European Medicines Agency

London, 4 August 2006
EMEA/CHMP/142335/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

SUMMARY INFORMATION ON REFERRAL OPINION

PURSUANT TO ARTICLE 30 OF COUNCIL DIRECTIVE 2001/83/EC FOR

Neurontin and associated names (See Annex I)

International Non-Proprietary Name (INN): Gabapentin

BACKGROUND INFORMATION

Gabapentin (Neurontin and associated names) has been approved in several Member States for the treatment of epileptic syndromes and several types of neuropathic pain. The precise mechanism of action of gabapentin is not known. Gabapentin is structurally related to the neurotransmitter GABA (gamma-aminobutyric acid) and interacts with GABA synapses.

On 2nd September 2004, Italy (Agencizia Italiana del Farmaco) presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, in order to harmonise the nationally authorised summaries of product characteristics, PL and labelling of the medicinal product Neurontin and associated names.
The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) of Neurontin (and associated names) approved across EU Member States, Iceland and Norway, in particular with respect to indications, posology, contra-indications, undesirable effects and sections dealing with the recommendations for use due to divergent national decisions.

The procedure started on 21 October 2004. The Marketing Authorisation Holder provided supplementary information on 20 April 2005, 20 December 2005, 27 March 2006 and 9 May 2006.

During its 29 May – 1 June 2006 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 was acceptable and that they should be amended.

The CHMP gave a positive opinion on 1 June 2006 recommending the harmonisation of the SPC, labelling and package leaflet for Neurontin 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 4 August 2006.

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 16
E-mail: mail@emea.eu.int http://www.emea.eu.int