European Medicines Agency
Evaluation of Medicines for Human Use

London, 21 August 2006
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

OPINION FOLLOWING AN ARTICLE 29(2)[1] REFERRAL FOR

Ceftriaxone Tyrol Pharma and associated names

International Non-Proprietary Name (INN): Ceftriaxone

BACKGROUND INFORMATION

Ceftriaxone Tyrol Pharma and associated names, 1g and 2 g powder for solution for injection/infusion, is an antibiotic, being a third generation cephalosporin. It is indicated for the treatment of the following infections when caused by micro-organisms that are susceptible to ceftriaxone and if parenteral treatment is necessary:

- sepsis
- bacterial meningitis
- infections of bones or joints
- infections of skin or soft tissues
- pneumonia

Ceftriaxone is indicated for perioperative prophylaxis in patients with a certain risk of severe postoperative infections. Depending on the mode of surgery and the expected spectrum of pathogens ceftriaxone should be combined with an appropriate antimicrobial agent with additional anaerobic coverage.

Sandoz GmbH submitted applications for mutual recognition of Ceftriaxone Tyrol Pharma and associated names, 1g and 2g, solution for injection/infusion on the basis of the marketing authorisation granted by Germany on 13 August 2002. The Mutual Recognition Procedure started on 24 March 2005. The Reference Member State was Germany and the Concerned Member States were Finland and the United Kingdom. These Member States were not been able to reach an agreement in respect of the Mutual Recognition of the Marketing Authorisation granted by the Reference Member State. The United Kingdom referred the reasons for disagreement to the EMEA on 16 August 2005.

Significant difference has been identified with regard to the proposed SPC compared to the SPC of the reference product in the UK. This refers to the dosing recommendation for the newborn and this was considered to be of serious public health concern. The posology in neonates where higher doses were proposed for neonates aged 15-27 days (80 mg/kg) while the standard dose is 20-50mg/kg in the UK for neonates 0-28 days.

The arbitration procedure started on 15 September 2005 with the adoption of a list of questions. The Rapporteur was Dr. Broich and Co-Rapporteurs were Dr. Hudson and Dr. Kuitunen. The Marketing Authorisation Holder provided written explanations on 28 November 2005.

During their May 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 Ceftriaxone Tyrol Pharma and associated names, that the objections raised by United Kingdom should

[1] Article 29(2) of Directive 2001/83/EC, as amended.

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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 majority on 1 June 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 21 August 2006.