European Medicines Agency
Evaluation of Medicines for Human Use

London, 14 November 2008
EMEA/CHMP/633842/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Lisonorm and associated names

International Non-Proprietary Name (INN): lisinopril + amlodipine

BACKGROUND INFORMATION

Lisonorm tablet contains 5mg amlodipine/ 10mg lisinopril and is an anti-hypertensive indicated in patients with blood pressure adequately controlled with lisinopril and amlodipine given concurrently at the same dose level.

Gedeon Richter Plc obtained a national marketing authorisation for Lisonorm which was authorised in Bulgaria on 29 December 2006, before Bulgaria joined the European Union.

Gedeon Richter Plc submitted a Marketing Authorisation Application (MAA) via mutual recognition procedure for Lisonorm on the basis of the marketing authorisation granted by Hungary on 30 April 2004. The Mutual Recognition Procedure started on 3 August 2007.

The Reference Member State was Hungary and the Concerned Member States were Czech Republic, Estonia, Hungary, Lithuania, Latvia, Poland, Romania and Slovak Republic. 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 and Latvia referred the reasons for disagreement to the EMEA on 1 February 2008. Concerns related to the formal proof of bioequivalence and the lack of a wide therapeutic experience which were considered a potential serious risk to public health.

The arbitration procedure started on 21 February 2008 with the adoption of a list of questions. The Rapporteur was Dr Ondřej Slanař (CZ) and Co-Rapporteur(s) was Prof János Borvendég (HU). The Marketing Authorisation Holder provided written explanations on 2 June 2008.

During their July 2008 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 Lisonorm, that the objections raised by Czech Republic and Latvia should not prevent the granting of a Marketing Authorisation. The Summary of Product Characteristics, Labelling and Package Leaflet of the Reference Member State should be amended. A positive opinion was adopted by consensus on 24 July 2008.

The list of the 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 12 November 2008.

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

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