European Medicines Agency
Evaluation of Medicines for Human Use

21 February 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(2)[1] REFERRAL FOR

Lansoprazol-ratiopharm 15 mg and 30 mg

International Non-Proprietary Name (INN): Lansoprazole

BACKGROUND INFORMATION

Lansoprazol-ratiopharm (lansoprazole) is a proton pump inhibitor that inhibits gastric acid secretion and is used for treatment of duodenal and gastric ulcer, reflux oesophagitis, gastro-oesophageal reflux disease, treatment and prophylaxis of NSAID-associated gastric and duodenal ulcers, Zollinger-Ellison syndrome, and in combination with appropriate antibacterial therapeutic regimens for the eradication of *Helicobacter pylori* and prevention of relapse of peptic ulcers in patients with *H. pylori* associated ulcers.

A Marketing Authorisation for Lansoprazol-ratiopharm (15 mg and 30 mg) was previously granted to ratiopharm GmbH in Finland on 7 November 2003. A Mutual Recognition Procedure was started on 16 September 2004. The Reference Member State was Finland and the Concerned Member States were Austria, Belgium, Denmark, Germany, Italy, Luxembourg, the Netherlands, Portugal, Sweden and United Kingdom. The Concerned Member States have not been able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. The application was withdrawn in the Netherlands and United Kingdom. Portugal and Germany referred the reasons for disagreement to the EMEA on 15 December 2004.

Significant differences in comparison to the reference product have been identified with regard to the indication section of the SPCs. For the 15 mg dosage form the therapeutic indication “Helicobacter pylori eradication” is not approved for the reference medicinal product marketed in Portugal. The applicant should provide clinical data to support the use of 15 mg capsules for Helicobacter pylori eradication. In particular, the data of the bioequivalence of the 2x15 mg capsules and the 30 mg capsules, and the possible need for a reduced dose of lansoprazole in this therapeutic indication.

Significant differences in comparison to the reference product have been identified with regard to the posology section of the SPCs. The SPC of the reference product in Germany contains specific doses and dosing schedules for the combinations of lansoprazole and antibiotics recommended for eradication of Helicobacter pylori.

The arbitration procedure started on 20 January 2005. The Rapporteur and Co-Rapporteur appointed were Sif Ormarsdottir/Tomas Salmonson, Gottfried Kreutz/Julia Dunne respectively. The Marketing Authorisation Holder provided written explanations on 20 July 2005.

During its September 2005 meeting, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, was of the opinion that the benefit/risk ratio is favourable for Lansoprazol-ratiopharm. Changes to the SPC section 4.2 (Posology and Methods of

[1] Article 29(2) of Directive 2001/83/EC, as amended.

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Administration) giving a detailed dosing recommendation for antibiotics, in accordance with “Points to consider on wording of *Helicobacter pylori* eradication therapy in selected SPC sections”, were agreed by CHMP and a positive opinion was adopted on 15 September 2005.

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

The final opinion was converted into a Decision by the European Commission on 21 February 2006.