BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Registration Ltd. submitted on 15 January 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for PEGASYS, 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: P. Nilsson Co-Rapporteur: F. de Andres-Trelles

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 30 January 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 12 April 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 3 May 2001.
- During the meeting on 29-31 May 2001 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 1 June 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 9 November 2001.
- The response Assessment Report on the company's responses to the List of Questions was circulated to all CPMP members on 11 January 2002.
- During the meeting on 19-21 March 2002 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion by consensus vote for granting a Marketing Authorisation to PEGASYS on 21 March 2002.