BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant DuPont Pharmaceuticals Limited submitted on 29 June 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Sustiva (efavirenz). After agreement by the CPMP on 28 January 1998, this medicinal product has been referred to Part B of the Annex of the Council Regulation (EEC) 2309/93 of the 22 July 1993 as amended.

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

Rapporteur: Prof. R. Gaspar Co-Rapporteur: Dr. P. Sjöberg

Licensing status:

Sustiva was not licensed in any country outside or inside the European Union at the time of the submission of the application. Sustiva has been licensed in the USA on 17 September 1998.

2. Steps taken for the assessment of the product

- The procedure started on 24 July 1998.
- The Rapporteur's assessment report was circulated to all CPMP members on 8 October 1998. The Co-Rapporteur's assessment report was circulated to all CPMP members on 2 October 1998.
- The draft consolidated list of questions was circulated to all CPMP members on 11 November 1998 for discussion at the November plenary meeting. The CPMP adopted the consolidated list of questions on 19 November 1998.
- The applicant submitted the responses to the CPMP consolidated list of questions to all CPMP members on 1 December 1998 and the evaluation restarted at the December CPMP meeting.
- The joint Rapporteur/Co-Rapporteur assessment report on the responses to the consolidated list of questions was circulated to all CPMP members on 20 January 1999.
- During the meeting in 23 – 24 February 1999, the CPMP agreed on a list of outstanding issues to be addressed by the applicant during an oral explanation which was held before the CPMP on 23 February 1999. In the light of the overall data submitted and the scientific discussion within the Committee, the CPMP issued by consensus a positive opinion for granting Marketing Authorisation for Sustiva 50, 100 and 200 mg hard capsules on 24 February 1999.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which issued the corresponding Decisions on 28 May 1999.