European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 July 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR

Lamictal and associated names

International Non-Proprietary Name (INN): lamotrigine

BACKGROUND INFORMATION

Lamictal and associated names, 25 mg, 50 mg, 100 mg, 200 mg tablet and 2 mg, 5 mg, 25 mg, 50 mg, 100 mg, 200 mg, dispersible / chewable tablet, is an antiepileptic drug, used for the treatment of epilepsy and Bipolar Disorder.

On 1 March 2007, GlaxoSmithKline Research & Development Limited 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 Lamictal and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) including quality aspects of Lamictal and associated names approved across EU Member States, with respect to the indication,

Epilepsy

Adults and children above 12 years
Lamictal is indicated for use as adjunctive or monotherapy in the treatment of epilepsy, for partial seizures and generalised seizures, including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome.

Children 2 to 12 years
Lamictal is indicated as adjunctive therapy in the treatment of epilepsy, for partial seizures and generalised seizures including tonic-clonic seizures and the seizures associated with Lennox-Gastaut Syndrome.

After epileptic control has been achieved during adjunctive therapy, concomitant antiepileptic drugs (AEDs) may be withdrawn and patients continued on Lamictal monotherapy.

Bipolar disorder

Adults 18 years and above
Lamictal is indicated for the prevention of mood episodes in patients with bipolar disorder, predominantly by preventing depressive episodes.

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With respect to quality aspects,

The drug substance and the drug product have been appropriately described and generally satisfactory documentation has been provided. The excipients used in the formulations of the drug product and manufacturing processes are standard for the proposed pharmaceutical forms. The results indicate that the drug substance and drug product can be reproducibly manufactured.

The procedure started on 29 March 2007. The Marketing Authorisation Holder provided supplementary information on 16 October 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 Lamictal 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 23 July 2008.