BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Bristol-Myers Squibb Gilead Sciences And Merck Sharp & Dohme Limited submitted on 5 October 2006 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for Atripla, through the centralised procedure falling within the Article 3(1) and point 3 of Annex of Regulation (EC) No 726/2004. The eligibility to the centralised procedure was agreed upon by the EMEA/CHMP on 14 December 2005

The legal basis for this application refers to:

Article 10(b) of Directive 2001/83/EC, as amended – relating to applications for new fixed combination products

The application submitted is a complete dossier composed of administrative information, complete quality data, and appropriate non-clinical and clinical data for a new fixed combination medicinal product.

The applicant applied for the following indication: "Atripla is a fixed-dose combination of efavirenz, emtricitabine and tenofovir disoproxil fumarate. It is indicated for use alone as a single tablet regimen or in combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults."

Scientific Advice:
The applicant did not seek scientific advice at the CHMP.

Licensing status:
Atripla has been given a Marketing Authorisation in the United States of America on 12.07.2006.

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

Rapporteur: K. Broich
Co-Rapporteur: E. Abadie/P. Deprijck

2. Steps taken for the assessment of the product

- Accelerated Assessment procedure was not accepted by the CHMP on 21 September 2006.
- The application was received by the EMEA on 5 October 2006.
- The procedure started on 25 October 2006.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 12 January 2007. The Co-Rapporteur's first Assessment Report was circulated to all CHMP members on 17 January 2007.
- During the meeting on 19-22 February 2007, 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 February 2007.
  The applicant submitted the responses to the CHMP consolidated List of Questions on 11 May 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 22 June 2007.
- During the CHMP meeting on 16-19 July 2007, 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 10 August 2007.
- The Rapporteurs circulated the Joint Assessment Report on the applicant's responses to the list of outstanding issues to all CHMP members on 3 September 2007.

- During the CHMP meeting on 17-20 September 2007 it was considered no longer necessary that outstanding issues are addressed by the applicant during an oral explanation before the CHMP.
- During the meeting on 15-18 October 2007, 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 Atripla on 18 October 2007. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 16 October 2007.
- The CHMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 13 December 2007.