BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Abbott Laboratories Limited submitted on 27 June 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Kaletra, through the centralised procedure. After agreement by the CPMP on 21 December 1999, this medicinal product has been referred to Part B 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. Eric Abadie Co-Rapporteur: Dr. Jean-Louis Robert

Licensing status:

The product was not licensed in any country at the time of submission of the application. Kaletra was granted a license in the United States on 15 September 2000.

2. Steps taken for the assessment of the product

- The procedure started on 18 July 2000.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 29 September 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 26 September 2000.
- The summary report of the inspection carried out at the manufacturing site RP Scherer between 31 July-3 August 2000 by the Medicines Control Agency, was issued on 19 September 2000.
- During the meeting on 14-16 November 2000, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- 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 16 November 2000.
- The applicant submitted the responses to the CPMP consolidated list of questions on 24 November 2000.
- The Rapporteur circulated the joint assessment report on the applicant’s responses to the list of questions to all CPMP Members on 4 December 2000.
- The Rapporteur circulated an assessment report on the Purkinje Fibers study to all CPMP Members on 11 December 2000.
- During the meeting on 12-14 December 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 under exceptional circumstances to Kaletra soft capsules and oral solution on 14 December 2000. The applicant provided a letter of undertaking of the specific obligations and follow-up measures to be fulfilled post-authorisation on 13 December 2000.
- The EMEA forwarded the opinion to the European Commission who issued on 20 March 2001 the respective Decision for granting a Marketing Authorisation under exceptional circumstances to Kaletra soft capsules and oral solution.