via email

RESTRICTED POLICY

Our Ref: KG1211

Mr Guinness

From: Dr A Rejman CA-OPU2

Date: 12 November 1996

Copy: Mrs Silvester MCA
Ms Corrigan

RECOMBINANT FACTOR VIII AND VAT

1. I have been passed a copy of the statement by Professor Tuddenham on behalf of Baxter for the tribunal which is to be held later this week and early next week.

2. In his statement Professor Tuddenham is making reference to the supposed increased safety of recombinant Factor VIII and I understand that a significant proportion of the discovery documents from Baxter are cuttings from the lay press regarding recombinant Factor VIII.

3. As you are aware, the tribunal is to decide whether recombinant Factor VIII should be exempted under the terms of the VAT Act which is based on the EC VAT Directive. Efficacy and safety do not play a part in such a decision.

4. It is likely that Counsel for the VAT Office will ask for the tribunal to consider specifically those aspects relating to VAT and for claims on safety to be disregarded.

5. My understanding is that the manufacturers of recombinant Factor VIII are not allowed to claim in their promotional literature that their product is safer than virally inactivated plasma derived blood products. However, the tribunal is being held in public, and it may be that the manufacturers realise that they will lose the argument on VAT and will be using this as a forum for promoting their product.

6. In his witness statement, Professor Tuddenham makes no reference to inhibitor production.

Dr A Rejman
GRO-C
EH