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

London, 30 May 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
DORIBAX

International Nonproprietary Name (INN): ***doripenem***

On 30 May 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Doribax, 500 mg, powder for solution for infusion intended for the treatment of nosocomial pneumonia (including ventilator–associated pneumonia), complicated intra-abdominal infections and complicated urinary tract infections. The applicant for this medicinal product is Janssen-Cilag International NV.

The active substance of Doribax is doripenem monohydrate, an injectable, sterile, synthetic, broad-spectrum carbapenem (β-lactam) antibacterial agent *(*J01DH04*)*. Doribax exerts its bactericidal activity by inhibiting bacterial cell wall biosynthesis. Doribax inactivates multiple essential penicillin-binding proteins (PBPs) resulting in inhibition of cell wall synthesis with subsequent cell death.

The benefits with Doribax are its demonstrated non-inferiority in the studied populations compared to levofloxacin in complicated urinary tract infections (cUTIs), compared to meropenem in complicated intra-abdominal infections (cIAIs), and compared to piperacillin/tazobactam and imipenem in nosocomial pneumonia.The most common adverse reactions are headache, diarrhoea and nausea.

A pharmacovigilance plan for Doribax, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indication is:
Doribax is indicated for the treatment of the following infections in adults (see SPC sections 4.4 and 5.1):

- Nosocomial pneumonia (including ventilator–associated pneumonia)
- Complicated intra-abdominal infections
- Complicated urinary tract infections.

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

It is proposed that Doribax is prescribed by physicians experienced in the treatment of nosocomial pneumonia (including ventilator–associated pneumonia), complicated intra-abdominal infections and complicated urinary tract infections (including pyelonephritis).
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 Doribax 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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