European Medicines Agency
Evaluation of Medicines for Human Use

London, 7 October 2008
Doc. Ref. EMEA/CHMP/384874/2008

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR

Ciprofloxacin Bayer and associated names

International Non-Proprietary Name (INN): ciprofloxacin

BACKGROUND INFORMATION

Ciprofloxacin Bayer and associated names is an antibiotic, indicated for the treatment of uncomplicated and complicated infections, including severe infections, caused by ciprofloxacin susceptible pathogens. It is available as immediate release film coated tablets, modified release film coated tablets, granules and solutions for oral suspension, solutions for infusion in bags, solutions for infusion in bottles and sachets.

On 22 June 2007, France presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the nationally authorised Summaries of Product Characteristics (SPC), Labelling and Package Leaflet of the medicinal product Ciprofloxacin Bayer and associated names.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) of Ciprofloxacin Bayer and associated names approved across EU Member States, with respect to the indications, the posology, the contra-indications and the special warnings and precautions for use.

This medicinal product belongs to the list of products identified in 2007 for SPC harmonisation.

The procedure started on 19 July 2007. The Marketing Authorisation Holder provided supplementary information on 23 November 2007 and 22 April 2008.

During its July 2008 meeting, the CHMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC, Labelling and Package Leaflet was acceptable and that they should be amended.

The CHMP gave a positive opinion on 24 July 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet for Ciprofloxacin Bayer and associated names.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC, Labelling and Package Leaflet in Annex III.

A Decision was issued by the European Commission on 7 October 2008.

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