



## SCOTTISH HOME AND HEALTH DEPARTMENT

St Andrew's House Edinburgh EH1 3DE

Telephone 031-550-850 ext 244 2419

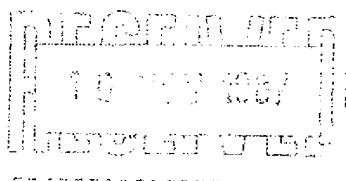
Professor J D Cash  
National Medical Director  
Scottish National Blood  
Transfusion Service  
Headquarters Unit  
Ellen's Glen Road  
Edinburgh  
EH17 7QT

*Copy to Dr Ludlam (for info) ✓  
16/11/87*

*✓  
Jr*

NQL/5/1

9 November 1987



*Dear John.*

### CLINICAL TRIALS: COMPENSATION

1. Thank you for your letter of 8 July about compensation for clinical trials.
2. Let me deal first with Factor VIII. In his letter of 6 February, Mr Murray confirmed that approval had been given to compensation arrangements at the non-therapeutic stage—that is, for patients receiving heat-treated Factor VIII not as an integral part of their treatment but for efficacy trial purposes. We have reassessed the position in respect of the therapeutic stage and now conclude that the compensation arrangements for heat-treated Factor VIII may be applied to therapeutic trials also. The compensation arrangements are as set out in Mr Murray's letter of 10 June; they are as in the guidelines recommended by the Association of the British Pharmaceutical Industry and in appropriate cases involve a panel of 3 assessors as outlined in that letter.
3. The information which you supplied about other PFC products is helpful. We are, however, still considering the difficult question of the extension of compensation arrangements to other products, whether for therapeutic or non-therapeutic trials. Such consideration must we believe be given product by product and I shall write again as soon as we are in a position to comment further.
4. I have copied this letter to Jim Donald.

*Yours sincerely,*

*D MacNiven*

D MACNIVEN