I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Janssen-Cilag International N.V. submitted on 22 October 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA), in accordance with the Centralised Procedure falling within the scope of Part A of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993, as amended.

The Rapporteur and Co-Rapporteur appointed by the CPMP and the evaluation teams were:

Rapporteur: Dr. D. Jefferys Co-Rapporteur: Prof. J-H. Trouvin

Licensing status

Regranex has been given a marketing authorisation in the following countries:

USA	16 December 1997
Israel	29 October 1998
Mexico	29 October 1998
Singapore	9 December 1998
Brazil	21 December 1998
Canada	30 December 1998
Argentina	30 December 1998

A new drug application was filed in the following countries: South Africa, South Korea, Australia, Switzerland, Russia, Thailand, New Zealand and PR China.

2. Steps taken for the assessment of the product

- The procedure started on 21 November 1997.
- During its meeting on 16-17 December 1997, the CPMP decided that a GMP inspection of the manufacturing facilities for the active ingredient and packaging is necessary.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 4 February 1998. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 2 February 1998.
- During its meeting on 23-26 March 1998, 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 26 March 1998.
- On 27 May 1998 a meeting took place between Rapporteur, Co-Rapporteur and Company.
- The company submitted the responses to the consolidated list of questions on 25 August 1998.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 26 October 1998.
- During its meeting on 17-19 November 1998, the CPMP agreed on a list of outstanding issues (pharmaceutical and clinical aspects) to be addressed by the company in an oral explanation. The clock was stopped in order to allow the applicant to prepare for the oral explanation scheduled during the December CPMP meeting.
- The applicant submitted on 2 December 1998 responses to the outstanding issues which were identified in the list of outstanding issues adopted during the CPMP meeting of 17-19 November 1998.
- An assessment of the response to the outstanding issues, clinical aspects was circulated to the CPMP members on 10 December 1998.
- An assessment of the response to the outstanding issues, pharmaceutical aspects was circulated to the CPMP members on 10 December 1998.

- An oral presentation was held at the CPMP meeting on 16 December 1998, to address the remaining outstanding issues.
- The CPMP, during their meeting on 15-17 December 1998, considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The applicant (Janssen-Cilag International N.V.) provided a letter of undertaking on the commitments to be fulfilled as requested by the CPMP, dated 16 December 1998.
- During the meeting on 15-17 December 1998 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 for Regranex on 17 December 1998**.**
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decisions on 29 March 1999.