BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant SP Europe, 73, rue de Stalle, B-1180 Bruxelles submitted on 8 March 1999 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Alfatronol, through the centralised procedure.

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

Rapporteur: Dr. E. Abadie Co-Rapporteur: Pharm. G. De Greef

Licensing status:

The interferon alfa-2b from SP Europe has been already approved in Europe via the ex-concertation procedure with the tradename IntronA. The Summary of Product Characteristics of IntronA has been subsequently harmonised through a referral under Article 11 of Council directive 75/319/EEC (submission by the Company on 14 December 1995, CPMP opinion issued on 18 December 1996 and Decision of European Commission on 26 June 1997), during which procedure the whole dossier was assessed by CPMP.

Alfatronol is a new trade name for IntronA, the interferon alfa-2b from SP Europe. The qualitative and quantitative composition of the medicinal product of IntronA and the centrally approved Alfatronol are strictly identical.

IntronA is approved in Europe for the treatment of chronic hepatitis B and C, hairy cell leukaemia, chronic myelogenous leukaemia, multiple myeloma, follicular non-Hodgkin's lymphoma, carcinoid tumours, AIDS-related Kaposi sarcoma and malignant melanoma.

Further to the approval of the centralised application of Alfatronol, the main changes of the labelling (compared to the article 11 labelling) are the following:

- Inclusion of the possible association of interferon alfa-2b and cytosine arabinoside for the treatment of chronic myelogenous leukaemia;
- Deletion of the AIDS-related Kaposi's sarcoma indication;
- Inclusion of the concomitant administration of ribavirin and interferon alfa-2b for the first line treatment of chronic hepatitis C.

After the granting of the marketing Authorisation of Alfatronol by the European Commission, SP Europe committed to withdraw the nationally authorised IntronA, and to transfer this trade name to the centrally authorised product.

2. Steps taken for the assessment of the product

- The procedure started on 26 March 1999.
- The Rapporteur's first assessment report was circulated to all CPMP members on 14 April 1999.
- The Co-Rapporteur's first assessment report was circulated to all CPMP members on 14 April 1999.
- During its meeting on 18-20 May 1999, the CPMP agreed on the consolidated list of questions to be sent to the company. The final consolidated list of questions was sent to the company on 20 May 1999.
- During it's meeting on 22-24 June 1999, the CPMP agreed that a GMP inspection of the manufacturing site was not necessary.
- The company submitted the responses to the consolidated list of questions on 9 August 1999.
- The Rapporteur and the Co-Rapporteur circulated the joint response assessment report on the company's responses to the list of questions to all CPMP members on 27 September 1999.

- The CPMP, during their meeting on 19-21 October 1999, considered the responses provided by the company and discussed the recommendations presented by the Rapporteur. Amendments were discussed to the Summary of Product Characteristics and Package Leaflet texts.
- The applicant provided a letter of undertaking on the follow-up measures to be fulfilled as requested by the CPMP, dated 21 October 1999.
- During the meeting on 21 October 1999 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 for IntronA.
- The European Commission granted a Marketing Authorisation for the medicinal product Alfatronol on 9 March 2000.