0005

IN CONFIDENCE

NOTES FOR SCOTTISH HEALTH SERVICE HAEMOPHILIA CENTRE/ TRANSFUSION SERVICE DIRECTORS' MEETING: MAY 1988

April 1988

JDC/SHHD/4/88/1

These notes have been produced to facilitate discussion with regard to future SNBTS planning for the production of blood products required for the management of patients with haemostatic or thrombotic disorders within the Scottish Health Service. All annual figures contained in these notes refer to years ending 31st March and do not include Northern Ireland. Directors will wish to note that some figures have been included for 1988.

I am indebted to SNBTS Director colleagues who have been responsible for providing, through the national statistical returns, much valuable information, and in particular to Dr Perry for information on PFC's activities (Appendix VI).

FACTOR VIII CONCENTRATES

FRESH PLASMA PROCUREMENT FOR FACTOR VIII

The total annual SNBTS figures (Kg) can be summarised as follows (Regional figures in Appendix 1):

1983	1984	1985	1986	1987	1988
40,739	51,017	52,480	53,005	54,775	51,200

Provisional data indicates a significant fall in fresh plasma procurement in 1987/88 - 7%. This has arisen due to the fall in blood donors attending routine sessions throughout Scotland.

ISSUES OF FACTOR VIII CONCENTRATES

The figures below provide a summary position of trends since 1983 (details in Appendices II and III), and are derived from issues from PFC to RTC and cryoprecitate from RTCs to Wards or Haematology Departments:

	1983	1984	1985	1986	1987
Cryoppt. (donations)	12,953	11,646	12,693	16,801	12,851
FVIII Concentrate Intermediate VIII/ new formulation	4.86	9.26	7.40	5.52	
HT-NY					7.35
Z8					0.09
(m.i.u.)					

COMMERCIAL FACTOR VIII CONCENTRATES

The information obtained by the SNBTS is summarised below (m.i.u.) (details in Appendix IV):

1983	1984	1985	1986	1987
1.04	0.11	0.03	0.13*	0.19*

* This material was of porcine origin.

SUMMARY (Details in Appendix V)

	1983	1984	1985	1986	1987
Cryoppt.	1.27	1.16	1.27	1.68	1.28
PFC	4.86	9.26	7.40	5.52	7.44
Commercial	1.04	0.11	0.03	0.13	0.19
N/A					
Total	7.17	10.53	8.70	7.34	8.91

COMMENTS

1. Increase in Use of Factor VIII Concentrates

The decline in the use of factor VIII concentrates since 1986 appears to have reversed. The size of this reversal is substantial. I should be emphasised that the Oxford returns are a closer reflection of actual clinical use. As no current Oxford data is available (see below) it seems worth analysing RTC issues to Haemophilia Centres. These can be summarised for PFC products as follows:

1983	1984	1985	1986	1987	1988
4.97	6.07	7.15	5.83	7.32	10.56

It is concluded that there is now a very substantial increase in the use of factor VIII concentrates throughout the SHS (further details in Dr Perry's Report - Appendix VII).

2. Future Production Targets

In the light of the usage trends, production difficulties at PFC, fall in plasma supply to PFC and the consequent depletion of national stocks (see Appendix VII) SNBTS Directors are currently

reviewing previously shelved plans to increase FFP production (for PFC).

Directors may wish to note that consideration may have to be given to the purchase of factor VIII concentrates in 1988/89.

3. HIV (SNBTS) Activities

(a) Donation Screening Tests

A SNBTS group (chaired by Dr Cuthbertson) has been established to assess, among other things, new generations of donation screening kits. This group is proving to be an important feature in maintaining the standards of routine HIV donation screening. SNBTS Directors are currently reviewing the performance of the Service's HIV reference laboratories with a view to enhancing the quality of this work.

(b) PFC Heat Treatment Programmes

(i) It is noted that PFC has succeeded in producing coagulation factor concentrates (VIII and IX) which are dry heat treated at 80°C/72 hours.

(ii) PFC staff are currently engaged in validating their fractionation processes and heat treatments in the context of HIV. This exercise has progressed less than satisfactorily to date but recent developments are expected to expedite matters in the near future.

(c) Higher Purity Product

Work continues at PFC to develop a high purity product that meets the needs of the SHS. Full details of the emerging programme are contained in Dr Perry's Report (Appendix VII).

OXFORD RETURNS

Due to a number of personnel and computing difficulties the data normally received from the Oxford Haemophilia Centre are not available at this time.

FACTOR IX CONCENTRATES

SUPPLY TRENDS

PFC issues to RTCs since 1983 are summarised below (Regional details in Appendix VI).

	1983	1984	1985	1986	1987	1988
PFC DEFIX (m.i.u. of IX)	1.05	1.31	1.59	1.17	2.09	2.65
PFC PPSB (10^3 i.u. of IX)	35	46	18	22.4	14.4	
Commercial "Activated" Products (10^3 iu)	115	Nil	181	263	792	

COMMENTS

1. Directors will wish to note the substantial and continuing increase in the demand for factor IX concentrates. There is no doubt that the size of this escalation has put major pressure on the Service. It is assumed that the major cause of this escalation is the increasing use of these concentrates in the management of haemophilia A patients with inhibitors. Comments on further possible increase in demand would be most welcome.

2. The SNBTS Directors have requested that PFC explores ways of producing a factor IX concentrate that will be more appropriate than that which is currently available for the management of haemophilia A patients with inhibitors. This programme is now on-going (see Appendix VII) and comments from Haemophilia Directors would be most welcome, and in particular, on ways in which we can obtain information on what proportion of current use of factor IX concentrates is destined for haemophilia A patients with inhibitors.

3. Directors will wish to note that in the 12 month period since our

last meeting there have been several reports in the literature which have indicated that heat treatments do not appear to diminish the efficacy of factor IX concentrates in the management of haemophilia A patients with inhibitors. Comments from Haemophilia Directors would be welcomed.

4. Directors will wish to note the approach received by the British Society of Haematology with regard to the putative use of factor IX concentrates in oral anticoagulant research.

5. Directors may also wish to be reminded that PFC no longer produces PPSB.

ANTI-THROMBIN III CONCENTRATE

(See Dr Perry's Report (Appendix VII))

PFC SUPPLIES TO BELFAST

	1983	1984	1985	1986	1987
Factor VIII (m.iu)	0.15	1.03	1.70	1.89	1.64 *
DEFIX (m.iu)	Nil	0.14	0.58	0.32	0.16
PPSB (m.iu)	Nil	0.008	0.018	0.024	0.011

* HT-NY product

NEW PRODUCTS

(See Dr Perry's report: Appendix VII)

CLINICAL TRIALS/PRODUCT SURVEILLANCE MANAGER

Directors will wish to know that the first appointee to this post is Dr R R C Stewart, previously of Sandoz Ltd.. Dr Stewart will be responsible for co-ordinating all SNBTS clinical trials and it is anticipated he will become well known to colleagues in our Haemophilia Centres.