BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Pfizer Limited submitted on 27 February 2003 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Lyrica, through the centralised procedure. After agreement by the CPMP on 20 November 2002, 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 CPMP were:
Rapporteur: B. van Zwieten-Boot Co-Rapporteur: C. Sampaio

Scientific Advice:
The applicant did not seek scientific advice at the CPMP.

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 March 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 6 June 2003 . The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 18 June 2003 .
- During the meeting on 22-24 July 2003, the CPMP 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 25 July 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 14 October 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 21 November 2003.
- During the CPMP meeting on 16-18 December 2003, the CPMP agreed on a list of outstanding issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the CPMP list of outstanding issues on 14 January 2004.
- The Rapporteurs circulated a Joint Assessment Report on the applicant's responses to the List of outstanding issues to all CPMP members on 13 February 2004.
- During the CPMP meeting on 24-26 February 2004, the Committee and the Applicant agreed that there was no need for an Oral Explanation.
- During the meeting on 23-25 March 2004, the CPMP, 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 Lyrica on 25 March 2004.
- The CPMP opinions were forwarded, in all official languages of The European Union, to the European Commission, which adopted corresponding Decision on 6 July 2004.