BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Immunomedics B. V., Netherlands, submitted on 31 July 1995 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application to obtain a marketing authorisation in accordance with the Centralised Procedure for the medicinal product LeukoScan (Sulesomab) falling within the scope of Part A of the Annex to Council Regulation EEC No. 2309/93.

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

Rapporteur: Prof. R. Kurth Co-Rapporteur: Dr. D. Jefferys

Licensing status:

LeukoScan has no previous marketing authorisations and no pending, rejected, withdrawn or suspended applications.

2. Steps taken for the assessment of the product

- During the CPMP meeting on 21-22 November 1995, the Rapporteur and Co-rapporteur identified the major concerns in Parts II and III of the dossier.
- The Rapporteur's initial assessment report was circulated to all the members of the CPMP on 12 December 1995.
- The Co-rapporteur's initial assessment report was circulated to all the members of the CPMP on 10 December 1995.
- The Biotechnology Working Party (BWP) during their meeting on 8-9 January 1996 agreed on the draft list of questions on Part II (Biological and pharmaceutical aspects) for finalisation by the CPMP.
- The CPMP during their meeting on 16-18 January 1996, finalised the list of questions to be addressed by the company.
- The CPMP consolidated list of questions was sent to the company on 17 January 1996 (Stop of the clock).
- Inspections of the Immunomedics Inc. Facilities at Newark, NJ, USA took place on 22-24 January 1996, and indicated major deficiencies and failures to comply with Good Manufacturing Practice (GMP) standards. It was also pointed out that the importing company of LeukoScan in the European Economic Area (EEA) has to be determined and a Site Master File should be forwarded the following 3 months.
- Inspections of Pharmacia Inc., Facilities, Albuquerque, USA took place on 25-26 January 1996, and indicated major deficiencies and failures to comply with GMP standards.
- Pharmacia's response to the inspections issues, dated 28 February 1996, was considered inadequate and additional data were requested on 6 March 1996. After reviewing the company's response of. 8 March 1996, the CPMP concluded that the GMP issues have not been resolved and a re-inspection was recommended before the finalisation of the CPMP scientific evaluation. The above conclusion was sent to Pharmacia on 14 March 1996.
- On the basis of Pharmacia's responses dated 29 April 1996 to the Inspector's questions put on 14 March 1996, the outstanding issues have finally been resolved.
- The applicant submitted the responses to the consolidated CPMP list of questions on 19 July 1996 and the clock restarted.

- After a meeting that took place between Rapporteur and Co-Rapporteur on 4 September 1996, the applicant was asked to submit additional details on quality issues.
- The Rapporteur/Co-Rapporteur the responses' assessment report and joint recommendation was circulated to CPMP members on 16 September 1996.
- The inspector confirmed on 3 October 1996 that the remaining GMP issues were solved.
- The Company presented for a hearing at the BWP meeting on 7 October 1996 to discuss outstanding biopharmaceutical points. The BWP prepared a recommendation for the CPMP consideration at their meeting on 15 October 1996.
- The CPMP during its meeting on 15-17 October 1996 on the basis of the favourable benefit-risk assessment issued a positive opinion for granting a marketing authorisation to LeukoScan.