BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Aventis Pharma Deutschland GmbH submitted on 6 September 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Optisulin, 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.

Previously the company had submitted on 29 March 1999 an application for a MA for Lantus, which is identical in every respect to Optisulin.

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

Rapporteur: Dr. Hans van Bronswijk Co-Rapporteur: Dr. Per Nilsson

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 at the September 1999 CPMP meeting
- Since Optisulin and Lantus are identical medicinal products the same consolidated list of questions as for Lantus was adopted for Optisulin during the CPMP meeting on 21-23 September 1999. The final consolidated list of questions was sent to the company on 24 September 1999.
- The company submitted the responses to the consolidated list of questions on 28 October 1999.
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 22 December 1999.
- During the meeting on 15-17 February 2000, the company gave an oral explanation of outstanding issues relating to toxico-pharmacological and clinical aspects.
- During the meeting on 15-17 February 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 Optisulin on 17 February 2000.