European Medicines Agency
Evaluation of Medicines for Human Use

London, 11 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR

Singulair and associated names

International Non-Proprietary Name (INN): montelukast

BACKGROUND INFORMATION

Singulair and associated names, 4mg, chewable tablets and oral granules, is a leukotriene-1 receptor antagonist used for the add-on treatment (concomitantly with inhaled steroids), as alternative monotherapy to low-dose inhaled corticosteroids, and to prevent exercise-induced bronchoconstriction.

On 13 September 2007, Merck Sharp & Dohme presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the nationally authorised Summaries of Product Characteristics (SPC), Labelling and Package Leaflet including quality aspects of the medicinal product Singulair and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) including quality aspects of Singulair and associated names approved across EU Member States, with respect to the following indications: Treatment of asthma as add-on therapy in patients with mild to moderate persistent asthma who are inadequately controlled on inhaled corticosteroids and in whom “as-needed” short acting β-agonists provide inadequate clinical control of asthma; as an alternative treatment option to low-dose inhaled corticosteroids for patients with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids; prophylaxis of asthma in paediatric patients in which the predominant component is exercise-induced bronchoconstriction.

The procedure started on 20 September 2007. The Marketing Authorisation Holder provided supplementary information on 6 December 2007.

During its 21 - 24 April 2008 meeting, the CHMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC, Labelling and Package leaflet including the quality aspects was acceptable and that they should be amended.

The CHMP gave a positive opinion on 24 April 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet including quality aspects for Singulair and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC, Labelling and Package Leaflet in Annex III.

A Decision was issued by the European Commission on 11 July 2008.

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