BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Actelion Registration Ltd submitted on 08 February 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) through the centralised procedure for Tracleer, which was designated as an orphan medicinal product EU/3/01/019 on 14 February 2001.

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

Rapporteur: Eric Abadie Co-Rapporteur: Per Nilsson

Scientific Advice:

The applicant received Scientific Advice from the CPMP on 04 September 2000. The Scientific Advice pertained to the clinical part of the dossier.

Licensing status:

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 27 February 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 11 May 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 8 May 2001.
- During the meeting on 26-28 June 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 27 June 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 11 October 2001.
- The summary report of the inspection carried out at the manufacturing site Almedica HPS AG between 23-24 August 2001 was issued on 29 January 2002.
- The integrated inspection report of a GCP inspection of the multicentre, phase III, clinical trial AC-052-351, was issued on 1st November 2001.
- The (Co)Rapporteurs circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 27 November 2001 (Annex 5)
- During the meeting on 11-13 December 2001, the CPMP agreed on a List of outstanding issues to be addressed by the Company in writting or during an oral explanation (Annex 6).
- The company submitted the responses to the CPMP consolidated List of outstanding issues on 4 January 2002 and 5 February 2002.
- The (Co)Rapporteurs circulated response Assessment Reports on the company's responses to the List of outstanding issues to all CPMP members on 28 January 2002 and 12 February 2002 (Annexes 7)
- During the meeting on 19-21 February 2002 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 on 21 February 2002.
- The CPMP Opinion was forwarded in all official languages of the European Commission, which adopted the corresponding Decision on 15 May 2002.