BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd., UK submitted on 8 July 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Prometax hard capsules, through the centralised procedure.

This submission concerns an abridged application for four strengths of Prometax hard capsules, 1.5 mg, 3 mg, 4.5 mg, 6 mg. The application has been made in accordance with Chapter II, Article 4.8(a)(i) of Council Directive 65/65/EEC of 26 January 1995 as amended. The marketing authorisation holder of Exelon hard capsules, Novartis Europharm Limited, UK, consented to the pharmacological, toxicological and clinical data contained in the original file for Exelon to be used for the purpose of examining this application.

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

Rapporteur: Dr. E. Abadie Co-Rapporteur: Dr. P. Sjöberg

Licensing status

The product, under the trade name Exelon, was authorised in the EU through the centralised procedure on 12 May 1998.

2. Steps taken for the assessment of the product

- The procedure started on 24 July 1998.
- The Rapporteur's assessment report was circulated to all CPMP Members on 31 August 1998.
- During the meeting on 16-17 September 1998 the CPMP, in the light of the overall data submitted and the discussion within the Committee, issued a positive opinion (majority) for granting a Marketing Authorisation for Prometax hard capsules on 16 September 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 4 December 1998.