BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant SP Europe, submitted on 07 January 1998 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Integrilin solution for infusion 0.75 mg/ml and for Integrilin solution for injection 2 mg/ml. After agreement by the CPMP on 22 November 1995, this medicinal product is referred to Part B of the Annex to Council Regulation No (EC) 2309/93 of 22 July 1993.

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

Rapporteur: Dr E. Abadie Co-Rapporteur: Prof. G. Vicari

Licensing status:

The product was licensed in Switzerland (PTCA indication) on 27 February 1997.

2. Steps taken for the assessment of the product

- The procedure started on 29 January 1998.
- The Rapporteur's first assessment report was circulated to all CPMP Members on 15 April 1998.
- The Co-Rapporteur's first assessment report was circulated to all CPMP Members on 15 April 1998.
- During the meeting on 27 May 1998 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 28 May 1998.
- The applicant submitted the responses to the consolidated list of questions on 02 October 1998.
- 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 November 1998.
- List of outstanding issues was adopted at the CPMP meting on 15 December 1998.
- The applicant requested on 11 January 1999 a postponement of the oral explanation scheduled for the January 1999 CPMP meeting.
- The applicant submitted a draft response to the list of outstanding issues to the EMEA on 25 January 1999. The final response on the list of outstanding issues was submitted by the applicant on 01 February 1999.
- The applicant gave an oral presentation on 23 February 1999 during the CPMP meeting and the remaining issues were presented.
- 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 Integrilin on 25 February 1999.
- The Commission services submitted the draft decision concerning Integrilin to the Standing Committee on Medicinal products for human use, on the 09 April 1999. Written observation was received within the written procedure laid down by Article 3 of Commission Regulation (EC) No. 1662/95 of 7 July 1995. Since the written observation raised a question of scientific and technical nature, the procedure was suspended.
- On 10 May 1999 in accordance with Article 10 (3) of Council Regulation (EEC) No 2309/93, the European Commission requested the CPMP to consider a question of scientific and technical nature on the wording of section 4.1 of the SPC (Therapeutic indication) by replacing "Integrilin is indicated for the prevention of early new myocardial infarction" with "Integrilin is indicated for the prevention of early myocardial infarction".

- During its meeting of 18-20 May 1999 the CPMP considered the European Commission's request and sent a letter of reply dated 20 May 1999 to inform the European Commission of the outcome of their discussions concerning the issue raised in the letter of 10 May 1999.
- The services of the Commission informed the members of the Standing Committee on Medicinal Products for human use of the outcome of the CPMP discussions on the 02 June 1999 and requested final opinions by written procedure by 02 July 1999.
- The CPMP Opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 1 July 1999.