BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Roche Registration Ltd. submitted on 31 May 1996 to the European Agency for the Evaluation of Medicinal Products (EMEA), an application to obtain Marketing Authorisation for the medicinal product Tasmar tablets 100 and 200 mg in accordance with the Centralised Procedure falling within the scope of 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. D. Lyons

Co-Rapporteur: Dr. P. Sjöberg

Licensing status

The product was not licensed in any country inside or outside the EU at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 18 June 1996.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 15 August 1996. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 23 August 1996.
- During the July 1996 CPMP meeting, it was agreed to perform a GMP inspection on the Swiss manufacturing facilities for the finished medicinal product.
- During the CPMP plenary meeting on 14-17 October 1996, 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 17 October 1996.
- The company submitted the responses to the consolidated list of questions on 18 December 1996.
- The Rapporteur/Co-Rapporteur circulated the joint assessment report on the company's responses to the list of questions to all CPMP Members on 17 January 1997.
- A hearing was held on 18 February 1997, at the CPMP meeting to address the remaining outstanding issues (nephrotoxicity in rats, diarrhoea, increasing dyskinesia, patients with fluctuating disease, safety and efficacy in non-fluctuating disease). This resulted in amendments of the Summary of Product Characteristics, Package Leaflet and Labelling.
- The Co-Rapporteur, on 06 March 1997 gave his position on the use of Tasmar in non-fluctuating Parkinson's disease patients.
- During its meeting on 17-19 March 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 on the Indications and Package Leaflet texts.
- The CPMP issued a positive opinion for granting a Marketing Authorisation to TASMAR 100 mg and 200 mg film coated tablets, on 19 March 1997.