BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Amgen Europe B.V. submitted on 17 December 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Aranesp, 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: Prof. R. Bass Co-Rapporteur: Dr. D. Brasseur

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 21 January 2000.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 3 April 2000. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 4 April 2000.
- The CPMP at its meeting of 11-13 April 2000 decided that there was a need for a GMP inspection of the active substance manufacturing site. An inspection of three contract laboratories (Rockville, MD; Malvern, PA; Camden, New Jersey) was also requested.
- During the meeting on 23-24 May 2000 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 May 2000.
- The company submitted the responses to the CPMP consolidated list of questions on 12 October 2000.
- The company submitted on 22 November 2000 Certificates of suitability from the European Pharmacopoeia for two of the suppliers of the Foetal bovine serum used during the manufacture of Aranesp.
- The Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 24 November 2000.
- During the CPMP meeting on 12-14 December 2000, 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 January 2001 responses to the outstanding quality questions from the response assessment report.
- The Rapporteur circulated an Amendment to the Response Assessment Report on Part II to all CPMP members on 10 January 2001.
- During the BWP meeting of 16-17 January 2001, all outstanding quality issues were discussed. The BWP prepared a Recommendation to the CPMP.

- The applicant submitted to the EMEA and the CPMP members on 10 and 16 January 2001 background documentation for the oral explanation.

- The Rapporteur and Co-Rapporteur circulated an Amendment to the Joint Assessment Report on 19 January 2001.

- During the CPMP meeting of 23-25 January 2001, the outstanding issues were addressed by the applicant during an oral explanation before the CPMP.

- During the meeting on 27 February – 1 March 2001, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting Marketing Authorisations to Aranesp on 1 March 2001.

- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 8 June 2001.