NATIONAL DIRECTORATE OF THE NBTS

NBTS/CBLA Liaison Committee

Minutes of the fourteenth meeting of the NBTS/CBLA Liaison Committee held on Thursday 19th March 1992 in Gateway House, Manchester.

Present: Dr. H.H. Gunson (In the Chair)
Dr. C.C. Entwistle
Mrs. G. Fryers
Dr. J.F. Harrison
Dr. R.S. Lane
Dr. D. Lee
Dr. R.J. Moore
Mr. B.J. Savery
Dr. T.J. Snape

1. **Apologies for Absence**

Apologies were received from Dr. E.A.E. Robinson, Mr. B.J. Crowley.

2. **Minutes of Last Meeting**

The minutes of the last meeting were accepted as a true record.

3. **Matters Arising**

3.1 Distribution Charges Policy

Mrs. Fryers reported that BPL had written to RTCs and had been able to offer an allocation to cover distribution costs. Colindale, South Thames and Northern would not be entering into distribution arrangements but negotiations with other RTCs were continuing.

3.2 Provision of Specific Plasma

The plasma targets for 92/93 agreed with RTCs to meet BPLs previously stated requirements were discussed.

3.21 Anti-CMV

Dr. Snape for BPL said that the collapse of the market for the product meant BPL no longer had a requirement for this plasma and in fact had considerable quantities in stock. There was strong protest from BTS members at the short notice and potential loss of planned revenue so late in the planning process. It was regretted that the committee

However, it was finally agreed that since the plasma could not be used, RTCs would be asked to stop production although this would not be instantaneous.

Action - Dr. Gunson

3.22 Anti-HBs

Dr. Snape said BPL had an immediate requirement for an additional 1 tonne of anti-HBs plasma for the manufacture and trial of an IV IgG. RTCs would be asked to bid.

Action - Dr. Gunson

3.23 Anti-VZ

Dr. Entwistle reported that the standard provided by BPL for this plasma had changed and thereby excluded previously acceptable plasma. Dr. Snape undertook to investigate.

Action - Dr. Snape

3.24 Anti-D

Dr. Lee gave advance warning of the probable outcome of the ante-natal prophylaxis trial. It is likely that the trial will indicate that 2 x 250 i.u. of anti-D does not give sufficient protection and that recommended practice will be 2 x 500 i.u. This would have obvious implications for increasing consumption and it was agreed to keep the plasma requirement under review.

3.3 BPL forecast plasma requirement

Dr. Snape presented the requirements for 1993/94 and 1994/95. For both years, the total was 530 - 540 tonnes excluding specifics. Specifics would be:

Anti-D	3.0 tonnes
Anti-tetanus	5.5 tonnes
Anti-VZ	1.0 tonnes
Anti-HBs	0.5 tonnes
Anti-rabies	0.15 tonnes
Anti-HA	1.0 tonnes ($\geq$100iu/ml)
Anti-CMV	no requirement

It was agreed that these figures would need to be confirmed in the preceding Autumn so that they could be incorporated in business plans.

3.4 Positive identification of plasma packs at Elstree

The arrangement for bar-code reading all packs at Elstree for comparison with a master electronic record from the RTC have so far been disappointing. Several RTCs have not provided adequate data and BPLs checking capability has not been satisfactory. It was agreed that the problems should be identified and solved as soon as possible.

Action - Dr. Moore
Dr. Snape

3.5 Virally inactivated plasma for therapeutic use

Dr. Gunson reported that Professor Allain has entered into an agreement with Octapharma for East Anglia, Northern and West Midlands RTCs to provide 300 kg of plasma which will be processed free of charge. The resulting product would be used in a clinical trial protocol prepared by Professor Allain.

Dr. Lane said that CBLA and Octapharma had agreed a draft contract for a second trial with plasma from another three centres. The MCA have said the product is likely to be licensable and the trial should therefore take place under a CTX certificate and with full ethical approval.

It was agreed that since both trials were complementary it would be sensible to work under the same CTX and avoid duplication. Dr. Lane would liaise with Professor Allain.

Action - Dr. Lane

3.6 Plasma specification

The plasma specification was agreed and signed.
Dr. Snape would write to all RTDs to provide reassurance about the likely take-up of concessionary plasma for 1992/93.

Action - Dr. Snape

The specification would come into force from 1st July to allow computer reprogramming but the testing requirements would come into effect from 1st April. It was agreed that in future a rapid update mechanism should be established to incorporate small agreed changes in the specification.

4. **Sale of Factor VIII SM**

Mrs. Fryers said that the special offer on Factor VIII SM should have been sent to RTDs who contract on behalf of users. BPL regretted the omission.

5. **Testing of plasma donations for HCV**

Dr. Snape presented a paper showing that although HCV testing started in September 1991, many RTCs had only recently stopped sending remnants of non-tested plasmas to BPL. BPL would be sending a formal letter to all RTCs asking them to ensure only HCV tested plasma was sent from now on. The procedure is to ensure that BPL can build stocks consisting solely of tested plasma so that EC directives and commercial pressures can be met.

6. **Any other business**

Dr. Snape reported that individual fractionation of plasma from single RTCs had shown at least one centre with a plasma which would not meet the Factor VIII levels stated in BPLs product licence. This was probably because the plasma was cooled in a cold room rather than a blast freezer. It was agreed that such feedback was crucial to improving practice and should be disseminated widely when available.

Action - Dr. Snape

7. **Date, venue and time of next meeting**

The next meeting will take place at Elstree on Monday 15th June 1992, to commence at 10.30.