The European Agency for the Evaluation of Medicinal Products

September 2002
CPMP/3962/02

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
OPINION FOLLOWING AN ARTICLE 36 REFERRAL

Cerivastatin

International Nonproprietary Name (INN): Cerivastatin

BACKGROUND INFORMATION

Cerivastatin is an HMG CoA reductase inhibitor authorised in Europe through the Mutual Recognition system at doses of 0.1- 0.4mg for the treatment of hyperlipidaemia.

On 19 September 2001, Portugal notified the EMEA of a referral under Article 15a of Directive 75/319/EEC (now Article 36 of Directive 2001/83/EC) regarding all cerivastatin containing medicinal products approved under a Mutual Recognition procedure. Portugal requested that a full assessment of the risk-benefit of cerivastatin be carried out because of concerns regarding a possible increased risk of rhabdomyolysis.

The Procedure was started at the September 2001 CPMP meeting. Written explanations were provided by the Marketing Authorisation Holders on 23 October 2001 with supplementary information on 31 October 2001.

On 4 January 2002 the EMEA received a fax from Bayer announcing that they intended to withdraw all marketing authorisations for cerivastatin containing medicinal products by 15 January 2002 and would not seek to reintroduce cerivastatin. They requested that the Article 36 procedure be terminated. The CPMP discussed the request to terminate the Article 36 procedure at its January meeting. It was decided that there was still a public health issue to be resolved and decided to continue the procedure in line with section 4 of Chapter 3 of The Notice to Applicants Volume 2A.

On 14 February 2002 the EMEA received from Bayer the response to the List of Outstanding Issues.

An oral explanation to the CPMP took place on 20 March 2002. The CPMP adopted an Opinion on 21 March 2002 recommending the withdrawal of the Marketing Authorisation for cerivastatin containing medicinal products authorised under the Mutual Recognition Procedure.

The Scientific conclusions are provided in Annex II.

The final Opinion was converted into a Decision by the European Commission on 22 August 2002.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 86 68
E-mail: mail@emea.eu.int http://www.emea.eu.int