BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novo Nordisk A/S submitted on 2 June 2000 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Prandin, through the centralised procedure.

This submission concerns an abridged application for three strengths of Prandin tablets 0.5 mg, 1 mg and 2 mg. This application has been in accordance with Chapter II, Article 4.8.a. (i) of Council Directive 65/65/EEC of 26 January 1995, as amended. The Marketing Authorisation Holder of NovoNorm tablets, Novo Nordisk A/S, Denmark, consented to the pharmacological, toxicological and clinial data contained in the original file of NoveNorm to be used in the purpose of this application.

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

Rapporteur: Dr S. Bronswijk Co-Rapporteur: Pharm J. Genoux-Hames

Licensing status:

This product was not licensed in the European Union at the time of submission of the application. However, an essentially similar product, under the name of NovoNorm, was authorised in the EU through the centralised procedure on 17 August 1998.

2. Steps taken for the assessment of the product

- The procedure started on 20 June 2000.
- The Rapporteur and Co-Rapporteur's joint assessment report was circulated to all CPMP Members on 14 August 2000.
- During the meeting on 19-21 September 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 to Prandin on 21 September 2000.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 29 January 2001.