BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Ciba Europharm UK submitted on 16 June 1995, to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain a Marketing Authorisation for the medicinal product REVASC (desirudin) in accordance with the Centralised Procedure falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

The CPMP confirmed the status of the Rapporteur and Co-Rapporteur, were as follows:

Rapporteur: Dr. David Lyons Co-Rapporteur: Dr. David Jefferys

The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 11 July 1995.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 9 October 1995.
- The Co-rapporteur's first assessment report was circulated to all CPMP Members on 9 October 1995.
- During the plenary meeting on 21-22 November 1995, the CPMP adopted a revised timetable.
- During the CPMP plenary meeting on 20 December 1995, 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 21 December 1995.
- In March 1996, following the manufacturing issues identified after the inspection, the CPMP decided that the answers and response assessment report should be reviewed in conjunction with the next inspection.
- The Company submitted the responses to the consolidated list of questions on 29 March 1996.
- The Rapporteur circulated the response assessment report on the Company's answers to the list of questions to all CPMP Members on 14 May 1996.
- The Co-rapporteur circulated the response assessment report on the Company's answers to the list of questions to all CPMP Members on 29 May 1996.
- During the June 1996 meeting, the CPMP identified the remaining clinical issues to be clarified by the company during the oral presentation held at the September CPMP meeting.
- The CPMP in their meeting in July 1996, requested additional quality data and clarifications from the Company.
- An oral presentation on the outstanding clinical issues took place during the September 1996 CPMP meeting with respect to the indication, the suitability of the dose according to body weight and the duration of use of Revasc.
- The company provided additional pharmaceutical information on 24 September 1996.
- The (Co)-Rapporteur's joint assessment report was circulated on 24th October 1996 and indicated that the outstanding pharmaceutical queries, including the 5 critical issues, had been satisfactorily resolved.

- The Rapporteur informed the CPMP at its meeting on November 1996, that the applicant could not manufacture a sterile product at the manufacturing site stated in the dossier. Therefore, Ciba-Geigy proposed to move the site of manufacture from Ciba, Switzerland to Dr. Madaus in Germany.
- At the December 1996 meeting of the CPMP, a status report on the proposed manufacturing sites for the active ingredient and the finished product was discussed together with the timing of the inspection, which was planned for 17th and 18th February 1997.
- In January 1997, the company submitted a revised part IA and part IIB of the dossier. They decided to replace the bovine derived peptone with soya peptone in the fermentation medium used in the production of the active ingredient. Supporting data were provided to the Rapporteur and Co-Rapporteur on 15 January 1997. In addition, a description of the manufacturing process (Part IIB data) was provided for the finished product at the Dr. Madaus site.
- During the January 1997 CPMP meeting, a timetable (CPMP/067/97) for the assessment of this new pharmaceutical data submitted was adopted.
- The joint (Co)-Rapporteur Assessment Report on the updated pharmaceutical part of the dossier was circulated to CPMP members on 3 February 1997.
- The product related inspection at Dr. Madaus took place during 17-18 February 1997. A favourable inspection report was provided on 13/03/97.
- The CPMP during their meeting of 17-20 March 1997 issued a positive opinion for granting a marketing authorisation to Revasc on 19 March 1997.