BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Glaxo Group Ltd submitted on 30 June 1995 an application for Marketing Authorisation to the EMEA for 3TC (later EPIVIR) tablets 150 mg and oral solution 10 mg/ml, through the Centralised procedure. After agreement by the CPMP, this medicinal product was referred to List B status in the Annex of the Council regulation EEC No. 2309/93, indent 7 as it contains a new active substance.

The Rapporteur and the Co-rapporteur appointed by the CPMP were as follows:

Rapporteur: Dr. P. Le Courtois Co-Rapporteur: Prof. A. Hildebrandt

Licensing status:

EPIVIR has been approved in several non-EU countries including:

USA on 17 November 1995, Canada on 11 December 1995, Australia on 29 February 1996

2. Steps taken for the assessment of the product

- The Rapporteur's initial assessment report was circulated to all CPMP Members on 25 September 1995.
- The Co-Rapporteur's initial assessment reports were circulated to all CPMP Members on 25 September 1995.
- During their November 1995 meeting the CPMP agreed on a consolidated list of questions as prepared by the Rapporteur and Co-Rapporteur. The list including comments on the proposed brand name was sent to the company on 24 November 1995, when the clock was stopped.
- A preliminary GCP inspection report, prepared by the French competent authorities, was circulated during the CPMP December 1995 meeting. Questions on the biological database were raised during this inspection. The Rapporteur requested the company to provide an explanation before the clock could be re-started.
- During the CPMP meeting in January 1996, the new proposed brand name for the product was announced: EPIVIR.
- The company submitted their responses to the consolidated list of questions on Parts II and III on 31 January 1996.
- A final GCP inspection report, by the French competent authorities, was circulated on 20 February 1996.
- The company submitted their responses to the consolidated list of questions on Parts I and IV on 7 March 1996.
- The Rapporteur and Co-Rapporteur's joint assessment report on the company's responses was circulated to all CPMP Members on 22 March 1996.
- On 22 March 1996 the company submitted additional stability data for the oral solution.
- The Rapporteur's additional assessment report was circulated on 15 April 1996.
- During its meeting in April 1996, the CPMP discussed the recommendations presented by the Rapporteur and Co-Rapporteur. A hearing with the company took place on 17 April 1996, to address the final outstanding issues.
- On 17 April 1996 the company submitted to the EMEA their letter of commitment to provide, within the specific time frame, the results of the additional studies.

In light of the overall data submitted and the scientific discussion within the Committee, the CPMP issued a positive Opinion for granting a Marketing Authorisation, under exceptional circumstances, for the two different oral presentations of EPIVIR, on 18 April 1996. The CPMP Opinions were forwarded, in all official languages of the European Union, to the European Commission which adopted the corresponding Decisions on 8 August 1996.