European Medicines Agency
Evaluation of Medicines for Human Use

London, 10 May 2005
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(2) REFERRAL

Rigevidon

International Non-Proprietary Name (INN): **levonorgestrel and ethinylestradiol**

BACKGROUND INFORMATION

Rigevidon is a combined oral contraceptive (COC) containing 150µg levonorgestrel (LNG) and 30µg ethinylestradiol (EE2).

A Marketing Authorisation for Rigevidon was granted to Medimpex France SA by Denmark on 10 March 2003. The application for Mutual Recognition for Rigevidon was submitted to Denmark and the Mutual Recognition Procedure started on 30 April 2004.

The referral procedure was triggered by the Netherlands, in relation to the acceptance criteria, in bioequivalence studies, of pharmacokinetics parameters, which may need to be tightened, if Rigevidon could be considered as a medicinal product with a narrow therapeutic range.

The arbitration procedure started on 16 September 2004.

During its January 2005 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that a marketing authorisation should be granted. A positive opinion was therefore adopted on 20 January 2005.

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

The final opinion was converted into a Decision by the European Commission on 10 May 2005.

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