BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novo Nordisk A/S, Denmark submitted on 2 September 1999 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 NovoMix 30 (insulin aspart) falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93.

NovoMix 30 is a mixture of 30% soluble insulin aspart and 70% insulin aspart protamine crystals.

On 7 September 1999, a Community Marketing Authorisation has been granted for 100% soluble insulin aspart, named NovoRapid (EU/1/99/119/001-008). In order to avoid misleading information on the release profile of the mixture, the applicant wishes to market the mixture under a different name ("NovoMix 30" instead of "NovoRapid"). On this basis, a separate full application in accordance with Directive 65/65/EEC, as described in the Notice to Applicants, was submitted.

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

Rapporteur:	Dr. Per Sjöberg Dr. Per Nilsson	Co-Rapporteur:	Dr. Gorm Jensen Dr. Mark Ainsworth

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 24 September 1999.
- The Rapporteur's first assessment report was circulated to all members of the CPMP on 30 November 1999.
- The Co-Rapporteur's first assessment report was circulated to all members of the CPMP on 2 December 1999.
- During its meeting on 18-20 January 2000, the CPMP agreed on the consolidated list of questions to be sent to the applicant on 18 January 2000.
- The applicant submitted the responses to the consolidated list of questions on 8 February 2000.
- 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 10 March 2000.
- During the meeting on 11-13 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 for the different NovoMix 30 presentations on 13 April 2000.