BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Eli Lilly Nederland BV, Netherlands submitted on 22 April 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Zyprexa Velotab, through the centralised procedure.

The Rapporteur appointed by the CPMP was as follows:

Rapporteur: Dr. M Toivonen

Licensing status:

Olanzapine 2.5, 5, 7.5 and 10 mg coated tablets have been registered in the EU since 27 September 1996 as Zyprexa (EU/1/96/022/001-101) and Olansek (EU/1/96/021/001-010).

2. Steps taken for the assessment of the product

- The procedure started on 27 April 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 11 May 1999.
- During its meeting on 22-24 June 1999, 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 June 1999.
- The company submitted the complete responses to the consolidated list of questions on 13 July 1999.
- The Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP Members on 27 August 1999.
- During the CPMP meeting on 23 September 1999, the possible public health issues related to the qualifier in the proposed tradename Zyprexa Zydis were addressed by the applicant during a hearing before the CPMP.
- The applicant provided supplementary information regarding changing the tradename into Zyprexa Velotab on 13 October 1999.
- During the meeting on 19-21 October 1999 the CPMP considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. In the light of the overall data submitted and the scientific discussion within the Committee, the CPMP issued a positive opinion for granting a Marketing Authorisation for Zyprexa Velotab on 21 October 1999.
- The Commission issued a marketing authorisation valid throughout the European Union for Zyprexa Velotab on 3 February 2000.