BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Roche Registration Ltd submitted on 29 September 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Xeloda, through the centralised procedure. After agreement by the CPMP in July 1997, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993, as amended. The CPMP confirmed on 25 March 1999 the Part B status.

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

Rapporteur:	Prof. A. Hildebrandt (until September 2000) Prof. R. Bass (from September 2000)	Co-Rapporteur:	Dr. M. Toivonen

Scientific Advice

The applicant received Scientific Advice from the CPMP on 20 June 1996. The Scientific Advice pertained to Part IV of the dossier, but did refer to another indication.

Licensing status

The product was approved in 22 countries, including the USA and Canada, at the time of the submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 22 October 1999.
- The Rapporteur's initial assessment report was circulated to all CPMP Members on 3 January 2000 (Annex 1). The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 4 January 2000 (Annex 2).
- During the meeting on 15-17 February 2000 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 18 February 2000 (Annex 3).
- The Applicant submitted the responses to the consolidated List of Questions on 12 June 2000.
- The Rapporteur circulated the Joint Response Assessment Report on the Applicant’s responses to the List of Questions to all CPMP Members on 23 August 2000 (Annex 4).
- The CPMP, during its September 2000 plenary meeting, adopted a list of outstanding issues to be addressed by the Applicant in an oral explanation. The final list was forwarded to the applicant on 21 September 2000 (Annex 5).
- The Applicant submitted the responses to the outstanding list of issues on 2 October 2000.
- The Rapporteur circulated the Joint Response Assessment Report on the Applicant’s responses to the list of outstanding issues to all CPMP Members on 9 October 2000 (Annex 6).
- During the CPMP meeting on 17-19 October 2000, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- 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 to Xeloda on 19 October 2000.