BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Amgen Europe B.V. submitted on 7 May 2001 applications for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Neulasta, 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: Dr. F. Rotblat Co-Rapporteur: Dr. B. van Zwieten-Boot

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 22 May 2001.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 30 July 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 2 August 2001.
- During the meeting on 18-20 September 2001 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 20 September 2001.
- During the meeting on 18-20 September 2001 the CPMP agreed that there was no need for an inspection of the manufacturing sites for Pegfilgrastrim.
- The company submitted the responses to the CPMP consolidated List of Questions on 18 March 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 25 April 2002.
- The company submitted answers to outstanding quality questions on 16 May 2002. The Rapporteur circulated an Addendum to the Response Assessment Report to all CPMP members on 17 May 2002.
- During the meeting on 28 – 30 May 2002 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 Neulasta on 30 May 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 August 2002.