BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pfizer Limited submitted on 12 September 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for ECALTA, through the centralised procedure under Article 3 (2) (a) of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 1 June 2006.

The legal basis for this application refers to:

Article 8.3 of Directive 2001/83/EC, as amended - complete and independent application

The application submitted is a complete dossier: composed of administrative information, complete quality data, non-clinical and clinical data based on applicants' own tests and studies and/or bibliographic literature substituting/supporting certain test(s) or study(ies).

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

Licensing status:
Anidulafungin has been given a Marketing Authorisation in the United States of America on 17 February 2006.

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

Rapporteur: Frits Lekkerkerker/Pieter de Graeff
Co-Rapporteur: Jens Ersbøll
CHMP Peer reviewer: Karl Broich

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 12 September 2006.
- The procedure started on 27 September 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 6 December 2006. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 13 December 2006.
- During the meeting on 22-24 January 2007, the CHMP 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 25 January 2007.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 March 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 1 May 2007.
- During the CHMP meeting on 21-24 May 2007, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 8 June 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding Issues to all CHMP members on 2 July 2007.
- During the meeting on 16-19 July 2007, the CHMP, 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 ECALTA on 19 July 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 18 July 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 20 September 2007.