BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novo Nordisk A/S submitted on 16 June 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for NovoNorm, through the centralised procedure. After agreement by the CPMP on 20 March 1997, this medicinal product was referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

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

Rapporteur: W. van der Giesen Co-Rapporteur: J. Genoux-Hames

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

- The procedure started on 25 July 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 2 October 1997. The Co-rapporteur's first assessment report was circulated to all CPMP Members on 1 October 1997.
- During the meeting on 17-19 November 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 November 1997.
- The company submitted the responses to the consolidated list of questions on 12 January 1998.
- The Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 27 February 1997.
- The company submitted further response to issues related to cardiovascular safety on 23 February and 2 April 1998.
- During the CPMP meeting on 20 April 1998, outstanding issues were addressed by the applicant during a hearing before the CPMP.
- During the meeting on 21-23 April 1998 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 NovoNorm on 22 April 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decisions on 17 August 1998.