BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant, Roche Registration Limited, submitted on 23 September 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Fuzeon (enfuvirtide), through the centralised procedure. After agreement by the CPMP on 21 February 2002, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Dr Per Nilsson Co-Rapporteur: Prof Beatrix Silva-Lima

Scientific Advice:
The applicant received Scientific Advice from the CPMP on 25 May 2000, 16 November 2000 and 15 December 2000. The Scientific Advice pertained to part II, III and IV of the dossier.

Licensing status:
The product was not licensed in any country at the time of submission of the application. Fuzeon was licensed in the United States on 13 March 2003.

2. Steps taken for the assessment of the product

- The applicant submitted to the CPMP a request for an accelerated procedure dated 11 July 2002 according to the CPMP guidance on "accelerated evaluation of products indicated for serious diseases (life-threatening or heavy disabling diseases), CPMP/495/96" rev.1 dated 18 September 2001. The CPMP, during its 23-25 July 2002 meeting, agreed to consider the possibility to adopt rapidly an opinion based on the recommendation of the Rapporteur and Co-rapporteur in their respective Assessment Reports.
- The procedure started on 21 October 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 27 December 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 7 January 2003.
- During the meeting on 18-20 February 2003, the CPMP agreed to accelerate the procedure and adopted a consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 20 February 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 27 February 2003.
- The Rapporteurs circulated an Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 7 March 2003.
- The Rapporteurs circulated an updated Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 14 March 2003.
- During the CPMP meeting on 18-19 March 2003, the CPMP agreed on a list of outstanding issues which were addressed by the applicant during a hearing before the CPMP held on 19 March 2003.
- 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 under exceptional circumstances to Fuzeon on 19 March 2003. The applicant provided on 19 March 2003 a letter of undertaking on the Specific Obligations and Follow-up measures to be fulfilled post-authorisation.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 27 May 2003.