BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Gilead Sciences International Limited submitted on 26 March 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Hepsera, through the centralised procedure. After agreement by the CPMP on 13 November 2001, 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 CPMP were:

Rapporteur: Dr E. Abadie Co-Rapporteur: Dr M. Ainsworth

Scientific Advice:

The applicant did not seek scientific advice at the CPMP.

Licensing status:

The product was not licensed in any country at the time of submission of the application. The product was licensed in the United States on 20 September 2002.

2. Steps taken for the assessment of the product

- The procedure started on 22 April 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 2 July 2002. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 24 June 2002.
- During the meeting on 23 – 25 July 2002 the CPMP 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 25 July 2002.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 13 September 2002.
- The Rapporteur/Co-rapporteur circulated the joint Assessment Report on the applicant's responses to the List of Questions to all CPMP members on 23 October 2002.
- The Rapporteur/Co-rapporteur circulated an overall recommendation to all CPMP members on 18 November 2002.
- During the meeting on 19-21 November 2002, the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued by consensus a positive opinion for granting a Marketing Authorisation to Hepsera on 21 November 2002. The applicant provided the letter of undertaking of the follow-up measures to be fulfilled post-authorisation on 21 November 2002.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 6 March 2003.