BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company The Liposome Company Ltd. submitted on 1 July 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Evacet, through the centralised procedure. During the procedure the name was changed to Myocet. After agreement by the CPMP on 24 June 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:	Prof. B. Odlind (from 25 March 1999 to 1 December 1999) Dr. P. Nilsson (from 1 December 1999)	Co-Rapporteur:	Prof. R. Gaspar (from 25 March 1999 to 1 January 2000) Prof. Guimarães Morais (from 1 January 2000)

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

- During the meeting on 20-22 April 1999 the CPMP considered the proposed trade name Evacet not acceptable.
- The procedure started on 30 July 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 8 October 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 14 October 1999.
- During the meeting on 16-18 November 1999 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 19 November 1999.
- The applicant submitted the responses to the CPMP consolidated list of questions on 7 February 2000.
- The summary report of the inspection carried out at the manufacturing site between 12-14 January 2000 was issued on 9 February 2000.
- In view of the objection to the trade name Evacet, the applicant proposed the trade name Myocet on 10 March 2000.
- The Rapporteur circulated the response assessment report on the company’s responses to the list of questions to all CPMP Members on 21 March 2000.
- The Applicant submitted on 12 April 2000 a letter of undertaking as requested by the CPMP’ confirming compliance with Follow-up Measures.
- During the meeting on 11-12 April 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 Myocet on 12 April 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 July 2000.