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re : SD treated FVIII

Dear Professor Allain,

It was not easy to compile reliable information concerning the commercial availability in Europe of SD treated FVIII for the period 1988-1990. However, I think that I have now the necessary data for Norway and some preliminary information for other countries.

1) Norway :

In 1985, the Norwegian Public Health Department decided to start the so-called "Norwegian Plasma Fractionation Project" aiming among others at providing virus inactivated blood products to Norwegian patients.

A pilot plasma fractionation project was initiated by the Norwegian Red Cross and national hospital blood centers and was gradually extended towards the end of 1988 to include 57 of the 62 blood banks in Norway. The complete Norwegian Plasma Fractionation Project started finally in January 1, 1989.
The first batch of SD treated FVIII was introduced by Octapharma in Norway June 1st 1988. As of January 1st, 1989 Norway was self-sufficient and Octapharma remained responsible for the administration of the project. Production took place in Lille until Sept. 30, 1989 and subsequently at Octapharma Vienna from Oct. 1, 1989 until present time.
SD treated FVIII produced for Norway could not be available outside Norway. The project is a self-sufficiency contract, and by contract the Norwegian Authorities were not allowed to sell the product abroad, moreover increased production was used to increase the quality of haemophilia treatment.

In summary, SD treated FVIII was available in Norway as of June 1, 1988 in the framework of a self-sufficiency fractionation contract between Octapharma and the Norwegian Authorities. The product could however only be used for the treatment of Norwegian haemophiliacs.

2) Situation in other countries :

My information is still very incomplete. I hope I can receive some more in a near future but it is not sure.
The first generation of SD treated FVIII concentrate (Octa V.I.) was introduced in Europe already in 1986 by Octapharma. The second generation (Octavi) was registered by Octapharma in Germany April 21, 1987. In Germany, the product was mainly used in Bonn at that moment.
In the period 1988-1990 SD treated FVIII concentrate was produced under license in several facilities : AIMA-Biagini, Italy; DRK Hagen, Biotest, Germany; Statens Serum Institute, Denmark; Octapharma, Austria; CRTS Lille, France.
In short, it seems that in the period 1988-90, SD treated FVIII was commercially available at least in Germany, Italy, France and Denmark.

I hope I can provide you with further information in the near future. In case you have other more specific questions, please let me know and I will try to answer.

Best regards.

Sincerely yours,

GRO-C

Jean-Louis Poplavsky