

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Gilead Sciences International Limited submitted on 12 March 2004 an application for Marketing Authorisation to the European Medicines Agency (EMA) for Truvada, through the centralised procedure. After agreement by the CHMP on 17 December 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. I. Hudson

Co-Rapporteur: Dr. E. Abadie

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

The product was not licensed 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 EMA on 12 March 2004.
- The procedure started on 29 March 2004.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 28 May 2004. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 11 June 2004.
- During the meeting on 27 – 29 July 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 29 July 2004.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 3 September 2004.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the consolidated List of Questions to all CHMP members on 13 October 2004.
- The Rapporteurs circulated a supplementary Joint Assessment Report to all CHMP members on 11 November 2004.
- During the meeting on 15 – 18 November 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 Truvada on 18 November 2004. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 12 November 2004.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 21 February 2005.