NATIONAL DIRECTORATE OF THE NBTS

NBTS/CBLA LIAISON COMMITTEE

Minutes of the tenth meeting held at CBLA on Wednesday 10th April 1991.

PRESENT: Dr. H.H. Gunson (in the Chair)
Dr. F.A. Ala
Mr. B.J. Crowley,
Mrs. G. Fryers
Dr. J.F. Harrison
Dr. R.S. Lane
Dr. E.A. Robinson
Mr. B.J. Savery

1. Apologies for absence - Dr. R.J. Moore

2. The minutes of the ninth meeting held on 16th January 1991 were approved.

3. Matters arising

3.1 **Pricing policy for Factor VIII**

It was stated at the last meeting that Factor VIII would be priced per vial. However, technical difficulties have been encountered in obtaining an average of 250 iu per vial with a spread of unitage acceptable to NIBSC. This policy could not, therefore, be implemented and Factor VIII will have to continue to be sold at a given price per unit. Mr. Crowley apologised for not advising the NBTS of the reversal of this decision.

3.2 It was agreed that HBs vaccinated donors could continue to donate high titre anti-HBs plasma.

3.3 As far as is known only South London RTC add a handling charge to BPL products for distribution, but the system for distributing products to SW/SE Thames was due to change in three months time. Dr. Harrison said she may have a problem with some hospitals since she delivered products to Haematology Departments and was receiving requests for them to be delivered to Pharmacies. Mrs. Fryers agreed to monitor the situation and liaise with Mr. Savery as appropriate.

Action - Mrs. Fryers

3.4 **Fractionation of anti-HCV tested plasma**

The discussion paper was considered and several comments were made. In general, the principle of ensuring that plasma which was fractionated was anti-HCV negative was agreed. The definition of

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whether PCR should be a definitive test for acceptance/non-acceptance of plasma was left open. Dr. Ala commented that undue attention seemed to be given to this virus, compared with, say, HBV. Dr. Gunson replied that this was due to the difficulties in obtaining the confirmatory anti-HCV tests, although RIBA 2nd generation did appear to be an improvement on earlier versions of the test.

Dr. Lane said that he had received a letter from MCA which stated that untested plasma could continue to be fractionated after HCV antibody testing was instituted.

3.5 Mr. Crowley stated that a small quantity of ALT tested plasma was required, BPL had recently received requests from KABI to manufacture anti-thrombin III for sale on the German market where ALT testing of starting plasma was obligatory.

BPL have contracted with three RTCs for specific quantities of ALT tested apheresed plasma.

4. PLASMA SUPPLY

4.1 Data for April 1990 to February 1991 indicated that the yearly target for 1990/91 would be met.

Dr. Lane commented that the quantity of recovered plasma during the past year was most encouraging compared with some years ago and considered that RTCs should be congratulated on this achievement.

4.2 Plasma requirements - 1991/92

4.21 A total of 497 tonnes of normal plasma had been requested by BPL. Dr. Moore's paper was discussed and the bids submitted by RTCs was accepted although it was approximately 11 tonnes over the target. This will allow some slippage which may occur from factors as yet unknown. Dr. Gunson said that the National Directorate would monitor the plasma collection quarterly and endeavour to maintain supplies on target.

Action - National Directorate

Dr. Robinson commented that the plasma supplied by Yorkshire was costing the RTC approximately £15 per kg more than the income she received.

4.22 With respect to specific plasmas, Dr. Lane agreed to look again at the quantities of each which had been requested.

Action - Dr. Lane

4.23 Anti-CMV immunoglobulin had shown a drop in sales of 30% since charging had been introduced and it was agreed that the monitoring system should be reviewed.

Action - Dr. Robinson/Mrs. Fryers

4.24 It was noted that one surgeon was using large quantities of HBsIg for liver transplant patients. These were being obtained commercially. It was difficult to know whether attempts should be made to produce HBsIg for this purpose from BPL since its use could cease if it was shown not to be effective.

4.25 It was announced that PHLS would, from 1st April 1991, purchase the specific immunoglobulins they handle on behalf of BPL, but will distribute the products free to users during the coming year.

5. **PROCEDURE FOR AMENDING SPECIFICATIONS FOR PLASMA SUPPLIED TO BPL**

The proposals to use QUIN for this purpose were agreed. It was noted that regulatory requirements carry much more weight than prior to the abolition of Crown Immunity and there were mandatory elements in the specification. However, it was agreed that the implementation of changes in the specification had to be carried out to agreed timescale which should allow for any economic effects of the changes.

Other changes may be desirable rather than mandatory and would have to be given appropriate priority.

6. **SERVICE AGREEMENTS (CONTRACTS) WITH RTCs FOR PLASMA SUPPLIES**

Mr. Crowley commented that these should be between RTCs (or their management bodies) and CBLA rather than with BPL.

It was agreed that Dr. Moore and Mr. Savery should consider this matter and present a report to a subsequent meeting of the Liaison Committee.

Action - Dr. Moore/Mr. Savery

7. Any other Business

7.1 Mrs. Fryers tabled two papers

(i) Current therapeutic ordering position by region

(ii) Current diagnostics ordering position by region

These are appended to the minutes (Appendix 1).

7.2 Dr. Robinson raised the question of shortening of the plasma quarantine procedure from 13 to 4 weeks.

It was noted that this could lead to certain problems in respect to delayed onset of infections. The specifications would need to be changed to take account of this.

Dr. Gunson commented that he would prefer to see the introduction of a checking procedure at BPL before this change was instituted and he hoped the pilot scheme could be introduced at an early date.

8. Date, time and place of next meeting

Friday 21st June 1991, National Directorate, Manchester, at 11.00 a.m.