BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Amgen Europe B.V submitted on 10 October 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Parareg, through the centralised procedure. After agreement by the CHMP on 1 May 2003, 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 CHMP were:

Rapporteur: Dr. Per Nilsson Co-Rapporteur: Dr. Josef Suko

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

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 October 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 9 January 2004 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 6 January 2004.
- During the meeting on 24-26 February 2004, the CHMP 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 26 February 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 14 May 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 24 June 2004.
- During the meeting on 27-29 July 2004, the CHMP, 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 Parareg on 29 July 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 28 July 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 22 October 2004.

Medicinal product no longer authorised

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