BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Boehringer Ingelheim International GmbH submitted on 4 June 1997 an application for the marketing authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Viramune (nevirapine) 200 mg tablet through the centralised procedure. After agreement by the CPMP on 16 October 1996, this medicinal product is referred to Part B of the Annex of the Council Regulation (EEC) 2309/93, of the 22 July 1993.

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

Rapporteur: Prof. M. Forte Co-Rapporteur: Pharm. G. De Greef

Licensing status:

Viramune is licensed in several non-EU countries including USA in 21 June 1996.

2. Steps taken for the assessment of the product

- The procedure started on 20 June 1997.
- The Rapporteur's assessment report was circulated to all CPMP members on 4 September 1997. The Co-Rapporteur's assessment report was circulated to all CPMP members on 5 September 1997.
- The preliminary Rapporteur's and Co-Rapporteur's overall recommendation on the medicinal product was circulated to all CPMP members on 14 October 1997.
- The applicant provided on 16 October 1997 to all CPMP members, responses on outstanding pharmaceutical and clinical issues.
- On the basis of the responses provided by the company, the final Rapporteur and Co-Rapporteur recommendation was circulated on 20 October 1997.
- A hearing was held on 21 October 1997, during the plenary CPMP meeting, where the company addressed in particularly the therapeutic role of Viramune and the strategy for the inclusion of nevirapine in combination regimens.
- The applicant, as requested by the CPMP, signed a letter of undertaking on the specific obligations and follow-up measures, on 22 October 1997.
- The CPMP, in the light of the overall data submitted and the scientific discussion considered the provisional risk/benefit to be favourable and issued on 22 October 1997 a positive opinion for granting the Marketing Authorisation under exceptional circumstances.
- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding decision on 5 February 1998.