BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ligand Pharmaceuticals UK Limited submitted on 8 February 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Panretin, through the centralised procedure. After agreement by the CPMP on 22 October 1998 this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur:	Dr. D. Jefferys (until March 2000) Dr. F. Rotblat (from March 2000)	Co-Rapporteur:	Prof. S. Garattini

Licensing status:

At the time of the submission Panretin had been given a Marketing Authorisation in one country, the USA.

2. Steps taken for the assessment of the product

- The procedure started on 26 February 1999.
- The Rapporteur's assessment report was circulated to all CPMP Members on 7 May 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 13 May 1999.
- During the meeting on 22-23 June 1999 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 24 June 1999.
- The summary report of the inspection carried out at the manufacturing site on 19-20 August 1999 was issued on 30 September 1999.
- The company submitted the responses to the consolidated list of questions on 20 December 1999.
- The Rapporteur circulated the Joint Rapporteur/Co-Rapporteur Assessment Report, on the responses to the list of questions provided by the Applicant, to all CPMP Members on 3 March 2000.
- During the meeting on 14-16 March 2000 the CPMP agreed on the List of Outstanding Issues to be sent to the Applicant. The List of Outstanding Issues was sent to the Applicant on 16 March 2000.
- The Applicant submitted written responses to the List of Outstanding Issues on 6 June 2000.
- During the CPMP meeting on 27 June 2000, outstanding issues were addressed by the Applicant during an Oral Explanation before the CPMP.
- During the meeting on 27-29 June 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 Panretin on 29 June 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on11 October 2000.