25 September 2014
EMA/CHMP/490903/2014
Committee for Medicinal Products for Human Use (CHMP)

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

# Duaklir Genuair

## aclidinium bromide/ formoterol fumarate dihydrate

On 25 September 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Duaklir Genuair, 340 µg / 12 µg, inhalation powder intended as a maintenance bronchodilator treatment for airflow obstruction and relief of 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 substances of Duaklir Genuair are aclidinium bromide and formoterol fumarate dihydrate, aclidinium is a long-acting muscarinic antagonist and formoterol is a long-acting $\beta_2$-adrenergic agonist that inhibits acetylcholine-induced bronchoconstriction (ATC code: R03AL05).

The benefits with Duaklir 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 nasopharyngitis and headache.

A pharmacovigilance plan for Duaklir 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 Duaklir Genuair and therefore recommends the granting of the marketing authorisation.

[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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