European Medicines Agency

4 July 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION

PERSUANT TO ARTICLE 6(13) OF COMMISSSION REGULATION (EC) No 1084/2003 FOR

SERETIDE DISKUS and associated names (See Annex I)

International Non-Proprietary Name (INN): **salmeterol / fluticasone**

BACKGROUND INFORMATION

Seretide Diskus and associated names (see Annex I) contain salmeterol and fluticasone propionate, a fixed dose combination of the long acting β-agonist salmeterol and the inhaled corticosteroid fluticasone propionate and is indicated for the regular treatment of asthma where use of a combination product (long-acting beta-2-agonist and inhaled corticosteroid) is appropriate: - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta-2-agonist or - patients already adequately controlled on both inhaled corticosteroid and long-acting beta-2-agonist.

In several EU Member States Seretide Diskus and associated names are approved through the Mutual Recognition Procedure (MRP). In the MRP Sweden is the Reference Member State (RMS) and Austria, Belgium, Denmark, Finland, France, Greece, Germany, Italy, Ireland, Luxembourg, The Netherlands, Portugal, Spain and the United Kingdom are Concerned Member States (CMS).

The Marketing Authorisation Holders submitted a type II variation subject to the MRP in July 2004 to extend the indication to include initial maintenance therapy with the fixed dose combination in patients with chronic persistent asthma. The RMS and CMSs rejected the type II variation based on the grounds that the overall risk/benefit was unfavourable for the initial maintenance therapy indication.

On 12 August 2005 the Marketing Authorisation Holders presented to the EMEA a referral under article 6(13) of Commission Regulation (EC) No 1084/2003. On the basis of the grounds for referral, the point considered by the CHMP was whether it is appropriate to introduce initial maintenance therapy with the fixed dose combination of salmeterol and fluticasone propionate in all patients with chronic persistent asthma.

The referral procedure started on 19 September 2005. The Rapporteur and Co-Rapporteur appointed were Dr D Lyons and Dr G Calvo Rojas, respectively. Supplementary information was provided by the Marketing Authorisation Holders on 3 February 2006 and written explanations were given on 30 March 2006.

Based on evaluation of the available data and the Rapporteur's assessment reports, the CHMP adopted an opinion on 27 April 2006 recommending the variation to the terms of the Marketing Authorisations with amendments to the Summary of Product Characteristics, Labelling and Package leaflet .

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

The final opinion was converted into a Decision by the European Commission on 4 July 2006.

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*__Note__: the information given in this document and Annexes reflect only the CHMP Opinion dated 27 April 2006. The Member States competent authorities will continue to keep the product under regular review.

