NATIONAL DIRECTORATE OF THE NBTS

NBTS/CBLA LIAISON COMMITTEE

Minutes of the fifth meeting held on Thursday 16th November 1989 in Room 86, Hannibal House.

PRESENT:
- Dr. H.H. Gunson (in the Chair)
- Dr. Marcela Contreras
- Mr. B.J. Crowley
- Dr. I.D. Fraser (representing Dr. Ala)
- Mrs. Gaynor Fryers
- Dr. R.S. Lane
- Dr. D. Lee
- Dr. R.J. Moore

1. Apologies for absence - Dr. F.A. Ala

   The Chairman welcomed Mrs. Fryers and Dr. Fraser.

2. The minutes of the third meeting (10th August 1989) were approved.

3. Matters arising :

   3.1 Dr. Donald's paper recommended a uniform unit price per iu of anti-D for all plasmas. The break-even point for recovered plasma was 50 iu per g and for apheresed plasma 82 iu per g compared with the present banding system. This did not take account of the decision of the Committee at its last meeting that there should be a minimum price of such plasma up to 50 iu per g with a price per unit thereafter.

   Dr. Lee expressed concern that since most of the plasma came from apheresis that if donations between 50 iu and 82 iu per g were discontinued this may lead to a significant exclusion of plasma. This could have a serious effect on donors who were rejected and whilst current supplies may withstand such a reduction this may not be so in the future if antenatal prophylaxis was widely introduced or if losses occurred as had happened in the past.

   Mr. Crowley commented that BPL should maintain sufficient stocks of material for the production of products of which they were sole suppliers to ensure continuity of supply.

   It was agreed that Dr. Lane would provide, within one week, a specification for anti-D plasma stating the minimum level of anti-D required for the production of anti-D Ig and the maximum level of anti-D which was acceptable for inclusion into pools of normal fresh frozen plasma. A minimum price of £60 per Kg would be set for the minimum anti-D level and an appropriate

price per unit thereafter, this amount being determined by the budget allocation for the purchase of anti-D plasma.

Action - Dr. Lane

3.2 CBLA will respond to the agreed changes in prices for recovered and apheresed anti-tetanus plasma.

3.3 **Anti-CMV immunoglobulin**

Mrs. Fryers reported that 300 vials of anti-CMV Ig had been received from Scotland. A further delivery was expected of approximately 400 vials but the date for this delivery was not known.

It was agreed that Divisions would investigate the demand for this product in the respective regions and report to Mrs. Fryers before the end of 1989.

Action - Chairmen of Divisions

Dr. Contreras commented that Dr. P.D. Griffiths had queried whether the anti-CMV content of the Ig was an essential constituent in the i.v. Ig. It was suggested that she should discuss a possible trial with Dr. Griffiths.

Anti CMV/g will be distributed free of charge for the present.

3.4 **Trial of Autopheresis C plasma ex platelets**

Dr. Fraser reported that the trial had commenced and Baxter had provided 900 sets for the collection of 300 Kg plasma. However, the amount of plasma obtained in the procedure was variable (from 0 to over 400 ml in Bristol in 285 procedures) and that the number of procedures had now had to be increased to 1500 in the three RTCs. The yield and quality of the platelets was satisfactory.

3.5 **Factors VIII content in vials**

Dr. Lane reported that the first dilution step had been satisfactorily concluded and the second 10% dilution would commence shortly. One complicating factor was that yields were continually increasing.

A development programme for a 500 iu vial was in progress. It was hoped that the feasibility report of producing 500iu in a 50 ml vial would be available in March/April 1990.

3.6 **Distribution of anti-HBsAg Ig**

Mr. Crowley reported that it had not been possible to obtain information from PHLS on the management of cross-charging and CBLA proposed to continue the

existing policy for distribution of immunoglobulin via the PHLS for a further year from April 1990.

The Chairman agreed to advise Dr. Craske accordingly.
Action - Dr. Gunson

3.7 **Barcoding source plasma and plasma products**

Dr. Lane reported that a meeting had been held between Dr. Fisher, Mr, Kirkham, Dr. Snape and Mr. Williams and a note of the meeting was placed on file. It was the intention to maintain momentum in this matter.

4. **Screening for anti-VZ**

The Chairman said that Dr. Robinson was concerned about the cost and accuracy of testing for anti-VZ when a small number of donations were involved.

Dr. Lane agreed that BPL would undertake this testing. The donation and sample for testing should be sent to BPL at the same time. If the level of anti-VZ was not satisfactory for Ig preparation the plasma would be diverted for normal use. It was agreed that every effort should be made to plasmapherese donors with high levels of anti-VZ.

RTCs who wished to continue screening are encouraged to do so. Dr. Contreras reported that she was investigating, with BPL, the use of an ELISA test for this purpose.

Dr. Lane agreed to draft a letter on anti-VZ screening and send it to the Chairman for distribution to RTDs.
Action - Dr. Lane

5. **Specification for plasma for fractionation**

5.1 Dr. Lee reported that a significant quantity of plasma from PRP on the Haemonetics PCS was less than 300 ml. The Chairman reported that Dr. Robinson had made the same comment. Dr. Lane agreed to look into the practicality of opening packs containing 250 ml plasma and would write to the Chairman.
Action - Dr. Lane

5.2 Dr. Lee agreed to discuss with Haemonetics the possibility of exchanging the stock held in Manchester of V50 surge sets for those with a tear-down pack when this became available.

6. **Cross-accounting for fractionated plasma products**

6.1 The Chairman reported that at a meeting at the DH on 14th November 1989, from the NBTS point of view, the policy of National self-sufficiency in all plasma products had been accepted and that the provision of 480-490 tonnes of plasma for BPL in 1990/91 was approved.

6.2 Mr. Crowley reported that CBLA had hoped that for a further year from April 1990 that the system which should have operated this year but has not in all RHAs, viz: that RHAs would purchase products on behalf of Districts and supply them free of charge, could have been agreed. However, it was stated at the DH meeting that BPL should compete with Industry with respect to price, service and product reputation. This will require a rescheduling of the budget which would have to be agreed by DH including any resulting losses which may be incurred by CBLA.

It had also been agreed that prices for plasma would not change in 1990/91.

6.3 Dr. Moore commented that the DH would not try to influence Regions on the policy which they wished to operate with respect to the purchase of fractionated products. This could lead to a variation in practices throughout the country. In some Regions the RHA may purchase the products and supply to Districts with or without an onward charge, and in others the responsibility for purchasing products may be devolved to Districts.

6.4 On 15th November 1989 the Chairman of CBLA, Mr. R. Wing, Dr. Moore and Dr. Lane attended a meeting of Regional Pharmacists. They were supportive of the concept of National self-sufficiency and were willing to co-operate in the promotion and maximum use of BPL products. They stated that it was important to act now whilst budgets were being determined and agreed to contact their respective RTDs to assist in determining the level and source of product use.

6.5 It was agreed that the Chairman would write to RTDs as soon as possible and request that they:

(i) Identify as far as possible the major users of Factor VIII and albumin products in the hospitals they service.

(ii) Ensure that they discuss with the Regional Pharmacist ways in which he/she can assist in defining the purchasing points for these products.

It was further agreed that the National Directorate and the CBLA will prepare a joint paper for Regional General Managers and Regional Treasurers reviewing the options which exist for appropriate budget holders and the preferred supply channels for BPL products, to maximise their uptake in the NHS.

7. Strategy and targets for specific plasmas

The strategy for the supply of immunoglobulins was contained in the sales plan for BPL. It was agreed that maximum and minimum inventory levels for specific plasmas should be

supplied to the National Directorate who would monitor the provision of specific plasmas. In conjunction with BPL deficiencies or excesses could be corrected, hopefully, before the situation became critical.

Action - Dr. Lane

8. **Payments for human plasma/serum for reagents**

Mr. Crowley agreed that plasma for this purpose would be purchased, at an agreed price, before the end of the financial year.

9. **Six monthly plasma returns**

9.1 It was noted that the quantity of plasma was in line with the target of 420 tonnes FFP for 1989/90.

9.2 Dr. Fraser commented that the total amount of plasma from S.W. Region was less than the total of FFP supplied. Dr. Moore agreed to look into this.

Action - Dr. Moore

9.3 Dr. Lane stated that unless there was an increase to the 480/490 tonne rate in the early part of 1990/91, the stock of plasma available at BPL would be insufficient to maintain an adequate amount in quarantine. The Chairman considered that with the developments proposed that the plasma supplied should begin to increase in early 1990.

10. **Any other business**

10.1 RTDs had been asked to bid for the surplus stocks of Factor VIII available at BPL. These amounted approximately to an additional 10,000 vials per month until the end of the financial year.

10.2 It was agreed that the National Directorate would look into the reporting of inventories of plasma products at RTCs so that BPL could have up-to-date information.

10.3 It was noted that one company had filed recombinent Factor VIII for FDA licencing.

10.4 Dr. Lane, in answer to a question by Dr. Contreras, stated that BPL had a Factor VIII development programme from human plasma sources.

11. The next meeting will be held at the National Directorate, Gateway House, Manchester on Thursday 1st February 1990.