BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Registration Ltd. submitted on 4 September 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Zenapax, 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. David Lyons Co-Rapporteur: Dr. Per Sjoberg

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 26 September 1997.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 5 December 1997.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 8 December 1997.
- During the CPMP plenary meeting on 28 January 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 29 January 1998.
- The company submitted the responses to the consolidated list of questions on 1 June 1998.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CPMP Members on 28 August 1998. The Co-Rapporteur circulated the responses assessment report on the company's responses to the list of questions to all CPMP Members on 28 August 1998.
- The applicant provided explanatory information on the quality issues during the October BWP. The applicant also provided written explanations at the October CPMP meeting in preparation of the oral presentation on the clinical issue. The CPMP considered that the responses of the applicant on the clinical issue were satisfactory and that the oral explanation was not needed. A timetable was then adopted for the assessment of the information on the outstanding quality issues.
- The CPMP, during their meeting on 17 November 1998 discussed the recommendations presented by the Rapporteur, considering the responses provided by the company were satisfactory. Prior to the scheduled hearing a pre-meeting with the applicant and CPMP experts took place on 17 November 1998. A number of the issues were then clarified and the follow-up measures were agreed. Therefore, the oral explanation at the CPMP was not needed anymore. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The CPMP during their meeting of 18 November 1998 issued a positive opinion for granting a marketing authorisation to Zenapax.
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 26 February 1999.

Medicinal product no longer authorised

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