European Medicines Agency
Evaluation of Medicines for Human Use

London, 25 September 2008
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
POST-AUTHORISATION SUMMARY OF POSITIVE OPINION*
for
CANCIDAS

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

On 25 September 2008 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion** to recommend the variation to the terms of the marketing authorisation for the medicinal product Cancidas. The Marketing Authorisation Holder for this medicinal product is Merck Sharp & Dohme Ltd.

The CHMP adopted a change to an indication as follows:

- "Treatment of invasive candidiasis in adult or paediatric patients.
- Treatment of invasive aspergillosis in adult or paediatric patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.
- Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropaenic adult or paediatric patients."

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

For information, the full indication(s) for Cancidas will be as follows***:

- "Treatment of invasive candidiasis in adult **or paediatric** patients.
- Treatment of invasive aspergillosis in adult **or paediatric** patients who are refractory to or intolerant of amphotericin B, lipid formulations of amphotericin B and/or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.
- Empirical therapy for presumed fungal infections (such as Candida or Aspergillus) in febrile, neutropaenic adult **or paediatric** patients."

* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the Opinion.

** Marketing Authorisation Holders 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.

*** The text in bold represents the new or the amended indication.

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