BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant BEHRINGWERKE AG, Germany submitted on 20 December 1995 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain Marketing Authorisation for the medicinal product Refludan in accordance with the Centralised Procedure falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

Licensing/authorisation status:

The product is not licensed in any country outside the EU.

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

Rapporteur:	Dr. P. Sjoberg
Assessors:	Dr. A. Johnsson
	Dr. U. Hammerling
	Dr. J.R. Wade
	Dr. P. Nilsson
Co-Rapporteur:	Dr. D. Jefferys
Assessors:	Mrs. M. Dow
	Dr. G. Turnbull
	Prof. J. Lewis
	Dr. F. Rotblat

2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report was circulated to all CPMP members on 11 March 1996.
- The Co-Rapporteur initial assessment report was circulated to all CPMP members on 11 March 1996.
- In their March meeting, the CPMP agreed the need of performing a inspection of the active substance manufacturing site "Roussel Uclaf", Roumanville, France.
- During the May CPMP meeting, a break out session took place for the preparation of the draft CPMP list of questions.
- The CPMP agreed on the consolidated list of questions to be sent to the applicant on 22 May 1996.
- The Inspection performed of the active substance manufacturing by the Agence du Medicament in the Roussel Uclaf manufacturing plant (chemical division, Roumanville, France) was concluded to be satisfactory on 24 July 1996.
- The applicant submitted the responses to the CPMP consolidated list of questions on 6 September 1996.
- The Rapporteur's assessment report of the responses to the consolidated list of questions was circulated to all CPMP members on 7 October 1996.
- The update overall Rapporteurs's assesment report on the outstanding issues was circulated to all CPMP members on 11 November 1996.

- Undertaking on the follow up measures issued by the Company was circulated on 19 November 1996.
- The CPMP in their meeting on 18-21 November 1996, on the basis of the favorable benefit-risk assessment, issued a positive opinion for granting a marketing authorisation to Refludan.
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decisions on 13 March 1997.