



COMMITTEE ON SAFETY
OF MEDICINES

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To Medical Director
Distillers Company Ltd
13 Milville Street
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/ 8 April 1990

Dear Sir/Madam

THE PROVISION OF PLASMA POOL SAMPLES FOR THE CONTROL TESTING OF BLOOD PRODUCTS

Blood products are well known to be capable of transmitting viruses to recipients. Patients receiving coagulation factors or some immunoglobulin preparations have developed therapy induced hepatitis B and non A, non B'. Both untreated factor VIII and IX concentrates have transmitted HIV to haemophiliacs.

The Committee on Safety of Medicines have recommended that in view of the limitations of testing for HB_sAg and antibodies to HIV in finished products and the greater sensitivity of tests on the plasma pool, manufacturers should submit formally to the National Institute for Biological Standards and Control samples of all plasma pools in addition to other samples and protocols required for batch release.

I would appreciate written confirmation of this at your earliest convenience.

Yours faithfully

GRO-C

L R WHITBREAD
Assistant Secretary