BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company, Genetics Institute of Europe B.V., submitted on 16 August 1996 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for BeneFIX, 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.

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

Rapporteur: R. Kurth, M. Haase (from Jan 98) Co-Rapporteur: J.H. Trouvin

Licensing status:
BeneFIX has received a marketing authorisation in the United States of America in February 1997, in Canada in March 1997, and in Switzerland in February 1998.

2. Steps taken for the assessment of the product

- The procedure started on 23 September 1996.
- The Rapporteur's initial assessment report was circulated to all CPMP Members on 25 November 96. The Co-Rapporteur's initial assessment report was circulated to all CPMP Members on 27 November 96.
- The draft-consolidated list of questions was circulated to all CPMP members on 16 January 1997.
- During the meeting on 21-23 January 97 the CPMP agreed the consolidated list of questions to be sent to the company on 21 January 97.
- The Rapporteur circulated samples pre-authorisation testing report on 20 January 1997.
- The final consolidated list of questions was sent to the company on 21 January 97.
- The company submitted the responses to the consolidated list of questions on 19 March 1997.
- The Rapporteur and Co-Rapporteur circulated the comments on the company's responses to the list of questions to all CPMP Members on 10 April 1997.
- The CPMP, during its meeting on 13-15 May 1997 discussed the recommendations presented by the Rapporteur and considered that the responses provided by the company were satisfactory. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts, particularly with reference to restriction of indication to the previously treated patients, to the adjustments of the dose and to the information on the development of inhibitors to BeneFIX.
- During the meeting on 14 May 1997 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 BeneFIX under exceptional circumstances.

  Pursuant to article 13 (2) of Council Regulation (EEC) No 2309/93 and Part 4 G of the Annex to Council Directive 75/318/EEC, the applicant agreed to provide final reports of the on-going clinical studies within a specific timeframe. These data will form the basis of a re-assessment of the benefit/risk ratio of BeneFIX.

  In addition, the applicant agreed also to submit to the EMEA, within the defined timeframe, further information requested by the CPMP on chemical, pharmaceutical, biological and complementary clinical data.

- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission that adopted the corresponding Decisions on 27 August 1997.