BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd, U.K. submitted on 7 October 1997, to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain Marketing Authorisation for the medicinal product Simulect 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.

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

Rapporteur: Prof. Kurth
from 1 Jan. 1998: Dr. M. Haase

Co-Rapporteur: Prof. G. Vicari

Licensing status:
Simulect has been given a marketing authorisation in the following countries:
U.S. on 12 May 1998, Switzerland on 7 April 1998, Argentina on 29 April 1998.

2. Steps taken for the assessment of the product

- The procedure started on 24 October 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 7 January 1998.
- The Co-rapporteur's first assessment report was circulated to all CPMP Members on 5 January 1998.
- During the CPMP plenary meeting on 23-25 February 1998, 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 February 1998.
- The company submitted the responses to the consolidated list of questions on 9 April 1998.
- The joint Rapporteur/Co-Rapporteur assessment report on the company's responses was circulated to all CPMP members on 15 May 1998.
- The CPMP requested an Inspection of the Manufacturing site of Novartis Pharma AG, Basel and Novartis Pharma AG, Stein. on the basis of the need to assess GMP compliance. The inspection took place on 30 March - 3 April 1998. The inspection report was forwarded to EMEA on 8 June 1998.
  The general impression of the Quality Assurance System and compliance with the EU GMP rules is positive.
- The BWP during their meeting on 16 June 1998 prepared a recommendation to the CPMP on quality aspects of the joint Rapporteur/Co-Rapporteur's assessment report on the company's responses.
- The CPMP, during their meeting on 23 June 1998 discussed the recommendations presented by the Rapporteur, considering the responses provided by the company were satisfactory. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The CPMP during their meeting of 21 - 23 June 1998, issued a positive opinion for granting a marketing authorisation to Simulect on 23 June 1998.
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decision on 9 October 1998.