BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Glaxo Group Limited, submitted on 25 March 1998 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application through the centralised procedure for the marketing authorisation for Zeffix (lamivudine) 100 mg film-coated tablets and 5-mg/ml oral solutions. After agreement by the CPMP on 29 January 1998, this medicinal product is referred to Part B of the Annex of the Council Regulation (EEC) 2309/93, of the 22 July 1993, as amended.

The Rapporteur and Co-Rapporteur appointed by the CPMP were as follows:
Rapporteur: Dr. E. Abadie Co-Rapporteur: Prof. A. Hildebrant

Licensing status:

Zeffix was not approved outside the European Union at the time of the submission of the application. On 8 December 1998, a marketing authorisation was issued in the USA.

2 Steps taken for the assessment of the product

- The evaluation procedure started on 24 April 1998.
- The Rapporteur's assessment report was circulated to all CPMP members on 17 June 1998. The Co-Rapporteur's assessment report was circulated to all CPMP members on 19 June 1998.
- An Ad-Hoc group of Experts on hepatitis B was convened by the CPMP to address the problem of the indication and duration of treatment. The meeting took place on 15 July 1998 and the recommendations of the group were circulated to all CPMP members in advance of the July CPMP meeting.
- The draft-consolidated list of questions was circulated to all CPMP members on 17 July 1998 for discussion at the July CPMP plenary meeting. The CPMP adopted the CPMP consolidated list of questions on 23 July 1998.
- The applicant submitted the responses to the CPMP consolidated list of questions on 21 September 1998 to all CPMP members and the evaluation restarted at the October CPMP meeting.
- The joint Rapporteur/Co-Rapporteur's assessment report on the responses to the consolidated list of questions was circulated to all CPMP members on 23 November 1998.
- During its December meeting, the CPMP considered that remaining issues needed to be solved before an opinion could be reached. The CPMP adopted therefore on 17 December 1998 a second consolidated list of questions.
- The applicant submitted the responses to this second list on 26 January 1999 and the evaluation restarted at the February CPMP meeting.
- The joint Rapporteur/Co-Rapporteur's assessment report on the responses to the second consolidated list of questions was circulated to all CPMP members on 2 March 1999.
- During its March 1999 meeting, the CPMP agreed to reconvene the Ad-Hoc group of experts on hepatitis B to discuss the remaining outstanding issues. The meeting took place on 6 April 1999. During this meeting the applicant made an oral explanation in front of the group to address each of the remaining issues.
- During its April CPMP meeting, the CPMP considered the recommendations of the group. An oral explanation took place in front of the CPMP on 21 April 1999. 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 under exceptional circumstances for Zeffix 100 mg film-coated tablets and 5 mg/ml oral solution on 22 April 1999.

- The CPMP opinions were forwarded in all official languages of the European Union were forwarded to the European Commission, which adopted the corresponding decisions on 29 July 1999.