BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Novo Nordisk A/S submitted on 4 June 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Actraphane, 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.

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

Rapporteur: M. Ainsworth Co-Rapporteur: P. Nilsson

Licensing status:

At the time of submission of the application for Marketing Authorisation, Actraphane had been given a Marketing Authorisation in the majority of EU Member States under Mutual Recognition or National Procedures:

2. Steps taken for the assessment of the product

- The procedure started on 19 June 2001
- The Rapporteur's first Assessment Report was circulated to all CPMP Members on 7 September 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP Members on 7 September 2001
- During the meeting on 16-18 October 2001 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 18 October 2001.
- The company submitted the responses to the consolidated List of Questions on 18 January 2002
- The Rapporteur and the Co-Rapporteur circulated the Joint Assessment Report on the company's responses to the List of Questions to all CPMP members on 22 February 2002
- During the meeting on 19-21 March 2002 the CPMP agreed on a list of outstanding issues.
- The company submitted additional information on 25 March 2002.
- The Rapporteur and the Co-Rapporteur circulated the response Assessment Report on the company's additional information on 15 April 2002.
- During the meeting on 23-25 April 2002 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 Actraphane on 25 April 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 7 October 2002.