BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Sanofi-Synthelabo submitted on 20 December 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Fasturtec, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. H. Van Bronswijk Co-Rapporteur: Prof. Dr. J.H. Trouvin

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 21 January 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 31 March 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 3 April 2000 .
- During the meeting on 23-25 May 2000 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 26 May 2000.
- The company submitted the responses to the CPMP consolidated List of Questions on 7 September 2000.
- The Rapporteur circulated the Joint Rapporteur/Co-rapporteur response Assessment Report on the company's responses to the List of Questions to all CPMP members on 25 October 2000.
- The company, Sanofi-Synthelabo, provided on 15 November 2000, a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP.
- During the meeting on 14-16 November 2000 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 Fasturtec on 16 November 2000.