BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Registration Ltd., submitted on 12 December 1996 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Xenical, through the centralised procedure. After agreement by the CPMP on 10-11 September 1996, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

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

Rapporteur:	Dr. E. Abadie	Co-Rapporteur: Prof. M. Marselos (then Dr. J. Yotaki from January 1998)

Licensing status

The product was not licensed in any country at the time of submission of the application. Applications were simultaneously submitted in the United States and Canada with other countries worldwide to follow shortly thereafter.

2. Steps taken for the assessment of the product

- The procedure started on 2 January 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 28 February 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 28 February 1997.
- During the February CPMP meeting, it was agreed to perform a GMP inspection on the Swiss manufacturing site for the finished medicinal product (i.e. F Hoffman-La Roche Ltd, Grenzacherstrasse, Basel).
- During the April 1997 meeting, 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 17 April 1997.
- The company submitted the responses to the consolidated list of questions on 10 September 1997.
- The Rapporteur and Co-Rapporteur circulated the joint assessment report on the company's responses to the list of questions to all CPMP Members on 24 October 1997.
- During the November 1997 meeting, the CPMP decided to have a hearing to address the remaining outstanding safety issues: efficacy (label recommendations for selection of responders), lipid soluble vitamin deficiencies, steatorrhoea and the risk of colon cancer, risk of breast cancer (relationship to treatment, sex hormone level) and the overall benefit/risk ratio.
- Following the hearing, the CPMP considered on 16 December 1997 that further information on issues relating to breast cancer, colon cancer, bone mineral density and efficacy (best way to select responders using ITT analysis) should be provided by the company prior to the finalisation of the opinion. The list of additional issues to be addressed by the company in writing was adopted by the CPMP and the clock was subsequently stopped.
- The Rapporteur circulated to all CPMP Members, on 11 March 1998, an assessment report on the company's responses to the additional issues.
- During the meeting on 23-25 March 1998, the company was requested to give additional oral presentation addressing the responders' analysis and the review of breast cancer. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet.
- The company provided a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP, dated 24 March 1998.

- During the meeting on 23-25 March 1998 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion (majority) for granting a Marketing Authorisation for Xenical on 25 March 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 29 July 1998.