BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company UCB S.A submitted on 25 January 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Keppra, through the centralised procedure. After agreement by the CPMP on 23-24 June 1998, 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 CPMP were:

Rapporteur: Dr. Brasseur Co-Rapporteur: Dr. Salmonson

Licensing status:

Keppra was given a Marketing Authorisation in the USA on 30 November 1999 and in Switzerland on 29 March 2000.

At the time of submission of the application for Marketing Authorisation, applications had been filed in the following countries: Australia, Argentina, Norway.

2. Steps taken for the assessment of the product

- The procedure started on 26 February 1999.
- Following a request from the Rapporteur a clock-stop for a GLP inspection was agreed by the CPMP on 22 April 1999. The inspection was carried out at one of the preclinical investigation sites in the UK on 19-27 May 1999. On 30 July 1999, after receiving the final UK Inspection Report, the CPMP agreed that the audit issues had not been entirely resolved and requested a further GLP inspection at the site of the preclinical analyses in Belgium. Following the final GLP inspection report, the clock was restarted on 24 September 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 8 October 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 5 October 1999.
- During the meeting on 16-18 November 1999 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 18 November 1999.
- The applicant submitted the responses to the CPMP consolidated list of questions on 28 March 2000 and 19 June 2000.
- The Rapporteur circulated the response assessment report on the applicant’s responses to the list of questions to all CPMP Members on 12 May 2000 and a complementary assessment report on 21 June 2000.
- During the meeting held 27-29 June 2000 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 Keppra on 29 June 2000. The European Commission adopted the corresponding decision on 29 September 2000.