BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Millenium & ILEX UK Ltd. submitted on 23 March 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for MabCampath, in accordance with the centralised procedure falling within the scope of Part A 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. J. Ersbøll Co-Rapporteur: Prof. S. Garattini

Licensing status:

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

2. Steps taken for the assessment of the product

- The procedure started on 14 April 2000.
- The applicant received Scientific Advice from the CPMP on 25 February 1998 and on 14 September 1998. The Scientific Advice pertained to parts II, III and IV of the dossier.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 22 June 2000 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP Members on 22 June 2000 (Annex 2)
- During the meeting on 25-27 July 2000 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 27 July 2000 (Annex 3).
- The company submitted the responses to the CPMP consolidated List of Questions on 22 November 2000.
- The summary report of the GCP inspection carried out at the manufacturing sites between 28 December 2000-3 January 2001 of the M & I UK Ltd The Surrey Research Park, Guildford, and Surrey was issued on 18 January 2001 (Annex 4).
- The Rapporteur and Co-Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 10 January 2001 (Annex 5)
- A list of outstanding issues to be addressed in writing and during an oral explanation by the Applicant was adopted by the CPMP on 23 January 2001.
- The company submitted the responses to the CPMP request for supplementary information on 12 February 2001.
- During the meeting on 27 February-01 March the CPMP discussed the applicant's responses to the outstanding issues and considered that an oral explanation was not necessary. The CPMP requested from the applicant a proposal for further clinical development of MabCampath.
- During the meeting on 27-29 March 2001 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 MabCampath on 28 March 2001.