EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 May 2012
EMA/CHMP/304272/2012 corr*
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion† (initial authorisation)

Eklira Genuair

aclidinium bromide

On 24 May 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 Eklira Genuair 322 µg, Inhalation powder, pre-dispensed, 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 Almirall, S.A. 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 Eklira Genuair is aclidinium bromide, a long-acting, inhaled anticholinergic agent (ATC Code R03BB05) that inhibits acetylcholine-induced bronchoconstriction.

The benefits with Eklira Genuair are its ability to relieve the symptoms experienced by patients with moderate to severe COPD in terms of lung function and quality of life (QoL). The most common side effects are headache and nasopharyngitis.

A pharmacovigilance plan for Eklira Genuair 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.

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

* Indication has been updated to clarify that the medicine is for adult patients.
† Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu