European Medicines Agency
Evaluation of Medicines for Human Use

London, 18 September 2007
EMEA/283378/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(4)[1] REFERRAL FOR

Lansoprazole and associated names

International Non-Proprietary Name (INN): lansoprazole

BACKGROUND INFORMATION

Lansoprazole 15 & 30 mg gastro-resistant capsules, hard are generic preparations containing lansoprazole as the active substance. Lansoprazole is a proton pump inhibitor that inhibits gastric acid secretion and is used for the treatment of duodenal and benign gastric ulcers, gastro-oesophageal reflux disease and associated conditions.

TEVA UK Limited submitted applications for mutual recognition of Lansoprazole and associated names, 15 and 30 mg, gastro-resistant capsules, hard, on the basis of the marketing authorisation granted by the United Kingdom on 9 December 2005. The Mutual Recognition Procedure started on 07 June 2006. The Reference Member State was the United Kingdom and the Concerned Member States were Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, the Netherlands, Norway, Poland, Portugal, the Slovak Republic, Spain and Sweden. These Member States were not able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. The Czech Republic, Spain and Portugal referred the reasons for disagreement to the EMEA on 30 November 2006.

The reasons for disagreement were, that some Member States have raised public health objections on the grounds that while bioequivalence was proven in the fasting state, the same was not the case under fed conditions.

The arbitration procedure started on 14 December 2006 with the adoption of a list of questions. The Rapporteur was Dr. Frits Lekkerkerker and Co-Rapporteur was Dr. Ian Hudson. The Marketing Authorisation Holder provided written explanations on 30 March 2007.

During their 18 – 21 June 2007 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 Lansoprazole and associated names, that the objections raised by the Czech Republic, Spain and Portugal should not prevent the granting of a Marketing Authorisation and that the valid Summary of Product Characteristics, labelling and package leaflet are the final versions achieved during the Coordination group procedure. A positive opinion was adopted by consensus on 21 June 2007.

The list of the product names concerned is given in Annex I. The scientific conclusions are provided in Annex II.

The final opinion was converted into a Decision by the European Commission on 18 September 2007.

[1] Article 29(4) of Directive 2001/83/EC, as amended.

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