BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant, Merck Sharp & Dohme Limited, submitted on 10 October 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Caspofungin MSD, through the centralised procedure. After agreement by the CPMP on 25 May 2000, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Pharm. De Greef Co-Rapporteur: Dr. Tomas Salmonson

Scientific Advice:
The applicant received Scientific Advice from the CPMP on 16 December 1999. The Scientific Advice pertained to Part IV (clinical development) of the dossier.

Licensing status:
Caspofungin has been given a Marketing Authorisation in the United States on 29 January 2001.

2. Steps taken for the assessment of the product

- The procedure started on 31 October 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 16 January 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 15 January 2001.
- During the meeting on 27 February-1 March 2001, the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 1 March 2001.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 22 March 2001.
- The draft summary report of the inspection carried out between 9-13 April 2001 at one of the manufacturing sites of the finished medicinal product was issued on 25 June 2001.
- The Rapporteur and Co-rapporteur circulated the joint Assessment Report on the applicant's responses to the consolidated List of Questions to all CPMP members on 7 May 2001.
- An updated joint Rapporteur/Co-Rapporteur Assessment Report on the responses provided by the applicant, was circulated to all CPMP members on 21 May 2001.
- During the CPMP meeting 29-31 May 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP. The CPMP agreed on a list of outstanding issues to be addressed in writing by the applicant. This list was sent to the applicant on 31 May 2001.
- The applicant submitted the responses to the list of outstanding issues on 25 June 2001.
- The Rapporteur and Co-Rapporteur circulated the joint Assessment Report on the applicant's responses to all CPMP members on 11 July 2001.
- The applicant provided an undertaking letter of the specific obligations and follow-up measures to be fulfilled post authorisation on 25 July 2001.
- During the meeting on 24-26 July 2001 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Caspofungin MSD on 26 July 2001.
- The EMEA forwarded the opinion to the European Commission who issued on 24 October 2001 the respective Decision for granting a Marketing Authorisation under exceptional circumstances to Caspofungin MSD.

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