European Medicines Agency
Evaluation of Medicines for Human Use

London, 24 January 2007
EMEA/CHMP/515890/2006

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Ciprofloxacine Kabi and associated names

International Non-Proprietary Name (INN): Ciprofloxacin

BACKGROUND INFORMATION

Ciprofloxacine Kabi and associated names, Solution for infusion, 2 mg/ml, 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.

Fresenius Kabi Nederland B.V. submitted applications for mutual recognition of Ciprofloxacine Kabi and associated names, Solution for infusion, 2 mg/ml on the basis of the marketing authorisation granted by Netherlands on 23 September 2005. The Mutual Recognition Procedure started on 17 December 2005. The Reference Member State was the Netherlands and the Concerned Member States were Austria, Belgium, Cyprus, Czech Republic, Germany, Denmark, Greece, Spain, Finland, Hungary, Italy, Poland, Portugal, Sweden, Slovak Republic 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 9 June 2006.
On the basis of the questions raised by the Member States, the points to be considered by the CHMP were the recommended dose in urinary tract infections and of the maximum adult daily dose.

The arbitration procedure started on 28 June 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 2 August 2006.

During their November 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 Ciprofloxacine Kabi 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 consensus on 16 November 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 24 January 2007.

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

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