BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Centocor B.V. submitted on 5 March 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Remicade, 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: Dr. P. Sjöberg Co-Rapporteur: Dr. M. Haase

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 27 March 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 8 June 1998. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 3 June 1998.
- During the meeting on 21 July 1998 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 22 July 1998.
- The company submitted the responses to the consolidated list of questions on 30 November 1998.
- The Rapporteur/Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 25 January 1999.
- The CPMP during their meeting on 24 February 1999 discussed the joint assessment report and decided to stop the clock for an oral presentation on clinical issues in March. A list of outstanding clinical and quality issues was adopted by the CPMP.
- Oral explanations were given by the Applicant on 23 March 1999. The CPMP decided to convene an expert group to address specific clinical points (ANNEX 4.6). Supplementary information with reference to ongoing studies on safety and post-marketing data on efficacy was requested from the applicant.
- The BWP during their meeting on 11 May 1999 prepared a recommendation to the CPMP on the outstanding quality aspects.
- An ad-hoc experts group meeting took place on 17 May 1999 to address open clinical issues on Remicade. The group prepared a recommendation to the CPMP on these issues.
- During the meeting on 18-20 May 1999 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 Remicade on 19 May 1999.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 August 1999.