BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Genzyme B.V., the Netherlands submitted on 30 June 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Renagel, through the centralised procedure. After agreement by the CPMP on 22-24 September 1997, this medicinal product is referred to Part B of the Annex to Council Regulation No. (EC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. M. Toivonen Co-Rapporteur: Dr. D. Brasseur

Licensing status:

A New Drug Application was filed in the United States of America in October 1997 and approved in October 1998. A New Drug Application filed in Israel was approved in September 1999.

2. Steps taken for the assessment of the product

- The procedure started on 24 July 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 30 September 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 7 October 1998.
- During its meeting on 17-19 November 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 19 November 1998.
- The company submitted the responses to the consolidated list of questions on 10 June 1999.
- 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 16 August 1999.
- The company submitted supplementary information on 10 September 1999.
- On 13 September 1999, the CPMP adopted a list of outstanding pharmaceutical and clinical issues to be addressed by the company in writing and in an oral explanation.
- The Rapporteur and the Co-Rapporteur circulated a further joint response assessment report, taking into account the company's responses on the outstanding issues, to all CPMP Members on 17 September 1999.
- A hearing was held at the CPMP meeting on 21 September 1999, to address the remaining outstanding clinical issues.
- The CPMP, during their meeting on 21-23 September 1999, 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.
- During the meeting on 21-23 September 1999 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion by consensus for granting a Marketing Authorisation for Renagel under exceptional circumstances on 23 September 1999.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 28 January 2000.