BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant SP Europe submitted on 7 September 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Neoclarityn, through the centralised procedure. After agreement by the CPMP on 22 April 1999, 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. Daniel Brasseur Co-Rapporteur: Prof. Hans Winkler

Scientific advice

The applicant received scientific advice from the CPMP on 27 May 1998. The Scientific Advice pertained to Part III and IV of the dossier.

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 procedure started on 24 September 1999.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 3 December 1999. The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 1 December 2000.
- During the meeting on 18-20 January 2000 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 24 January 2000.
- On 15 February 2000 the CPMP decided not to request an inspection of the manufacturing sites.
- The applicant submitted the responses to the consolidated list of questions on 15 June 2000.
- The Rapporteur circulated the Response Assessment Report on the applicant’s responses to the List of Questions to all CPMP Members on 21 August 2000.
- During the meeting on 19-21 September 2000 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 to Neoclarityn on 21 September 2000.