BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Novartis Europharm Ltd., UK submitted on 1 April 1997 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Exelon hard capsules, through the centralised procedure. After agreement by the CPMP on 18-21 November 1996, this medicinal product is referred to 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:

Rapporteur: Dr. E. Abadie 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 April 1997.
- During the 17-18 June CPMP meeting, a GMP inspection of the manufacturing site in Basel, Switzerland, was agreed upon.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 25 June 1997. The Co-Rapporteur's first assessment report was circulated to all CPMP members on 27 June 1997.
- During its meeting on 22-24 September 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 24 September 1997.
- The company submitted the responses to the consolidated list of questions on 10 November 1997.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP members on 9 December 1997.
- During its meeting on 16-17 December 1997, the CPMP agreed on a list of outstanding issues to be addressed by the company in writing and in an oral explanation.
- The company submitted the responses on the outstanding issues on 7 January 1998.
- The Rapporteur and the Co-Rapporteur circulated a further joint response assessment report, taking into account the company's responses on the outstanding issues, to all CPMP members on 26 January 1998.
- A hearing was held at the CPMP meeting on 27 January 1998, to address the remaining outstanding issues.
- The CPMP, during their meeting on 27-28 January 1998, considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- During the meeting on 27-28 January 1998 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion (majority) for granting a Marketing Authorisation for Exelon hard capsules on 28 January 1998.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decisions on 12 May 1998.