I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novo Nordisk A/S, Denmark submitted on 14 August 1998 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 NovoRapid (insulin aspart) falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93.

The CPMP appointed the Rapporteur and Co-Rapporteur as follows:

Rapporteur:	Dr. Per Sjöberg	Co-Rapporteur:	Dr. Gorm Jensen

Licensing status:

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 18 September 1998.
- The Rapporteur's first assessment report was circulated to all members of the CPMP on 27 November 1998.
- The Co-Rapporteur's first assessment report was circulated to all members of the CPMP on 1 December 1998.
- During its meeting on 26-28 January 1999, the CPMP agreed on the consolidated list of questions to be sent to the applicant on 27 January 1999.
- The applicant submitted the responses to the consolidated list of questions on 10 February 1999.
- During its meeting on 23-25 March 1999, the CPMP agreed on a list of questions to be addressed by an expert meeting on preclinical issues of insulin aspart.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the applicant's responses to the list of questions to all CPMP members on 7 April 1999.
- The expert meeting on preclinical issues was held on 19 April 1999.
- During its meeting on 20-22 April 1999, the CPMP agreed on a list of outstanding quality issues to be addressed by the company in writing.
- The applicant submitted the responses to the outstanding issues on 22 April 1999.
- A report from the Expert meeting on preclinical issues of insulin aspart was circulated to all CPMP members on 12 May 1999.
- The Rapporteur circulated a further assessment report, taking into account the company's responses on the outstanding quality issues, to all CPMP members on 12 May 1999.
- The applicant agreed to submit additional information regarding clinical data within the defined timeframe as indicated in the letter annexed to this assessment report, dated 19 May 1999.
- During the meeting on 18-20 May 1999 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 for the different NovoRapid presentations on 20 May 1999.