BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Eli Lilly Netherlands B.V. submitted on 10 October 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for CYMBALTA, through the centralised procedure. After agreement by the CHMP on 25 September 2003, 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. Gonzalo Calvo-Rojas Co-Rapporteur: Dr. Tomas Salmonson

Scientific Advice:

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

Licensing status:

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

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 10 October 2003.
- The procedure started on 27 October 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 9 January 2004 . The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 12 January 2004
- During the meeting on 24–26 February 2004, 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 February 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 16 April 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 1 June 2004.
- During the CHMP meeting on 22–23 June 2004, the CHMP agreed on a list of outstanding issues to be addressed in writing by the applicant.
- The applicant submitted the responses in writing to the CHMP list of outstanding issues on 10 August 2004.
- During the meeting on 14-16 September 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 Cymbalta on 16 September 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 15 September 2004.

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