BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Glaxo Group Limited submitted on 26 August 2005 an application in accordance with Article 58 of (EC) No Regulation 726/2004 to the European Medicines Agency (EMEA) for a scientific opinion in the context of cooperation with the World Health Organisation (WHO) for Lamivudine/zidovudineGSK film-coated tablets.

Lamivudine/zidovudine GSK film-coated tablets will exclusively be intended for markets outside the Community.

The application submitted is a complete dossier composed of administrative information, quality, non-clinical and clinical data with a letter from Glaxo Group Limited, the MAH of the centrally authorised product Combivir (lamivudine/zidovudine) allowing the cross reference to relevant non-clinical and clinical data of the Combivir application.

The Rapporteur appointed by the CHMP and the evaluation teams were:
Rapporteur: Dr Eric Abadie

EMEA Product Team Leader: Dr Caroline Le Barbier

2 Steps taken for the assessment of the product

- The eligibility by the World Health Organisation was agreed upon on 12 August 2005.
- The application was received by the EMEA on 26 August 2005.
- The procedure started on 19 September 2005.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 20 October 2005.
- During the meeting on 14-17 November 2005, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive scientific opinion to Lamivudine/zidovudine GSK film-coated-tablets on 17 November 2005.
- The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 09 November 2005.