BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Mannheim GmbH, Germany, submitted on 30 June 1995, an application for marketing authorisation to the European Evaluation Medicines Agency (EMEA) for the medicinal product Rapilysin 10 U through the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No. (EC) 2309/93.

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

Rapporteur Prof. D. A. Hildebrandt Co-Rapporteur Dr. Jensen

Licensing Status:

Rapilysin 10 U has been given Marketing Authorisations in the following countries outside the EU:

New Zealand
Norway
Slovakia
Switzerland
USA

2. Steps taken for the assessment of the product

- The Rapporteur's initial Assessment Report was circulated to all CPMP Members on 30 October 1995
- The Co-Rapporteur's initial Assessment Report was circulated to all CPMP Members on 30 October 1995
- The CPMP in its meeting on 19-21 December 1995 agreed on a consolidated list of questions as prepared by the Rapporteur and the Co-Rapporteur
- The company submitted the responses to the CPMP consolidated list of questions on 4 March 1996.
- The Rapporteur circulated the comments on the company's responses to the assessment report to all CPMP Members on 11 April 1996
- The Biotechnology Working Party report was forwarded to the CPMP on 13 May 1996.
- The CPMP during their meeting of 21-23 May 1996 issued a positive opinion for granting a marketing authorisation for Rapilysin 10 U.