European Medicines Agency
*Pre-Authorisation Evaluation of Medicines for Human Use*

London, 20 November 2008
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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE**
**SUMMARY OF POSITIVE OPINION***
**for**
**ZEVTERA**

International Nonproprietary Name (INN): ***ceftobiprole medocaril***

On 20 November 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Zevtera, 500 mg, powder for solution for infusion intended for treatment of complicated skin and soft tissue infections. The applicant for this medicinal product is Janssen-Cilag International NV.

The active substance of Zevtera is Ceftobiprole medocaril, a β-lactam anti-bacterial agent (other cephalosporins- ATC code: J01DI01). Ceftobiprole binds tightly to many common essential penicillin-binding proteins (PBPs) in both gram-positive and gram-negative bacteria. Inhibition of PBPs lead to incomplete cell wall synthesis and bacterial lysis.

The benefits with Zevtera are its bactericidal activity against most clinically important gram-positive (including methicillin-resistant Staphylococcus aureus [MRSA]) and various gram-negative bacteria. The most common side effects are nausea, infusion site reactions, vomiting, diarrhoea, headache and dysgeusia. Hyponatremia, hypersensitivity reaction and potential for seizures are recognised safety concerns. A pharmacovigilance plan for Zevtera, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is: "Zevtera is indicated in adults for the treatment of complicated skin and soft tissue infections (see sections 4.4 and 5.1).

In mixed infections where anaerobic bacteria are suspected, Zevtera should be co-administered with appropriate antibacterial agent(s).

Consideration should be given to official guidance on the appropriate use of antibacterial agents."

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Zevtera and therefore recommends the granting of the marketing authorisation.

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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