## BACKGROUND INFORMATION ON THE PROCEDURE

## 1. Submission of the dossier

The company Amgen Europe B.V. submitted on 23 June 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Kineret/Amceptor, 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. M. A. Ainsworth Co-Rapporteur: Prof. Cristina Sampaio

## **Licensing status:**

Kineret has been given a Marketing Authorisation in USA on 14 November 2001.

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 18 July 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 2 October 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 29 September 2000.
- During the meeting on 14-16 November 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 16 November 2000.
- The company submitted the responses to the CPMP consolidated List of Questions on 17 May 2001 and 4 July 2001
- The summary report of the inspection carried out at the manufacturing site between 2-5 April 2001 of the active substance manufacturing site (Amgen Inc., Boulder, Colorado, USA) was issued on 24 August 2001.
- The Rapporteur/Co-Rapporteur circulated the draft response Assessment Report on the company's responses to the List of Questions to all CPMP members on 5 July 2001.
- During the CPMP meeting on 25-27 July 2001, the CPMP adopted a list of outstanding issues to be addressed during an oral explanation.
- The Rapporteur's Assessment Report on the company's responses to the List of outstanding issues was circulated to all CPMP members on 9-10 October 2001.
- During the CPMP meeting on 16-18 October 2001, the outstanding issues were addressed by the applicant during a hearing before the CPMP.
- Following the oral explanation, the applicant withdrew on 6 November 2001 the application for Amceptor. The marketing authorisation is only sought for Kineret 100 mg solution for injection in prefilled syringe and in vial.
- The Rapporteur's Assessment Report on the company's responses to remaining issues to be solved before Opinion was circulated to all CPMP members on 8 November 2001.
- During the meeting on 13-15 November 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 Authorisation to Kineret on 15 November 2001.