BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Triangle Pharma Limited submitted on 6 December 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Emtriva (emtricitabine), through the centralised procedure. After agreement by the CPMP on 20 February 2002, 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. On 5 February 2003, the applicant informed the EMEA that further to the acquisition of Triangle Pharma Limited by Gilead Sciences Inc, the applicant for this application was changed to Gilead Sciences International Limited.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. I. Hudson Co-Rapporteur: Prof. B. Silva-Lima

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

Emtriva was not licensed in any country at the time of submission of the application. The product has been given a Marketing Authorisation in the United States on 2 July 2003.

2. Steps taken for the assessment of the product

- The applicant submitted to the CPMP a request for an accelerated procedure dated 26 November 2002 according to the CPMP guidance on "accelerated evaluation of products indicated for serious diseases (life-threatening or heavy disabling diseases), CPMP/495/96" rev.1 dated 18 September 2001. The CPMP, during its 17 – 18 December 2002 meeting, agreed to consider the possibility to adopt rapidly an opinion based on the recommendation of the Rapporteur and Co-rapporteur in their respective Assessment Reports.

- The procedure started on 6 January 2003.

- The Rapporteur's first Assessment Report was circulated to all CPMP members on 20 February 2003. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 11 March 2003.

- During the meeting on 23-25 April 2003, the CPMP, on the basis of the recommendation of the Rapporteur and Co-rapporteur in their respective Assessment Reports, agreed that the data did not support a rapid adoption of an opinion. The CPMP agreed therefore on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 25 April 2003.

- The applicant submitted the responses to the CPMP consolidated List of Questions on 14 May 2003.

- The summary report of the inspection carried out at the manufacturing site for the oral solution between 3 and 6 June 2003 was issued on 18 July 2003.

- The Rapporteur/co-rapporteur circulated the response Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 26 June 2003.

- The applicant provided a letter of undertaking of the follow-up measures to be fulfilled post-authorisation on 23 July 2003.

- During the meeting on 22 – 24 July 2003 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 to Emtriva 200 mg hard capsules and 10 mg/ml oral solution on 24 July 2003.

- The CPMP opinion was forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 24 October 2003.