanor Breezhaler is glycopyrronium bromide, an antiholinergic agent (R03BB06) that inhibits acetylcholine-induced bronchoconstriction.

The benefits with Tovanor Breezhaler are its ability to relieve the symptoms experienced by patients with chronic obstructive pulmonary disease (COPD) in terms of lung function. The most common side effects is dry mouth; the safety profile is further characterised by other symptoms related to the anticholinergic effects, gastrointestinal effects as well as adverse reactions related to local tolerability.

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

The approved indication is: maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

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.

* typographical error of ATC code has been corrected
† 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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The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Tovanor Breezhaler and therefore recommends the granting of the marketing authorisation.