5 November 1999
CPMP/1357/99

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
OPINION FOLLOWING AN ARTICLE 12 REFERRAL

VIGABATRIN

International Nonproprietary Name (INN): **Vigabatrin**

BACKGROUND INFORMATION

A referral under article 12 of Council Directive 75/319/EEC, as amended, was invoked by Finland on 12 October 1998, requesting the Committee for Proprietary Medicinal Products (CPMP) to "give an opinion on whether there is an unfavourable benefit/risk ratio for vigabatrin, especially in relation to its potential to induce serious visual field defects".

The Marketing Authorisation Holders provided written explanations on 27 November 1998, 15 March 1999 and 22 April 1999 and oral explanations at the April 1999 CPMP meeting.

On 20 May 1999 the CPMP adopted an Opinion recommending the maintenance of the Marketing Authorisations for all vigabatrin containing medicinal products according to the amended Summary of Product Characteristics (SPC) and under specific conditions.

A copy of the Opinion on vigabatrin containing medicinal products is available on the Internet together with the scientific conclusions and grounds for amendment of the SPC in Annex I, the list of the concerned Marketing Authorisation Holders and Marketing Authorisations in Annex II, the amended SPC in Annex III and the conditions of the Marketing Authorisations (CPMP requirements in relation to pre-clinical studies, clinical studies and patient follow-up) in Annex IV. Translations of such Opinion and its Annexes are available on the Internet in French, German and Spanish.

On the basis of the Opinion adopted by the CPMP the European Commission issued a Decision on 5 October 1999 which was addressed to the concerned Member States for compliance within 30 days.

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