BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Genzyme B.V. submitted on 5 July 2000 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Fabrazyme, 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. P. Kurki

Scientific Advice:

The applicant did not seek Scientific Advice at the CPMP.

Licensing status:

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 18 July 2000.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 28 September 2000 . The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 26 September 2000.
- During the meeting on 14-16 November 2000 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 16 November 2000.
- The company submitted the responses to the CPMP consolidated List of Questions on 11 December 2000.
- The Rapporteur circulated the joint response Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 23 January 2001.
- During the meeting on 27 February – 1 March 2001, the CPMP agreed on a list of outstanding issues to be addressed by the applicant in writing and if necessary during an oral explanation. The list of outstanding issues was sent to the applicant on 28 February 2001.
- The applicant provided written information on these outstanding issues to all CPMP members on 13 March 2001. The joint Rapporteur/Co-rapporteur assessment report on the written responses to the list of outstanding issues was circulated to all CPMP members on 21 March 2001.
- During the CPMP meeting on 27-29 March 2001, post-authorisation commitments were clarified by the applicant before the CPMP.
- During the meeting on 27 – 29 March 2001 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 Fabrazyme on 29 March 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 3 August 2001.