BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Introduction

The applicant Ligand Pharmaceuticals UK Ltd submitted on 24 November 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Targretin, through the centralised procedure. After agreement by the CPMP on 29 July 1999, 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 Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur:	Dr. E. Abadie	Co-Rapporteur:	Dr. D. Jefferys (until March 2000) Dr. F. Rotblat (from March 2000)

Scientific Advice

The Applicant did not seek Scientific Advice from the CPMP.

Licensing status

The product was not approved in any country at the time of the submission of the application. The product has subsequently been approved in the USA on 29 December 1999.

2. Steps taken for the assessment of the product

- The procedure started on 17 December 1999.
- The Rapporteur's initial assessment report was circulated to all CPMP Members on 24 February 2000. The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 3 March 2000.
- During the meeting on 11-13 April 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 13 April 2000.
- The Applicant submitted the responses to the consolidated List of Questions on 10 July 2000.
- The Rapporteur circulated the Joint Response Assessment Report on the Applicant’s responses to the List of Questions to all CPMP Members on 28 August 2000.
- The CPMP, during its September 2000 plenary meeting, adopted a list of outstanding issues to be addressed by the Applicant in writing. The final list was forwarded to the Applicant on 26 September 2000.
- The Applicant submitted the responses to the outstanding list of issues on 5 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 20 October 2000.
- 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 Targretin on 16 November 2000.