BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pfizer Limited submitted on 25 October 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for VFEND, through the centralised procedure. After agreement by the CPMP on 21 September 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: Dr. B. van Zwieten-Boot Co-Rapporteur: Dr. Eric Abadie

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

A new application was filed in the following countries: Submitted to the FDA in November. The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 28 November 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 16 February 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 21 February 2001.
- During the meeting on 27-29 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 29 March 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 28 June 2001 (Clock started in July CPMP).
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 5 September 2001.
- During the CPMP meeting on 18-20 September 2001, the CPMP agreed on a List of Oustanding Issues.
- During the CPMP meeting on 14 November 2001, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 11-13 December 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 Vfend on 13 December 2001.
- The CPMP Opinion was forwarded in all official languages of the European Commission, which adopted the corresponding Decision on 19 March 2002.