

Our Ref MWT/svs

10th October 1986.

Professor I.J. Temperley,
National Haemophilia Treatment Centre,
St. James Hospital,
P.O. Box 580,
Dublin 8.

Dear Professor Temperley,

KONYNE HT

You may remember that I wrote to you earlier this year concerning the assembly of information on the safety and efficacy of Konyne HT for submission to the Committee on Safety of Medicines.

You kindly agreed to help us in this matter and I would be grateful if we could now meet to discuss the situation.

Dr. J-P. Fallise, Cutter's Clinical Trial Monitor in Europe, would also like to meet you to discuss the possibility of conducting a safety study in Ireland with our new wet heat treated Factor VIII preparation, Koate HS. We would be grateful for your contribution to this multicentre study which will be commencing in the near future in the U.K.

Dr. Fallise will be visiting the U.K. during the week beginning 20th October and we would be happy to meet you on Thursday 23rd or Friday 24th October to discuss both matters if either of these dates would be convenient for you.

Mr. O'Donnell will be contacting you to discuss the possibility of arranging a meeting.

I am enclosing a copy of the clinical brochure for Koate HS and a draft protocol for the study for your consideration.

Yours sincerely,

Marie W. Tatt (Mrs.),
Regulatory Affairs Manager.