

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Genetics Institute of Europe B.V., Germany, submitted on 6 February 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for ReFacto, through the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No. (EC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. G. Jensen

Co-Rapporteur: Dr. van der Giesen

Licensing status:

A new drug application was filed in the following countries: USA, Switzerland and Canada.

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 February 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 13 May 1998. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 4 May 1998.
- During the meeting on 23 June 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 25 June 1998.
- The company submitted the responses to the consolidated list of questions on 28 August 1998.
- The Rapporteur and the Co-Rapporteur circulated the joint assessment report on the company's responses to the list of questions to all CPMP Members on 19 October 1998.
- During the meeting of 17-19 November 1998, the CPMP adopted a list of outstanding pharmaceutical issues to be addressed by the company prior to the opinion and additional issues to be addressed on a post-opinion basis. The list of outstanding issues adopted by the CPMP was sent to the company on 17 November 1998.
- The applicant at the December BWP meeting gave an oral presentation of the results of new virus validation studies performed. The BWP on 9 December 1998 adopted a recommendation to the CPMP in their meeting in December.
- During the meeting of 15-17 December 1998, the CPMP discussed the recommendations presented by the Rapporteur and considered satisfactory the responses submitted by the company.
- The Company signed a letter of undertaking regarding the follow-up measures on 15 December 1998
- During the meeting of 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 to ReFacto on 17 December 1998.