European Medicines Agency
Evaluation of Medicines for Human Use

London, 23 January 2008
EMEA/CHMP/350278/2007

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Ciprofloxacin Nycomed and associated names

International Non-Proprietary Name (INN): Ciprofloxacin

BACKGROUND INFORMATION

Ciprofloxacin Nycomed 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.

Nycomed Danmark ApS submitted applications for mutual recognition of **Ciprofloxacin Nycomed** and associated names, 2 mg/ml Solution for Infusion, on the basis of the marketing authorisation granted by United Kingdom on 23 March 2005. The Mutual Recognition Procedure started on 15 November 2005. The Reference Member State was United Kingdom and the Concerned Member States were Denmark, Finland, Norway and Sweden. These Member States were not able to reach an agreement with respect to the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. United Kingdom referred the reasons for disagreement to the EMEA on 5 May 2006.

Significant differences were identified with regards to the approved posology for complicated urinary tract infections and the maximum daily dose for this generic intravenous ciprofloxacin product. These issues were considered to be of serious public health concern. The proposed dosage regimen for complicated urinary tract infections (100 mg bid) was considered too low and should be changed to 200-400 mg twice daily. Further, as patients referred to parenteral treatment often are seriously ill, it was felt of importance that a maximum dosage of 1200 mg (400 mg three times daily) instead of 800 mg be permitted.

The arbitration procedure started on 1 June 2006 with the adoption of a list of questions. The Rapporteur was Dr Hudson and Co-Rapporteur(s) was Dr Ljungberg. The Marketing Authorisation Holder provided written explanations on 21 September 2006.

During their 13-16 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 for **Ciprofloxacin Nycomed** and associated names, that the objections raised by Norway and Sweden 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. On 21 June 2007 the CHMP, in order to focus and facilitate the translations of the specific amendments in the Summary of Product Characteristics, adopted a revised opinion with amended Annex II and Annex III, which was further reconsidered in October 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 18 January 2008.

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

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