BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Eli Lilly Netherlands B.V submitted on 7 February 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Yentreve, through the centralised procedure. After agreement by the CHMP on 17-19 September 2002, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr. Calvo Rojas Co-Rapporteur: Dr. Salmonson

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 19 November 1998. The Scientific Advice pertained to clinical aspects of the dossier.

Licensing status:

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 24 February 2003.
- The Rapporteur's first assessment report was circulated to all CHMP Members on 6 May 2003. The Co-Rapporteur's first assessment report was circulated to all CHMP Members on 6 May 2003.
- During the meeting on 24-26 June 2003, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 26 June 2003.
- The company submitted the responses to the consolidated list of questions on 14 November 2003.
- The Rapporteur circulated the response assessment report on the company's responses to the list of questions to all CHMP Members on 23 December 2003.
- During the CHMP meeting on 20-22 January 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP list of outstanding issues on 9 February 2004.
- During the meeting on 23-25 March 2004, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Yentreve on 24 March 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 24 March 2004.
- On 25 May 2004, a case of suicide attempt in a 43 year-old female patient in an open label phase III study was reported. The issue was brought to the attention of the CHMP during its meeting on 1-3 June 2004.
- The Commission, at the request of the EMEA, put the Standing Committee phase on hold pending the outcome of the CHMP discussion regarding the new safety information.

- During the meeting on 22-23 June 204 the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Yentreve on 23 June 2004.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 11 August 2004.