I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Wyeth Europa Ltd. submitted on 13 October 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Enbrel, 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. D. Jefferys Co-Rapporteur: Prof. F. de Andrés Trelles

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 20 November 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 28 January 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 3 February 1999.
- The CPMP at its meeting of 23-25 February 1999 decided that there was no need for a GMP inspection of the manufacturing sites of Enbrel.
- During the meeting on 22-24 March 1999 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 25 March 1999.
- The company submitted the responses to the CPMP consolidated list of questions on 8 June 1999.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 16 August 1999.
- During the CPMP meeting on 21 – 23 September 1999, the CPMP issued a list of outstanding questions to be addressed by the applicant during an oral explanation.
- The applicant submitted to the EMEA and the CPMP members on 8 October 1999 background documentation for the oral explanation.
- During the CPMP meeting of 19 – 21 October 1999 outstanding issues were addressed by the applicant during an oral explanation before the CPMP.
- During the meeting on 19 – 21 October 1999 the CPMP requested the company to submit information on the use of Enbrel in the indication 'Juvenile Chronic Arthritis'.
- The applicant submitted to the EMEA, Rapporteur and Co-rapporteur and CPMP members the clinical data on the use of Enbrel in the indication : Juvenile Chronic Arthritis (JCA) on 21 October 1999.
- The Rapporteur circulated (after consultation of the Co-Rapporteur) an additional assessment report on the JCA data to all CPMP Members on 5 November 1999.
- During the meeting on 16 – 18 November 1999, 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 Enbrel on 18 November 1999.