BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Eli Lilly Nederland B.V. submitted on 29 July 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Alimta, through the centralised procedure. After agreement by the CHMP on 14 August 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

The Rapporteur and Co-Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Dr Eric Abadie Co-Rapporteur: Prof Tilman Ott

Scientific Advice:

The applicant received Scientific Advice from the CHMP on 19 October 2000. The Scientific Advice pertained to the clinical aspects of the dossier.

Licensing status:

A new application was filed in the following countries: USA.

1.2 Steps taken for the assessment of the product

- The procedure started on 18 August 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 October 2003. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 30 October 2003
- During the meeting on 16-17 December 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 18 December 2003.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 12 March 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CHMP members on 27 April 2004.
- During the CHMP meeting on 1-3 June 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 8 June 2004.
- The Rapporteurs circulated the updated Joint Assessement Report on the applicant’s responses to the list of outstanding Issues on 11 and 14 June 2004.
- During the meeting on 22-23 June 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 Alimta on 23 June 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 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 20 September 2004.

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