

## Scottish Office Finance Division

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Your ref

Our ref

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CLINICAL TRIALS OF FACTOR VIII: ARRANGEMENTS FOR COMPENSATION

I have seen a copy of the DHSS response to your letter of 12 January to Mr Brunning and I am writing to confirm that the position in Scotland in relation to these matters is broadly the same.

I would also like to pick up two points from your 12 January letter. Firstly, you quote an SHHD source as advising that "whilst any side effects which might be experienced would probably involve some discomfort, there is no likelihood of any permanent damage". I cannot be sure exactly what was said by my colleague but I assume he was trying to convey that

- (a) side effects are unlikely but
- (b) any which do occur will most probably be of an uncomfortable variety causing no permanent damage.

However, as DHSS have indicated, we cannot dismiss the theoretical possibility that transmission of non-A and non-B hepatitis and the HIV (AIDS) virus could occur.

You also asked how the new proposals differ from previous arrangements for clinical testing of Factor VIII, which were carried out without any compensation scheme being agreed. I do not think that the general testing regime is any different, although we hope that the process has been improved. It is rather the recognition - albeit theoretical - of an increased risk factor to hemophiliacs from infected blood products and the advent of the ABPI guidelines, which we consider reasonable and appropriate in cases of this nature, which have made the difference.

Finally, I should mention again the very tight deadline for decision as far as Scotland is concerned. As I indicated in my earlier letter, our

existing supply of Factor VIII is likely to be exhausted during the course of this month and it will be more than awkward for us if clinical trials of the efficacy of the replacement supply are delayed. I should therefore be grateful for your response by the end of this week - by telephone if necessary.

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