European Medicines Agency
Evaluation of Medicines for Human Use

London, 11/10/2006
EMEA/CHMP/423308/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Doxagamma 4 mg prolonged release tablets and associated names

International Non-Proprietary Name (INN): Doxazosin

BACKGROUND INFORMATION

Doxagamma 4 mg prolonged release tablets and associated names (doxazosin) is a receptor alfa blocking agent used in the treatment of patients with essential hypertension and in the symptomatic treatment of patients with benign prostatic hyperplasia.

Generics Ltd. submitted applications for mutual recognition of Doxagamma 4 mg prolonged release tablets and associated names on the basis of the marketing authorisation granted by the Denmark on 30 September 2002. The Mutual Recognition Procedure started on 15 September 2005. The Reference Member State was Denmark and the Concerned Member States were: United Kingdom. These Member States were not been able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. The Denmark referred the reasons for disagreement to the EMEA on 3 March 2006.

The scope of the referral was to agree whether Doxagamma 4mg prolonged release tablets differ significantly with regards to the release profile from the originator product with potential for increased incidence of adverse events such as dizziness and hypotension, whether there were significant differences in performance of test batches in the single dose phase of studies 5208 and 1995 and whether the applicant has deviated from CHMP guidelines on the design of the bioequivalence studies, particularly in relation to the effect of food.

The arbitration procedure started on 23 March 2006. The CHMP appointed Dr. J.F.F. Lekkerkerker (Netherlands) as Rapporteur and Dr. Hudson (United Kingdom) as Co-rapporteur. The Marketing Authorisation Holder provided written explanations on 08 April 2006. Oral explanations were given by the Marketing Authorisation Holder on 27 June 2006.

During the June 2006 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 Doxagamma 4 mg prolonged release tablets and associated names, that the objections raised should not prevent the granting of a Marketing Authorisation and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. A positive opinion was adopted 28 June 2006.

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 11/10/2006.

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

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