BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Agouron Pharmaceuticals (Europe) Ltd., submitted on 13 February 1997 to the European Agency for the Evaluation of Medicinal Products (EMEA) an application for the marketing authorisation of the medicinal product Viracept (nelfinavir) falling within the scope of Part B of the Annex of the Council Regulation (EEC) 2309/93, of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:
Rapporteur: Dr. D Jefferys Co-Rapporteur: Prof J.A.G. Morais

Licensing status:

Viracept has been granted a license in several non-EU countries including USA, where it was approved for adult and paediatric use in March 1997. In Switzerland it was approved for adult administration in June 1997 and for paediatric administration in April 1999.

2. Steps taken for the assessment of the product

- A request for the inspection of the finished product-manufacturing site in the USA was agreed during the March 1997 CPMP meeting and the United Kingdom Inspectorate performed the inspection.
- The assessment report of the Co-Rapporteur was circulated to all members of the CPMP on 10 April 1997.
- The assessment report of the Rapporteur was circulated to all members of the CPMP on 11 April 1997.
- During the May 1997 CPMP meeting, a consolidated list of questions was agreed upon which was sent to the applicant on 14 May 1997.
- The applicant submitted the responses to the consolidated list of questions on 6 June 1997.
- The joint Rapporteur/Co-Rapporteur assessment of the responses was circulated to all CPMP members on 17 July 1997.
- The applicant provided supplementary information on 10 September 1997.
- In agreement with Agouron Pharmaceuticals (Europe) Limited on the 19 September 1997 Roche Registration Limited duly replaced Agouron Pharmaceuticals (Europe) Limited as the applicant for the above-mentioned marketing authorisation.
- The future marketing authorisation holder signed a letter of undertaking on follow-up measures on 24 September 1997.
- The CPMP on the basis of the favorable benefit-risk assessment issued a positive opinion for granting a marketing authorisation in exceptional circumstances to Viracept on 24 September 1997.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decision on 22 January 1998.