BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Baxter AG submitted on 30 December 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for CEPROTIN, 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, as amended.

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

Rapporteur: Dr. M. Haase Co-Rapporteur: Prof. S. Garratini

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 4 April 2000. The Co-Rapporteur's first Assessment Report was circulated to all CPMP Members on 31 March 2000.
- During the CPMP meeting in May 2000 the CPMP agreed on the consolidated List of Questions to be sent to the company. The final consolidated List of Questions was sent to the company on 25 May 2000.
- The company submitted the responses to the CPMP consolidated List of Questions on 25 January 2001.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 26 February 2001.
- 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 Authorisation to CEPROTIN on 29 March 2001.