BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Mannheim GmbH. submitted on 10 October 1995 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for NeoRecormon, 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 CPMP were:

Rapporteur: A.G. Hildebrandt Co-Rapporteur: J.H. Trouvin

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 1 November 1995.
- The Rapporteur's initial assessment report was circulated to all CPMP Members on 15 February 1996. The Co-Rapporteur's assessment report was circulated to all CPMP Members on 15 February 1996.
- The CPMP consolidated list of questions was sent to the company on 15 March 1996 and the clock was stopped.
- The company submitted the responses to the CPMP consolidated list of questions on 1 August 1996 and the clock was restarted.
- The Rapporteur's and Co-Rapporteur's assessment reports to the company's responses was circulated to all CPMP members on 15 September 1996.
- A hearing with the company took place on 15 October 1996, to address the final outstanding issues.
- Amendments were made accordingly to the Summary of Product Characteristics and Package Leaflet texts.
- In the light of the overall data submitted and the scientific discussion within the Committee, the CPMP issued a positive opinion for granting a marketing authorisation for the 14 different presentations of NeoRecormon on 16 October 1996.
- The CPMP Opinions were forwarded in all official languages of the EU to the European Commission, which adopted the corresponding Decisions on 16 July 1997.