

BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant, Gilead Sciences International Limited, submitted on 4 May 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMA) for Viread, through the centralised procedure. After agreement by the CPMP on 23 January 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 and the evaluation teams were:

Rapporteur: Dr. Eric Abadie

Co-Rapporteur: Prof. De Andres-Trelles

Scientific Advice

The applicant did not seek a Scientific Advice from the CPMP.

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 CPMP during its 24-26 April 2001 agreed to accelerate the evaluation procedure for this medicinal product considering its potential high therapeutic interest.
- The procedure started on 22 May 2001.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 26 June 2001.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 6 July 2001.
- During the meeting on 24-26 July 2001, the CPMP agreed on a list of outstanding issues to be addressed in writing. The final list was sent to the applicant on 26 July 2001.
- The applicant submitted the responses to the list of outstanding issues on 24 August 2001.
- The Rapporteur and Co-rapporteur circulated the joint assessment report on the responses to the list of outstanding issues to all CPMP Members on 25 September 2001.
- During the CPMP meeting 16-18 October 2001, 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 under exceptional circumstances to Viread on 18 October 2001. The applicant provided an undertaking letter of the specific obligations and follow-up measures to be fulfilled post authorisation on 17 October 2001.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 5 February 2002.