I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novo Nordisk A/S submitted on 7 November 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Levemir, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended.

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

Rapporteur: Dr. M. Ainsworth
Co-Rapporteur: Dr F. Lekkerkerker

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 18 November 2002.
- The Rapporteur's and Co-Rapporteur's first Assessment Reports were circulated to all CPMP members on 31 January 2003.
- During the meeting on 18-20 March 2003 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 21 March 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 13 May 2003
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 23 June 2003.
- During the CPMP meeting on 22-24 July 2003, the CPMP agreed on a list of outstanding issues to be addressed in an oral explanation and/or in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CPMP members on 3 December 2003.
- During the CPMP meeting on 16-17 December 2003, the CPMP agreed on a list of outstanding issues to be addressed in an oral explanation and/or in writing by the applicant.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CPMP members on 4 February 2004.
- During the CPMP meeting on 25 February 2004, outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- During the meeting on 24-26 February 2004, 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 Levemir on 26 February 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 26 February 2004.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 1 June 2004.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. Manufacturing Authorisation Holder

Manufacturer of the active substance

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsvaerd
Denmark

Manufacturer of the finished product

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsvaerd
Denmark

Manufacturer responsible for import and batch release in the European Economic Area

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsvaerd
Denmark

Manufacturing authorisation issued on October 2002 by the Danish Medicines Agency.

2. Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

3. Specific obligations of the Marketing Authorisation Holder

As requested by the CPMP, the Applicant agreed to address a number of follow-up measures within an agreed timeframe.