BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The Company Bayer AG, Germany submitted on 5 February 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for KOGENATE Bayer, 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. Manfred Haase Co-Rapporteur: Prof. Bo Odlind/Dr Tomas Salmonson

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 26 February 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 13 May 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 7 May 1999.
- During the meeting on 22-23 June 1999 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 24 June 1999.
- The Company submitted the responses to the CPMP consolidated list of questions on 22 October 1999.
- The report of the testing of samples by the Paul Ehrlich Institut was issued on 26 August 1999.
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 17 December 1999.
- During the CPMP meeting on 18-20 January 2000, the CPMP adopted a list of unresolved issues that was sent to the Company on 20 January 2000.
- The Applicant provided written information on these unresolved issues on 24 February 2000. The joint assessment reports on this written information were circulated on 3 March 2000 for Part II and 13 March 2000 for Part IV.
- A clarification meeting on the outstanding issues took place during the BWP meeting on 7-8 March 2000.
- During the meeting on 14-16 March 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 KOGENATE Bayer on 16 March 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 4 August 2000.