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IN CONFIDENCECENTRAL BLOOD LABORATORIES AUTHORITY

Minutes of the sixteenth meeting of the Central Blood Laboratories Authority held on the 1 February 1985 in the Board Room, the Crest at 11.00 a.m.

Present: Mr R D Smart (Chairman)  
Mr A S Jerwood  
Dr D P Thomas

In attendance: Professor A Bloom  
Dame Phyllis Friend  
Dr H H Gunson  
Dr G A Stewart (from item 85/6)  
Mr W P N Armour (Secretary)  
Dr A M Holburn, Director (BGRL)  
Dr R S Lane, Director (BPL)  
██████████ (DHSS)

PART 11/85 Apologies for Absence

An apology for absence was received from Mr M G Storey.

2/85 Membership

The Chairman reported that he had received a letter from Dr E L Harris, advising that his membership of the Authority had ceased from the end of November 1984. The meeting agreed that the Chairman should write to Dr Harris to express appreciation of his work with the Authority and to extend good wishes.

██████████ offered apologies on behalf of DHSS on the shortfall in the membership, indicating that replacements awaited confirmation by Ministers. The Chairman confirmed that the Authority had a properly constituted quorum for the current meeting and welcomed Dame Phyllis Friend, Professor Bloom, Dr Gunson and Dr Stewart, as guests on this occasion, inviting them to contribute to the meeting albeit without voting rights.

3/85 Minutes of Previous Meeting

The minutes of the meeting held on 28 November 1984 were approved and signed by the Chairman, subject to the following amendment:

Item 88/84 (88.3) second paragraph, second sentence to read: 'It was noted that the anti-A and anti-B monoclonals were of a better standard than the human material and hospitals were not required to pay for these products'.

4/85

Matters Arising from the Minutes4.1 Mr R D Smart

The Chairman expressed his gratitude for the messages of good wishes received before [REDACTED]; he thanked Mr A S Jerwood for acting on his behalf during this period.

4.2 Logo

The Chairman displayed the artwork and proposed adoption of the BPL and BGRL logos with the provision that the crown be changed to the appropriate 'Edward' style, and also that the CBLA's own logo should consist of the twin hearts with the CBLA horizontally below. The meeting concurred. The Chairman ruled that the prize be awarded to the winner of the internal competition held to design the logo.

4.3 Central Committee for Research & Development in Blood Transfusion

Professor Bloom made reference to a letter circulated by BPL and requested clarification of the distribution of Factor 8 and heat treated Factor 8 following a discussion in the Central Committee for Research and Development in Blood Transfusion. He indicated that the distribution direct to Haemophilia Directors, although probably welcomed by H.C.D's was a disturbing change made without discussion with Blood Transfusion Directors and differed from the agreement made with Haemophilia Directors. This concern was reinforced by Dr Gunson who discussed the principles of this change. Dr Lane referred to the meeting held at Elstree with the Haemophilia Directors on 10 December 1984 and the agreements reached. He stated that all Factor 8 concentrate was not suitable for heat treatment; that samples of standard Factor 8 lost potency when heat-treated; and that large quantities of Factor 8 not heat treated remained in stock. He pointed out that a reference had been made to the Committee on the Safety of Medicines and gave details of an intensive trial of Factor 8Y. He highlighted the following problems; the continuity of supply against its limited availability, the difficulty of pro-rata distribution; the relevance of the trial to the license application; and the shortest way to establish Factor 8Y. He expected a return to normal distribution in the Summer of 1985. Dr Thomas referred to the excess of Factor 8 now on the market saying that non-heat treated Factor 8 was no longer available commercially. He believed the Committee on the Safety of Medicines was licensing standard Factor 8 when heat-treated without trial.

He pointed out that BPL had no product license and thought that a license was necessary, despite Crown privilege. Dr Lane stressed the desirability of producing this new safer product (Factor 8Y) as early as possible. There was considerable discussion on the interim situation and the problems that a poor decision now would create for the long term.

The Chairman reviewed the need to consult Haemophilia Directors and Blood Transfusion Directors on the distribution on the limited amounts of heat-treated Factor 8 available and stressed the need to continue liaison with Dr Gunson and Professor Bloom's Committee. The Director BPL should then decide priorities on the basis of advice available. It was noted that Professor Bloom's Committee would next meet on the 18 February. The Chairman pointed out that the assessment on Factor 8 was good and that for any trial, the smallest number of patients necessary to establish protocol should be determined. It was agreed to proceed with Factor 8Y from April and use the small amount now available for protocol trials. Dr Gunson and Professor Bloom would advise the Director, BPL of their views. ██████████ referring to the license situation stressed the need to apply for any variations as soon as possible.

5/85

#### Plasma Supply

A report prepared jointly by Dr Gunson and the Director BPL on plasma supply (CBLA 85/1) was received and noted. Dr Gunson introduced the subject against the background of the failure of some Regions to make provision for meeting their targets. ██████████ outlined the Government's policy on funding. It was noted that 'Top Slicing' was not favoured since the cash had already been allocated, was known, and identified. The Chairman stated that the DHSS should be asked to ensure plasma deliveries against this cash allocation to avoid the factory having insufficient source material on commissioning. He pointed out that although less heat treated Factor 8 would be produced from a given pool, the BPL product value remained ahead of that from commercial sources. Mr Williams said that the matter of securing increased supplies following cash allocations was under consideration at the Department but the post-Griffiths reorganisation appeared to cloud methods of dealing with this type of situation. ██████████ was asked to provide a progress report for the March meeting.

In the subsequent discussion Dr Gunson introduced his recommendation on collection by plasmapheresis referring to the availability of plasmapheresis machines and the advantages of central funding.

There was further discussion following Professor Bloom's advice that some Haemophilia Directors were going over to commercial

heat-treated Factor 9. The meeting was advised that BPL was working on this problem and that results were expected by April. The Chairman asked that heat-treated Factor 9 and associated licensing arrangements be placed on the agenda for the Authority's March meeting.

With regard to Professor Brownlee's work on genetically engineered Factor 9, Professor Bloom indicated that CBLA should be prepared for a request for assistance.

6/85

#### Redevelopment of BPL

A copy of the minutes of the Project Control Committee (CBLA 85/2) was received and noted. Mr Jerwood informed the Authority that he would be meeting the Managing Director of MHNE to discuss the progress of the redevelopment. Although R M Douglas would be back on programme by April there was a problem with the ducting contractor. A meeting with the ducting firm's Chairman would be arranged during the 1st or 2nd week in February to resolve this problem.

Mr Jerwood then reported on his meeting with Mr Kenneth Clarke and Mr Chris France at which he was accompanied by Mr Armour. After the Minister had expressed his concern regarding finance, Mr Jerwood detailed the CBLA's situation, confirming that some communication problems had existed both at the CBLA and DHSS, and noted the need to address itself in future to all branches of the DHSS to ensure full and appropriate circulation of information. Mr Jerwood said that the Minister had allowed the £35.35m for the factory, but not the £3.5m required for the Warehouse and Quality Control building. These items would need to be separately discussed with Mr France. With regard to the possibility of income from foreign sales it was thought that although therapeutic material could be sold abroad there might be a difficulty with the FDA in view of the state of BPL's Quality Control accommodation. Mr Jerwood looked forward to receiving a record of the meeting with the Minister, a clarification of the £35.35m as a cash limit at 1984 prices and the possibilities for re-negotiating the £3.5m. The Secretary said that it was very important that there was an update to the Fast Track letter of the 22 June 1984. [REDACTED] would follow this up. The formal record of the Ministerial meeting was still awaited with appropriate papers and [REDACTED] indicated that the cash limit would be approved following the receipt of these documents.

7/85

#### Finance

The Chairman opened this item by saying that in future it would be dealt with in two parts as follows:-

(a) Finance

(b) Production

and that for the current meeting he would deal with the items in that order.

#### 7.1 Budget Statement

Copies of the budget statement and Secretary's report (CBLA 85/3) were received and noted. Mr Armour referred to the BGRL overspending and the possibility of transferring cash from Capital to Revenue and from BPL to BGRL.

#### 7.2 Revised and Forecast Estimates

A copy of the Secretary's report confirming Sub-Committee meetings held on 28 November 1984 and 14 January 1985 to examine in detail forecast estimates 1985/86 and the revised forecast estimates (CBLA 85/6) were received and noted. The differences arising from enforced changes in accounting procedures and that the BGRL overspend arose from the procedure for buying and distributing monoclonals was noted. Dr Thomas queried the need for Portacabins against the new factory background and he was advised that they were needed to enable Quality Control to cope with the increased load which the new factory would produce and that they were intended as temporary accommodation only. Following discussion the Chairman said that (a) there should be earlier presentation of the budget to the DHSS, (b) money spent on products saved money for the NHS and (c) an increased manpower target would need to be met if the requirement for self-sufficiency was to be achieved. It also presumed an adequate and increasing expenditure on R & D.

#### 7.3 Audit of Accounts 1 April 1983 - 31 March 1984

A copy of a report by the Auditor to the Secretary of State on the audit of the Accounts of the CBLA for the period 1 April 1983 - 31 March 1984 together with the Secretary's draft response (CBLA 85/7) was received and noted. The Authority members were asked to review the documents and advise the Secretary of any comments they wished to raise.

#### 7.4 Report on BPL Products

A copy of the report on the production and issue of BPL products (CBLA 85/4) was received and noted.

#### 7.5 Reports on BGRL Products

A copy of the report on BGRL production (CBLA 85/6) was received and noted. Dr Gunson referred to the possibility of charging and the Chairman noted that the choice lay between charging and running out of funds. There followed some

discussions on charges to the private sector but it was noted that this had not yet been approved. It was also thought that there would be difficulties in charging hospitals for products as some were supplied direct and others via Regions.

8/85 HTLV III Virus - RIA Test

Dr G A Stewart proclaimed an interest in this matter and withdrew from the meeting.

The Director advised that if given the antibody BPL could produce a test as an alternative to the Chester Beatty's work in association with industry, at a much lower cost. Dr Gunson confirmed the necessity for the test and referred to a Departmental working party considering the matter. It was noted that the CBLA role in this matter was not yet established but there would be a related capital requirement for equipment for RIA tests. The Chairman stressed that revenue sparing was as important as saving. Dr Gunson emphasised that the enzyme assay was a United States test and if the United Kingdom needed to be converted for enzyme testing it would pose a serious problem for the continuance of RIA testing. It was therefore considered vital that a British test be developed.

Dr G A Stewart re-joined the meeting at this point.

9/85 BPL Product Advertising

The Director BPL reviewed utilization of BPL products highlighting the need to advertise them. He referred to the DCMO's undertaking to examine what facilities existed in the DHSS to bring the products to the notice of users. At Mr Jerwood's suggestion the Chairman undertook to review the advertising potential and the BPL Director was asked to prepare a target list of approximately 50 names to be brought forward for March.

10/85 1985/86 Product Pricing

A copy of the Secretary's report and Product Price list for BPL 1985/86 (CBLA 85/8) was received and noted. The price list represented a 4% uplift from 1 April 1985. Factor 8 and Factor 8Y prices were not established on the list which was recommended to  for DHSS approval. The original Factor 8 would now be referred to as Standard Factor 8.

11/85 New Salary Scales and Terms and Conditions

The Secretary reported on the recent commercial job evaluation, and the visit by the DHSS Job Evaluation Section Chief in December. To date no comments had been received from DHSS. The current time-scale for factory completion now produced an urgency for development of the staff grading structure to enable satisfactory manning of the factory in time. The Director BPL expressed concern, referring to recent personnel gains and losses.

The Chairman asked [REDACTED] to refer this delay to 'P' Division and keep the Authority informed.

12/85 HC (85) 1 Advisory Committee on Dangerous Pathogens (ACDP)  
Interim Guidelines on Acquired Immune Deficiency Syndrome (AIDS)

A copy of this Health Circular together with Interim Guidelines on AIDS (CBLA 85/9) was received and noted.

The Director BPL reported that he had initiated an internal investigation within BPL covering all infective viruses and expected to be able to report in March. This action was endorsed and the Director BGRL indicated that he would follow a similar line of action.

13/85 HC (84) 18 Report of the DHSS/NHS Working Group (Salmon Report)

A copy of this Health Circular (CBLA 85/10) was received and noted.

Whilst it was considered that the Circular was not essentially applicable to the CBLA, the Secretary would report to the Authority if necessary.

14/85 Energy Policy

The Director BPL enlarged upon BPL's current energy policy which was recently boosted by a meeting held with the Minister of Fuel and Power. He would report conclusions.

15/85 Any Other Business

There was no other business.

16/85 Date of Next Meeting

The date of the next meeting was confirmed as 27 March 1985 to be held in the Crest at 11.00 a.m. There being no further business the meeting closed at 15.30 p.m.

CONFIDENTIALPART II17/85 BGRL

The Chairman thanked Dr Thomas and Dr Stewart for their report on BGRL which the Authority had accepted. It was agreed that the Chairman would counsel Dr Holburn. The Chairman indicated that he was not satisfied that BGRL presently satisfied the BTS requirements and proposed that the unit should continue at Oxford for 1985 whilst the possibility of transferring the manufacturing process to Elstree was considered. It was noted that the transfer of production to the present BPL building would produce changes to the job content of both Directors. It might also involve a new role for Dr Phillips. The specific advice of Dr Gunson would be sought on the detailed proposals but it was agreed that: -

- a) The R & D required expansion
- b) The Proposal required costing
- c) A Review of the control of QC would be required to assess any BPL QC involvement

An examination of the consequences of changing to this pattern of BGRL activity would be necessary. The development of monoclonal antibodies and the bovine serum albumin service would require the charging of Authorities if the DHSS would not fund them. [REDACTED] was asked to give the DHSS view as soon as possible.

18/85 Monoclonal Antibodies

The Secretary reported that he was ensuring the co-ordination of the work of Dr Anstee and Dr Bradley because there was a possibility of improving the overall monoclonal production. The Authority wished to keep this matter under review.

19/85 Staffing & Plasma Supply

Dr Thomas referred to the concern over staffing problems and plasma supply.

It was noted that [REDACTED] had been asked to act in the case of plasma supply. The concern over P Division's delays with the proposed staff grading structure would be raised again with the DHSS. The Chairman was prepared to discuss these points with [REDACTED] if necessary. Dame Phyllis Friend commented on the apparent high staff turn-over rate.

The Chairman recorded his thanks to the retiring Authority members.