IN CONFIDENCE

Minutes of Directors' Meeting held on
17th December 1986 in the HQ Unit

Present: Dr J D Cash (in the Chair)
Dr E Brookes
Miss M Corrie (Secretary)
Dr J Forrester (SHHD)
Mr J N Francis
Mr I D Fraser (Bristol)
Dr W M McClelland, NI
Dr R Mitchell (from Item 3)
Mr A J Murray (from Item 3(b)ix
Dr R J Perry
Mrs Elizabeth Porterfield (Minutes)
Dr S J Urbaniak
Dr W Whitrow

1. INTRODUCTION AND APOLOGIES FOR ABSENCE

An apology had been received from Dr H H Gunson and it was noted that Mr A J Murray would be late.

2. MINUTES OF PREVIOUS MEETING (9 October 1986)

The following amendments were agreed:

Page 2: Items 3(b) ii and iii should be transposed.

Page 6: Items 3(i) ii: amend second sentence to read: " . . . advised Directors that enquiries initiated by SNBTS might be counter-productive."

3. MATTERS ARISING

(a) Developments with the Private Sector (3a)

(i) **Substantive Agreement:**
Following Directors' meetings with the General Manager and the Chairman of the CSA a revised substantive agreement had been issued, effective from 1 January 1987. It would be necessary to institute appropriate servicing arrangements and to this end it was agreed that **Miss Corrie and Mr Francis had prepared a SOP which would be sent to Directors for comment.**

(ii) **Handling charges:**
The current arrangements for determining handling charges for RTC and PFC products were unsatisfactory due to lack of co-ordination. Dr Cash was hoping colleagues in CSA, SHHD and the DHSS would co-operate in evolving an improved method of calculating and promulgating the handling charges including an input by the SNBTS. (Note: the figures for RTC and BPL(PFC) produced products were issued six months apart).

(b) AIDS (3b)

(i) **Validation studies of PFC products:**
Dr Perry summarised the current studies underway at PFC. An interim report had been tabled at the Co-ordinating Group meeting on 18th November 1986 **and a further draft report of the model virus inactivation studies was in preparation. Dr Perry undertook to send a copy to Dr Forrester and Dr Fraser at the time of circulation to Directors (anticipated end January 1987).**

Information on the studies had been sent to Dr Lane (Director, BPL) as it emerged.

(ii) **Current status of HIV antibody positive donations:**

Inverness:	1 (none since last report)
Aberdeen:	Nil
Dundee:	3 (none since last report)
Edinburgh:	9 (+1 since last report)
Glasgow:	6 (+4 since last report)
Belfast:	2 (none since last report)

(iii) **Scottish membership of NBTS/CBLA Working Party on QA**
It was noted that Dr Bruce Cuthbertson had accepted the nomination to represent SNBTS on the Core Group of the above Working Party. Directors noted that it might be necessary to provide assistance to Dr Cuthbertson from time to time in areas of expertise with which he was not familiar.

(iv) **Seroconversion of previously ELISA +ve, WB-ve donors:**
As agreed at the previous meeting (and at the NBTS Directors meeting on 8th October 1986) Dr Fraser had written to Dr Alison Smithies, seeking the advice of the Expert Advisory Group on AIDS. There had been no response as yet; this item had not appeared on the agenda of the EAGA meeting held on 18 November 1986. The next meeting would be 27 January 1987.

(v) **Donor self-exclusion literature:**

A. This concerned the idea of a joint NBTS/SNBTS study of the efficacy of currently available donor information leaflets. **Dr Smithies had agreed that the idea should be pursued and it would be discussed in detail at the next meeting of NBTS Directors (21 January 1987).**

Dr Forrester reported that he had not been briefed on this matter by DHSS.

B. Dr McClelland sought further clarification/amendment of the donor self-exclusion criteria agreed at the Co-ordinating Group meeting of 18th November 1986.

Directors agreed that exclusion category 5 should be amended to read:
"Anyone who has ever had sex with anyone in the above groups, even on a single occasion."
Miss Corrie undertook to revise the criteria and reissue them to Directors.

It was agreed to withdraw AIDS leaflets with effect from 31st December 1986, notwithstanding the difficulties this would impose on the North and West due to their local call-up systems. Dr McClelland undertook to print copies of the revised exclusion criteria for issue by Dr Whitrow. Withdrawal was not practicable in the West as the content of the Autumn 1986 AIDS leaflet was incorporated in the call-up letter, but Dr Mitchell would prepare a supplementary leaflet (for issue to donors at sessions) detailing the revised self-exclusion categories.

(vi) HIV epidemiological study:
There was no progress to report. Dr Wallington had sent copies of the proposed study to Scottish Haemophilia Directors for comment but not all had responded.

(vii) Monitoring the accuracy of BTS anti-HIV screening:

A. Study of one year's testing in RTCs (for publication).
Dr Gunson had now received Scottish data and no further action was required.

B. Two year study of false negatives
Scottish Directors had not submitted their comments on this proposed study to Dr Gunson, who had subsequently advised Dr Cash that they should await further guidance from himself before responding.

C. Composition of donor panels
Dr Gunson had written to all NBTS Directors (and NI) seeking information on the age/sex ratio of donor panels. It was not clear whether he had contacted the SNBTS Directors and Dr Fraser agreed to advise Dr Gunson to contact Scottish Directors direct if such information was required from them.

(viii) DHSS AIDS Leaflet
SNBTS Directors were concerned that Scotland and England had issued different revised self-exclusion criteria.

It was agreed that a similar situation should be avoided in future and that this might best be achieved by the formation of a joint NBTS/SNBTS group to advise DHSS on the content of future messages to donors.

Dr Fraser would ask NBTS Directors to discuss this suggestion at their meeting on 21 January 1987.

It was hoped that such a group should include representatives from the Scottish and English Health Departments.

Because of the possible adverse effect of AIDS publicity on donations it was agreed to include a review of donor attendance figures on the agenda every six months. This would be discussed further at the January 1987 special meeting of the Co-ordinating Group for which Miss Corrie would prepare figures for the calendar year 1986.

(c) Notes on Transfusion (3d)

Work was progressing but Dr McClelland could not estimate a completion date.

(d) Directed donation and autologous transfusion (3e)

(i) **NBTS Advisory Committee**
No further meeting had yet been arranged (Committee last met March 1986). The Directors expressed concern at the infrequency of the meetings.

(ii) **Council on Scientific Affairs Report on the American Medical Association:**
Directors noted this report, which had been circulated, **and agreed that it would be necessary to consider the implementation of some form of autologous transfusion programme in the UK.**

(e) Unrelated bone marrow donations (3f)

(i) **UK**
Dr Fraser reported on the first meeting (27th November 1986) of the UK group established to assess the requirements for an unrelated bone marrow donor panel. (Dr Cash, Dr Gillon and Dr Yap, SE BTS were Scottish representatives). Two working groups had been established:

a. Convenor Dr Jack Gillon, Membership - Dr V Martlew, Dr Goffin, Dr Schwartz - to assess available literature and information for prospective bone marrow donors and to ensure uniformity.

b. Convenor - Dr Ben Bradley, Membership - Dr H C Gooi, Dr Schwartz, Dr Yap - to investigate DNA probe technology and banks: advise on suitability/competency of laboratories to carry out such work:

The main group would meet in February 1987 to assess progress.

The resource requirement for SNBTS RTCs to undertake recruitment and testing of bone marrow donors would be discussed at a forthcoming Co-ordinating Group.

(ii) **SNBTS**
The meeting scheduled for 16 December did not take place. **Miss Corrie undertook to check the current position with Dr Jack Gillon.**

(f) Surrogate testing for NANB (3g)

Nothing to report in the absence of Dr Gunson.

(g) Product Liability (3h)

(i) **CSA**

The General Manager had established that the responsible SHHD officer was the Chief Pharmacist and would arrange a meeting between himself, the Chief Pharmacist and Dr Cash.

Mr Murray advised that the provisions of the EEC document on product liability were now incorporated in the Consumer Protection Bill (Part I).

(ii) **NBTS**

There was nothing to report since the NBTS Advisory Committee had not met and the NBTS Directors had not discussed the matter.

(h) NIBSC (4)

NBTS Directors had supported the initiative to establish closer links with NIBSC and a joint letter (as agreed) had been sent by Drs Cash and Fraser to Dr Schild, Director of NIBSC. A positive response had been received and the first informal discussions between Drs Schild, Cash and Fraser would take place on 19 January 1987. A report would be made to Directors thereafter.

4. CLINICAL TRIAL CO-ORDINATORS

Dr Perry would circulate to Directors early in the New Year a full report of the recent meeting between SNBTS Clinical Trial Co-ordinators, himself and Dr Cash (in his capacity as Medical Adviser to PFC). He would also circulate a draft SOP for Clinical Trials for comment. It was noted Directors might wish to attend Dr Perry's forthcoming meeting with Dr Frances Rotblatt (DHSS).

Dr Perry summarised the current position of all current trials, as follows:

IVIgG/hypogammaglobinaemia: Trial was substantially completed and the information obtained had formed the basis of a product licence submission which was subsequently granted. Dr Yap would co-ordinate the continued surveillance of the product on a national basis.

Prophylactic trial: IVIgG in ITP: Dr R Crawford had co-ordinated this study, the information from which would form the basis of an application for a product licence variation. Follow-up of patients receiving product would continue.

IVIgG/measles: This study was not progressing as quickly as anticipated and it was now envisaged that completion would take three years, rather than two. The co-ordinators (Dr Ian Hann, RHSC, Glasgow and Dr R Crawford) had reported that in the children studied to date there were no apparent differences between the three groups of patients (control, IM product, IV product).

IVIgG/CMV (renal transplant): Dr Yap was due to assess the data obtained during this study of 33 renal transplant patients. A report would be available early in 1987.

Dr Cash noted his concern regarding an apparent loss of interest in this trial, thought to be due to the rotation of Senior Registrars, etc.

IVIgG/CMV (bone marrow transplant): It was now anticipated this study would take three years rather than two. There was no data yet available from the study of 33 patients.

The Hammersmith Hospital co-ordinator of this trial (Dr Apperley) was leaving in June 1987. **It was agreed to ensure that this trial was completed, if at all possible.**

IM Hepatitis A: Dr Perry gave a brief report on this study and **it was agreed that this topic would be included on the agenda of a future Co-ordinating Group.**

Burns Solution: As no report on the current status of the trial had been received from Dr Settle or Miss Sutherland Dr Cash had written seeking their views on the continuation of the trial.

New Factor VIII Product (Z8): Dr Cash reported that in vivo recovery and t/2 studies of Z8 might not be carried out in NI, SE and Glasgow as originally proposed until the Haemophilia Centre Directors concerned received from SHHD an assurance that compensation would be available in the event of adverse reactions, etc.

5. NBTS ANTI-D PLASMA SUPPLY

The current supply problems in England/Wales were noted. Dr Cash was particularly concerned that neither SHHD nor SNBTS had been approached to assist in alleviating the acute shortage. Mr Murray reported his informal discussions with DHSS colleagues, who had welcomed the approach. Directors agreed that as SNBTS stocks were in a strong position it was acceptable for them to meet individual requests from Directors in England and Wales in exceptional circumstances..

It was agreed that Dr Cash and Dr Perry would assess the current manufacture/supply situation in anticipation of a formal request for assistance from BPL.

6. EQUIPMENT DEFECT REPORTING

Following a recent incident in the NE when a centrifuge arm had broken loose, and Dr Urbaniak's difficulties in contacting the appropriate officer(s) listed in circulars 1982(GEN)31 & 32, SHHD had issued an addendum to the circulars.

It appeared there was also a reprinting system via CSA Supplies Division and Directors wished to know which should be used in the event of reoccurrence. It was agreed that Miss Corrie would take this up and endeavour to establish a satisfactory procedure for the future.

7. CBLA/CSA AGREEMENT: MONOCLONAL ANTIBODY Rh(D) CELL LINES

Dr Perry was confident that the cell lines would be made available early in 1987. Nothwithstanding this Dr Fraser reported CBLA were about to write to all Transfusion Directors offering the opportunity to evaluate two other CBLA anti-D monoclonal antibody cell lines. **It was agreed that once this letter was received Dr Perry would contact CBLA to establish the position regarding the proposed CSA/CBLA agreement.**

8. NEQAS ADVISORY PANEL FOR HAEMATOLOGY

Dr Fraser outlined the membership of the NEQAS Advisory Panel: representatives from the British Society for Haematology, Association of Clinical Pathologists and the IMLS. In addition, for the past six years the Chairman of the NBTS Directors meeting had been asked to sit as a member. The Chairman was, by tradition, nominated by the Royal College of Pathologists. The scheme was organised in 3 areas: serology, coagulation and haematology.

Dr Fraser had assumed the role of Organiser of the serology scheme following the retiral of Dr Holburn and consequently was no longer the NBTS Directors' representative. BBTS representation on the Panel had been sought and a steering group had been set up to consider membership. The Chairman of the Advisory Panel, Professor Alan Waters, had subsequently advised that it might be appropriate to continue the tradition of NBTS RTD representation. **It was agreed BBTS representation on the Panel was essential and Directors asked Dr Fraser to convey this SNBTS view to NBTS colleagues.**

9. UNIVERSITY OF SURREY: NBTS STUDY

Dr Cash explained the background to the request for SHHD advice on the release of information to Carol Sadler of the University of Surrey, who was undertaking an evaluation of the NBTS. It was agreed to supply to Mrs Sadler only information already published by ISD.

10. CENTRAL COMMITTEE FOR RESEARCH AND DEVELOPMENT IN BLOOD TRANSFUSION

Dr Gunson's letter of 11 December 1986 and the accompanying paper outlining proposals for restructuring the above Committee were tabled. **Directors agreed to consider the proposals at a future Co-ordinating Group and advise Dr Gunson/Dr Fraser of the outcome.**

11. DATE OF NEXT MEETING

Tuesday, 3rd March 1987.