BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company SP Europe, 73, rue de Stalle, B-1180 Bruxelles submitted on 8 March 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for PegIntron, 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 CHMP were:

Rapporteur: Dr P. Nilsson Co-Rapporteur: Prof. A. Hildebrandt

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 March 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 4 June 1999.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 14 June 1999.
- During its meeting on 27-29 July 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 30 July 1999.
- During its meeting on 27-29 July 1999, the CPMP agreed that a GMP inspection of the manufacturing site was not necessary.
- The company submitted the responses to the consolidated list of questions on 28 October 1999.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 20 December 1999.
- The applicant provided supplementary information on 11 January 2000.
- The applicant at an oral explanation in the CPMP on 18 January 2000 addressed outstanding questions.
- The applicant provided written explanations on 28 January 2000.

  Rapporteur's Assessment of additional written information was circulated on 31 January 2000.

  BWP discussed remaining quality points on the 8-9 February 2000 and issued a recommendation to CPMP.
- During the meeting on 15-17 February 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 for PegIntron.