BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Glaxo Group Limited submitted on 14 November 2003 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Kivexa, a fixed dose combination containing 600 mg abacavir and 300 mg lamivudine through the centralised procedure. After agreement by the CHMP on 24 July 2003, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

The Rapporteur and Co-Rapporteur appointed by the CHMP were:
Rapporteur: Dr. E. Abadie Co-Rapporteur: Prof. B. Silva-Lima

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.
Scientific recommendations were given by France on 28 January 2002.

Licensing status:

The product was not authorised for marketing in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The application was received by the EMEA on 14 November 2003.
- The procedure started on 22 December 2003.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 9 March 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 11 March 2004.
- During the meeting on 20-22 April 2004, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 22 April 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 11 May 2004.
- The Rapporteur/Co-Rapporteur circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 8 July 2004.
- The Rapporteur/Co-Rapporteur circulated an updated Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 23 July 04.
- During the CHMP meeting on 27 – 29 July 2004, the CHMP agreed on a List of Outstanding Issues to be addressed in writing and/or in an oral explanation by the applicant.
- The applicant submitted the responses to the CHMP List of Outstanding Issues on 9 August 2004.
- The Rapporteur/Co-Rapporteur circulated the Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 2 September 2004.
- The Rapporteur/Co-Rapporteur circulated an updated Joint Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 13 September 2004.
- During the meeting on 13 - 16 September 2004, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Kivexa on 16 September. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 14 September 2004.

- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 December 2004.