BACKGROUND INFORMATION ON THE PROCEDURE

For procedures finalised after 30 July 2005 please refer to module 8b.

1. Submission of the dossier

The company Glaxo Group Limited, submitted on 30 June 1997 an application for marketing authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Combivir (150 mg lamivudine/300 mg zidovudine) film coated tablet through the centralised procedure. After agreement by the CPMP on 19 March 1997, 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 Co-rapporteur appointed by the CPMP and the evaluation teams were as follows:

Rapporteur: Dr. E. Abadie Co-rapporteur: Prof. A.G. Hildebrandt

Licensing status

Combivir was licensed in the United States on 26 September 1997.

2. Steps taken for the assessment of the product

- The procedure started on 25 July 1997.
- The Rapporteur's assessment report was circulated to all CPMP Members on 1 October 1997. The Co-rapporteur's assessment report was circulated to all CPMP Members on 9 October 1997.
- The company circulated to all CPMP Members additional information on clinical data on 13 November 1997.
- The Co-rapporteur circulated an addendum to the assessment report on the clinical part on 14 November 1997. The Rapporteur circulated an addendum to the assessment report on the pharmaceutical part on 19 November 1997.
- The applicant provided a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP on 19 November 1997.
- The CPMP, in the light of the overall data submitted and the scientific discussion considered the risk/benefit profile to be favourable and issued on 19 November 1997 a positive Opinion for granting the Marketing Authorisation. The respective Commission Decision was issued on 18 March 1998.

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