BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company, Eli Lilly Nederland BV, submitted on 22 September 1995 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application to obtain marketing authorisation for the medicinal product Zyprexa (Olanzapine) 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 CHMP were:

Rapporteur: Dr C. Strömberg Co-Rapporteur: Dr P. Le Courtois

2. Steps taken for the assessment of the product

- The procedure started on 9 October 1995.
- The Rapporteur's initial Assessment Report was circulated to all Members of the CPMP on 7 December 1995. The Co-Rapporteur's Assessment Report was circulated to all Members of the CPMP on 14 December 1995.
- The CPMP consolidated list of comments was sent to the company on the 13 February 1996.
- The company submitted the responses to the first consolidated CPMP list of comments on the 8 March 1996.
- The Rapporteur's responses assessment report was circulated to all CPMP Members on 12 April 1996. The Co-Rapporteur's responses assessment report was circulated to all CPMP members on 11 April 1996.
- During the CPMP meeting on 15-17 April 1996 the clarifications given by the company were considered and it was proposed to have a full discussion during the May CPMP meeting and if necessary a hearing with the company.
- During the CPMP meeting on the 20-23 May 1996 a "break-out" session on Olanzapine was held. In this meeting a "list of outstanding issues to be answered by the company" was drafted and sent to the company. The clock was stopped.
- During the May CPMP meeting it was decided to convene an ad hoc expert working group in liaison with the Efficacy Working Party on the treatment of schizophrenia to be held on 6 June 1996 together with a Rapporteur/Co-Rapporteur meeting with the company on 7 June 1996. It was also decided to have a hearing with the company during the CPMP meeting, 18-20 June 1996.
- The expert group made recommendations to the CPMP on the criteria to be considered in the evaluation of antischizophrenia medicines eg. criteria for evaluating negative symptoms, extrapolation of efficacy results, definition of first line treatment.
- The CPMP, after the hearing with the company, discussed the Olanzapine dossier in view of the scientific recommendations put forward by the expert working group. Amendments were made accordingly to the Summary of Product Characteristics and Package Leaflet texts.
- The company, after having been consulted (letter dated 18 June 1996), agreed to submit to the EMEA chemical, pharmaceutical and clinical information requested by the CPMP.
- The CPMP on 19 June 1996 issued a positive Opinion for granting a Marketing Authorisation for Zyprexa.
- The Commission issued a marketing authorisation valid throughout the European Union for Zyprexa on 27 September 1996.