European Medicines Agency
Evaluation of Medicines for Human Use

London, 11 July 2007
EMEA/CHMP/75066/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Ciprofloxacin Hikma and associated names

International Non-Proprietary Name (INN): Ciprofloxacin

BACKGROUND INFORMATION

Ciprofloxacin Hikma and associated names, 2 mg/ml solution for infusion, is an antibiotic belonging to the quinolone family, effective *in vitro* against a large number of Gram-negative aerobic bacteria as well as against some Gram-positive organisms.

Hikma Farmaceutica Lda. submitted applications for mutual recognition of Ciprofloxacin Hikma and associated names, 2 mg/ml solution for infusion on the basis of the marketing authorisation granted by the Netherlands on 12 April 2005. The Mutual Recognition Procedure started on 28 January 2006. The Reference Member State was the Netherlands and the Concerned Member States were Austria, Germany, Ireland, Italy, and United Kingdom. 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 Netherlands referred the reasons for disagreement to the EMEA on 7 July 2006.
Significant differences have been identified with regard to dose in urinary tract infections and of the maximum adult daily dose. In addition, it was considered that the applicant should include in the Summary of Product Characteristics (point 5.1) the organisms listed in the breakpoints and susceptibility table relevant to the indications, as per the Note for Guidance on Evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 rev.1).

The arbitration procedure started on 27 July 2006 with the adoption of a list of questions. The Rapporteur was Dr Ian Hudson and Co-Rapporteur was Dr Bengt Ljungberg. The Marketing Authorisation Holder provided written explanations on 20 October 2006.

During their January 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 Ciprofloxacin Hikma 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 by on 24 January 2007.

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 July 2007.

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

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