European Medicines Agency
Evaluation of Medicines for Human Use

15 September 2005
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Lansoprazol HEXAL 15 mg and 30 mg

International Non-Proprietary Name (INN): Lansoprazole

BACKGROUND INFORMATION

Lansoprazol HEXAL (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 HEXAL (15 mg and 30 mg) was previously granted to Hexal AG 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, Denmark, Germany and Sweden. 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. 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 indications' section of the SPCs. The SPC of the reference product in Germany does not contain the indications related to the concomitant use of NSAIDs and the treatment and prevention of gastric and duodenal ulceration caused by these compounds.

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 13 April 2005.

During its June 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 HEXAL. The indications related to the concomitant use of NSAIDs and the treatment and prevention of gastric and duodenal ulceration caused by these compounds were supported.

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 15 September 2005.

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

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