BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Genzyme B.V. submitted on 1 December 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Thyrogen, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. M. Teeling Co-Rapporteur: Prof. A. Hildebrandt

Licensing status:

A new drug application has been submitted in the USA (Dec. 1997), authorisation has been granted on 30 November 1998.
Thyrogen was granted orphan drug status in the USA.

2. Steps taken for the assessment of the product

- The procedure started on 19 December 1997
- The Rapporteur's first assessment report was circulated to all CPMP Members on 27 February 1998. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 27 February 1998.
- Comments on points not covered by the Assessment report were due on 30 March 1998.
- The Rapporteur circulated a draft-consolidated list of questions on 9 April 1998.
- During the meeting on 21 April 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 23 April 1998.
- A GMP inspection of the manufacturing site for the active ingredient at Framingham was conducted on 26-29 May 1998. Contract laboratories for testing of the bioreactor harvest material were inspected on 1 June 1998, 3 June 1998 and 4 June 1998.
- The Company submitted the responses to the consolidated list of questions on 17 July 1998, and, as these were considered incomplete, submitted a full package of responses on 16 October 1998.
- The joint assessment report on the company's responses to the list of questions was circulated to all CPMP Members on 20 November 1998.
- The Company provided additional information on 29 January 1999.
- A discussion on the additional information was held at the BWP on 17 February 1999.
- The CPMP, during its meeting on 23-25 February 1999, followed the recommendation of the BWP by adopting a list of outstanding points and proposed on-going pharmaceutical commitments to be addressed by the Company. The CPMP agreed to an exceptional clock-stop requested by the Company to address the outstanding points.
- The manufacturing site at Allston Landing (USA) was inspected on 25 March 1999 to address an outstanding Quality Assurance issue.
- The Company submitted the responses to the outstanding points on 1 June 1999.

- The CPMP, during its meeting on 27-30 July 1999, discussed the recommendations presented by the Rapporteurs, considering the responses provided by the Company were satisfactory. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- During the meeting on 27-30 July 1999 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 Thyrogen.
- The CPMP wrote to the European Commission on 23 September 1999, informing the Commission that by end of August 1999 the Applicant had not fullfilled its commitment to submit important information relating to the quality of the medicinal product. The CPMP emphasised that the requested information needed to be reviewed before a Marketing Authorisation could be granted.
- In a letter dated 26 October 1999, the Commission informed the EMEA that the decision making process had been suspended and requested the CPMP to evaluate whether there were new questions of a scientific or technical nature,which had to be addressed in the Opinion of the Agency. In the meantime, the Applicant submitted the missing scientific data on 18 October 1999.
- The CPMP during its meeting of 14-16 December 1999 assessed the additional information and issued a positive opinion for granting a marketing authorisation to Thyrogen.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 9 March 2000..