BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Roche Registration Ltd submitted on 27 February 1997, to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain Marketing Authorisation for the medicinal product Mabthera 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 CPMP appointed the Rapporteur and the Co-Rapporteur were:

Rapporteur: H. Hovgaard Co-Rapporteur: Dr. W. F. van der Giesen

Licensing status :

The product was not licensed in any country at the time of submission of the application.

Mabthera has been given a Marketing Authorisation in the following countries: USA on 26 November 1997, Switzerland on 27 November 1997

2. Steps taken for the assessment of the product

- The procedure started on 21 March 1997
- The Rapporteur's first assessment report was circulated to all CPMP Members on 4 June 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 2 June 1997.
- During the CPMP plenary meeting on 22 July 1997 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 22 July 1997.
- The company submitted the responses to the consolidated list of questions on 12 September 1997.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 28 October 1997. The Co-Rapporteur circulated the responses assessment report on the company's responses to the list of questions to all CPMP Members on 7 November 1997.
- The CPMP during its meeting on 19 November 1997 decided to convene an ad-hoc group of clinical experts in order to give answers to outstanding clinical issues.
- The ad-hoc group of clinical experts met on 7 January 1998 and the report from that meeting was circulated to the CPMP members.
- An oral presentation by the company on clinical issues took place during the CPMP meeting on 27 January 1998.
- The CPMP, during its meeting on 27-28 January 1998 discussed the recommendations presented by the Rapporteur, Co-Rapporteur and the ad-hoc clinical experts group considering the responses and additional follow-up data provided by the company. Amendments were discussed to the Summary of Product Characteristics.
- The CPMP during its meeting of 27-28 January 1998, issued two positive opinions, one for each strength, for granting a marketing authorisation to Mabthera on 28 January 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 2 June 1998.