European Medicines Agency
Evaluation of Medicines for Human Use

London, 22 August 2007
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

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

Cefuroximaxetil and associated names

International Non-Proprietary Name (INN): cefuroxime (as axetil)

BACKGROUND INFORMATION

Cefuroximaxetil and associated names, 125 mg, 250 mg and 500 mg, coated tablets is a cephalosporin (β-lactam group of antibiotics), indicated for the treatment of mild to moderately severe infections caused by micro-organisms susceptible to cefuroxime, such as:

- upper respiratory tract infections: acute otitis media, sinusitis, tonsillitis and pharyngitis
- acute bronchitis, acute exacerbations of chronic bronchitis
- lower uncomplicated urinary tract infections: cystitis
- skin and soft tissue infections: furunculosis, pyoderma and impetigo
- uncomplicated gonorrhoea: urethritis and cervicitis
- treatment of early stage Lyme disease (stadium I) and subsequent prevention of late complications in adults and children above 12 years of age.

Sandoz B.V. submitted applications for mutual recognition of Cefuroximaxetil and associated names, 125 mg, 250 mg and 500 mg, coated tablets on the basis of the marketing authorisation granted by the Netherlands on 1 October 2004. The repeat-use Mutual Recognition Procedure started on 17 May 2006. The Reference Member State was the Netherlands and the Concerned Member States were Estonia, Greece, Portugal and Spain. 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. Spain referred the reasons for disagreement to the EMEA on 25 September 2006.

Significant difference was identified with regard to the indication "uncomplicated gonorrhoea: urethritis and cervicitis". This refers to the safety and efficacy of cefuroximaxetil in uncomplicated gonorrhoea and risk-benefit balance for this sought indication and this was considered to be a serious public health concern.

The arbitration procedure started on 18 October 2006 with the adoption of a list of questions. The Rapporteur was Dr Frits Lekkerkerker and Co-Rapporteur was Dr Gonzalo Calvo Rojas. The Marketing Authorisation Holder provided written explanations on 15 January 2007.

During their April 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 objections raised by Spain could be agreed and that the Summary of Product Characteristics, labelling and package leaflet of the Reference Member State should be amended. Existing Marketing Authorisations should be varied and pending Marketing Authorisation Applications should be granted to include these amendments. An opinion was adopted by consensus on 26 April 2007.

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

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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 22 August 2007.