LOTHIAN HEALTH BOARD

FACTOR VIII DISTRIBUTION

Royal Infirmary of Edinburgh and Associated Hospitals

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HAEMATOLOGY DEPARTMENT

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Mr. D. McIntosh,
General Manager,
Scottish National Blood Transfusion Service,
Headquarters Unit,
Ellen's Glen Road,
Edinburgh.

You: Ref 0034
Our Ref CAL/AT
Date 19 February 1991
Enquiries to
Ext. No. [redacted]

Dear Mr. McIntosh,

HIGH PURITY FACTOR VIII CONCENTRATE

I write further to my letter of 19th November and following the January 25th meeting of the Factor VIII Working Party on behalf of my colleagues in Scotland and Northern Ireland.

As you know we are keen to use a licensed factor VIII concentrate manufactured from locally collected plasma. We consider it important to use a product which has been manufactured by a method with a proven safety record. Furthermore, as you are well aware, we would prefer to use a product of higher specific activity than the current Z8. Our strong preference would therefore be for a licensed high purity factor VIII concentrate manufactured in Scotland from local donor plasma.

We appreciate that it will not be possible to reach this goal immediately as we discussed at the Factor VIII Working Party and plans have been laid for an interim arrangement. As you now know Directors consider that 4 million units of high purity factor VIII would suffice until 1st April 1992. We thank you for the offer to arrange for us to purchase an additional 1 million units but we do not consider this will be necessary. I understand as we do not wish to take up this option it will delay the issue of high purity products by 1 month until 1st April 1991.

We are keen to see details of the PUP studies including the individual ALT results on each of the sequential specimens from each recipient. We should also need reassurance that there were no documented HIV seroconversions to the CNTS product in France. The legal arrangements under which the concentrate will be administered need to be very clearly stated, particularly as the initial material will not be used under a CTX.

Clearly each prescribing physician will require a letter of indemnity.

We suggest that formal "recovery and half life studies" are not

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undertaken until we have high purity concentrate manufactured at Liberton. We would suggest delaying a visit to DDS until the in-house manufactured product is available.

We should like to recommend that in 1991-92 the 4 million units of high purity factor VIII is distributed as follows:

	Million Units
Glasgow (GRI + Yorkhill)	2.1
Edinburgh (+ other East Coast Centres)	1.4
Northern Ireland	0.5
TOTAL	4.0

Following the next meeting of Haemophilia Directors for Scotland and Northern Ireland on the 1st March we shall be in a position to make recommendation as to how 28 should be distributed for the next financial year.

I have been asked to bring to your attention again our pressing need for a high purity non-thrombogenic factor IX concentrate. There have been several episodes of thrombosis/DIC following the use of Liberton product and both Nationally and Internationally there will be a decline in use of current products in favour of those which are safer.

We all look forward to the introduction of a high purity factor VIII concentrate in Scotland and Northern Ireland and hope that, as arranged, distribution can begin on 1st April.

With best wishes,
Yours sincerely,

Christine Ludlam

C.A. Ludlam,
Consultant Haematologist.

c.c. Dr. D.J. King, Consultant Haematologist, Royal Aberdeen Children's Hospital, Cornhill Road, Aberdeen.
Dr. A. Dawson, Department of Medicine, Royal Infirmary, Aberdeen.
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Dr. I.D. Walker, Department of Haematology, Royal Infirmary, Glasgow.
Dr. E. Mayne, Department of Haematology, Royal Victoria Hospital, Belfast.
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