BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant, Hoechst Marion Roussel submitted on 24 March 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Ketek/Levviax, through the centralised procedure. After agreement by the CPMP on 13 April 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. On 12 February 2001, the applicant informed the EMEA about the merger of Hoechst Marion Roussel into Aventis Pharma S.A. This merger is effective since 31 December 2000.

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

Rapporteur: Dr. P. Nilsson Co-Rapporteur: Prof C. Sampaio

Scientific Advice:

The Applicant received Scientific Advice from the CPMP on 22 October 1998 and 17 December 1998 (follow-up). The Scientific Advice pertained to Part II 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 14 April 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 22 June 2000 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 26 June 2000 (Annex 2).
- During the meeting 25-27 July 2000 the CPMP adopted the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 26 July 2000 (Annex 3).
- The company submitted the responses to the CPMP consolidated List of Questions on 15 January 2001.
- The summary report of the inspection carried out on 16-19 January 2001 at the manufacturing site in Kansas City US has been issued by the Ministero della Sanitá, Italy and the Medical Products Agency, Sweden (Annex 4)
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 5 March 2001 (Annex 5)
- During the meeting on 27-29 March 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 Authorisations for Ketek and Levviax to Aventis Pharma S.A. on 29 March 2001.