BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Genzyme B.V. submitted on 6 January 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Cerezyme, 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. H. van Bronswijk Co-Rapporteur: Dr. D. Lyons

Licensing status:

Cerezyme has been given a Marketing Authorisation in in the United States on 23 May 1994 for the 160 litre manufacturing scale, followed by approvals of a supplement for the 320 litre manufacturing scale on 31 May 1996 and the 2000 litre manufacturing scale on 22 October 1996.

Cerezyme manufactured at the 2000 litre manufacturing scale has been given a marketing authorisation in Israel on 29 December 1996 and in Canada on 12 February 1997.

2. Steps taken for the assessment of the product

- The procedure started on 24 January 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 7 March 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 10 March 1997.
- During the meeting on 15 April 1997 the CPMP adopted a draft-consolidated list of questions and circulated it for comments by 15 April 1997.
- During the meeting on 16 April 1997 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 16 April 1997.
- On 14-18 April 1997 an inspection of the active substance manufacture and of the drug product manufacture took place at Allston, Massachusetts (USA). The Authority responsible for the inspection was the Medicines Control Agency (UK). The final Inspection Report on Cerezyme active substance manufacture was issued on 6 June 1997.
- The company submitted the responses to the consolidated list of questions on 7 May 1997.
- The Rapporteur and Co-Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 13 June 1997.
- During the meeting on 21 July 1997 the CPMP discussed the recommendations presented by the Rapporteur, considering the responses provided by the company were satisfactory. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts in order to ensure consistency among the two texts. Principal modifications consist in the addition of a sentence in section 4.1 of the SPC (Therapy should be directed by physicians knowledgeable in the management of Gaucher disease) and deletion, in section 4.4, of a warning on impairment of fertility (applicable to Ceredase, but not to Cerezyme).
- During the meeting on 23 July 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 Cerezyme on 23 July 1997.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 November 1997.