IN CONFIDENCE

CENTRAL BLOOD LABORATORIES AUTHORITY

Minutes of the twenty third meeting of the Central Blood Laboratories Authority held on 25 March, 1986 in the Board Room, the Crest.

Present:	Mr R D Smart (Chairman) Dr H H Gunson Mr A S Jerwood Mr W V S Seccombe Dr D P Thomas Mr C Walker Mr G A Wilson Mr R A Wing
In Attendance:	Mr W P N Armour (Secretary) Dr R S Lane (Director BPL) Dr R Moore (DHSS)

Part 1

18/86 Apologies for Absence

There were no apologies for absence received.

19/86 Minutes of Previous Meeting

The minutes of the meeting held on 28 January 1986 were approved and signed by the Chairman as a correct record.

20/86 Matters Arising from the Minutes

20.1 Overseas Marketing - Proposed Collaboration with Biotest - BPL Patent Situation

The Director BPL reported that he was still awaiting a report from Biotest on the material sent from BPL. He said that the despatch of material did raise the issue of product liability. The Chairman said that he had written to the Deputy Chief Medical Officer, DHSS in March 1985 about product liability but had not yet received a reply. Dr Moore agreed to follow this up.

It was noted that, following the meeting with the Procurement Executive of MoD on 4 March, patent applications on behalf of the Authority had been filed for Factor VIIIY.

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The Chairman emphasised the desirability of having patents on file as soon as possible. He said that he had made further enquiries of possible membership of Ringdoc but this would require the services of a full time, fully qualified Scientific Information Officer at BPL. He recommended therefore that the Authority should use a patent agent as necessary. This was agreed. The Secretary would carry through the arrangements for this.

20.2 Development of Monoclonal Antibodies

The Secretary reported that talks had been held with the various companies interested in exploiting Anti-D, including Celltech, Biotest and Bioscot. It was noted that Biotest and Bioscot were anxious to proceed whilst Celltech wished to evaluate the cell-line in the first instance. The Chairman thought that a strategy for diagnostics was required; Bioscot, however, did not have sufficient resources at present. After discussion it was agreed to invite Dr Gunson to give consideration to what constituted a portfolio to produce monoclonal antibodies for BGRL and the CSA, Scotland. After this exercise had been carried out, discussions could be held with the CSA.

20.3 Charging for BGRL Products

The Secretary reported that a price for monoclonal reagents and bovine serum albumin had now been agreed with DHSS. Charges to NHS Authorities would commence on 1 April 1986. It was noted that a slight discrepancy remained in regard to the cost of Anti-A, B. The Secretary would deal with this matter.

20.4 Central Committee for Research and Development in Blood Transfusion

The Secretary confirmed that a DHSS response had been received which gave approval in principle to the collaboration with Professor G Brownlee and Celltech in the production of Factor IX by genetically engineered methods. At a meeting held the previous day, Professor L Luzzatto, Chairman of the Genetic Engineering Sub-Committee, was informed of the latest position which included Authority finance being made available to enable the collaboration to get under way. It was noted that at the present time, Celltech had not given any financial commitment to the project. The Secretary, however, would be pursuing this issue with Celltech.

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21/86 Plasma Supply

The Director BPL commented on BPL's satisfactory position at the current time in regard to its supply of plasma. The effectiveness of the SAG programme was particularly relevant. He said that this position had created some difficulties in regard to storage but these difficulties would be alleviated when additional cold storage facilities were available in May.

Revised projection figures relating to plasma use, storage and production would be available at the next Authority meeting. Dr Moore said that he had postponed giving this information to Regions as the precise figures had not been available at the time

The Director BPL did highlight the main area of concern which was the four Regions which were not meeting their targets with no real solution likely to emerge within these Regions in the 4/5 year period.

Dr Gunson raised a question about the use of plasma tested for HTLV3 virus, and whether or not some of it already stored would have to be destroyed. The Director BPL expressed the view that there was not a problem concerning Factor 8 or 9 whilst all remaining plasma could be stored as Factor 2. He felt therefore that all the plasma currently stored would be used.

22/86 Redevelopment of BPL

22.1 Reports on the redevelopment, including the minutes of meetings of the Project Control Committee held on 28 February and 21 March, 1986 (CBLA 86/13) were received and noted.

Mr Jerwood referred to the fifth report of the Project Co-ordinator and said that a lot of problems at the current time concerned the major subcontracts. Theft and vandalism on site was also a major concern. A recommendation made by the PCC at its last meeting was that an additional two quantity surveyors should be appointed by BDP for a period of two months at an approximate expenditure of £8,000. The PCC's recommendation was agreed.

Mr Wing referred to the finishing dates outlined in the Project Co-ordinator's report and asked if they were likely to be realistic. The Secretary said that there was definitely an incentive for MHNE to adhere to the dates as they would lose money after this time.

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The Director BPL confirmed that the second meeting of Principals had taken place the previous day. In summary, he said that Mr G Walden, after receiving clear instructions from the MHNE Board to look closely at the project, had perceived considerable deficiencies in the site management. Immediate steps had been taken to rectify matters and a completely new programme had been produced which gave a finishing date at the end of September.

In addition, it was noted that Mr M Whitney, Project Co-ordinator, had now been invited to study both design and quantity surveying work in detail at Southampton. Mr Walden had subsequently been requested to return in April and identify the additional working that would be necessary to adhere to the new programme.

Members were informed of personality clashes throughout the redevelopment between the Project Manager MHNE (Mr E Ayre) and Project Manager CBLA (Mr W Jackson) and MHNE had made a recent request for Mr Jackson's removal from the redevelopment programme. The Secretary strongly recommended that Mr Jackson should remain as Project Manager as he was essential to early operation of the building but that at meetings with sub-contractors he should act as an observer only. This was agreed.

Mr Walker emphasised his lack of confidence in MHNE to complete the project at either the dates or costs specified and questioned again the possibility of legal redress for the CBLA. The Secretary confirmed that there was no redress as such with MHNE in the contract but he considered it might be possible to receive compensation in regard to either design errors or time deficiencies.

It was noted that legal advice had been obtained from Messrs Coward Chance in regard to the contract with MHNE. They had commented on the unsuitability of the contract, and, whilst it was probably not in the Authority's interests to sue MHNE, they felt CBLA might be advised to consult Counsel.

After discussion it was agreed to await events with MHNE's new programme whilst keeping in mind the legal possibilities open to the Authority.

22.2 A summary of BPL Commissioning Planning to date (CBLA 86/14) was received and noted.

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22.3 Master Plan - Warehousing and Q.C. Buildilng

The Secretary reported that the Master Plan was not yet complete. In regard to the Warehouse and Q.C. Building, it was noted that funding would be carried out through the normal NHS Capricode system. DHSS had asked the Authority therefore for details of the overall capital required for the necessary developments on the total site. The Secretary referred to the tendering procedure for consultants under Capricode and covered an exception formula whereby, for purposes of speed, the tendering procedure could be waived. He sought the approval of the Authority to extend BDP's current contract to act as project managers and design consultants in the new Warehouse and Q.C. Development to achieve maximum time benefit and to avoid waste of valuable production staff time. This was approved.

23/86 Finance

23.1 Budget Statement

Copies of the budget statement and Secretary's report (CBLA 86/15) were received and noted.

The Secretary reported the receipt of the interim cash limit 1986/7, which essentially was the same as the previous year, until an accurate requirement of funds had been prepared by the Authority because of the delay in commissioning the new building, particularly the staffing.

23.2 NHS Audit

The Secretary reported that a copy of the Final Report by the Statutory Auditor on the audit of the accounts of the CBLA for the year ended 31 March 1985 had been received. Statements of Accounts duly certified had also been received and he would circulate copies of the documents accordingly.

It was noted that the internal audit service provided by Barnet Health Authority during this period had not worked satisfactorily. The Secretary outlined the intention to use Deloittes on a temporary basis before going out to tender in the next financial year. He said that the position would be reviewed if it was felt necessary for the Authority to employ its own internal auditors as it expanded.

On the recommendation of the Secretary, the Authority approved an increase in the sum that could be written off by the Authority from £250 to £500.

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The Secretary informed the Authority of certain stock items which required writing-off, (copy appended in the minute book). Approval of the DHSS was necessary for this. This was agreed.

24/86 Production

24.1 Report on BPL Products

A copy of the report on the production and issue of BPL products (CBLA 86/16) was received and noted.

The Director BPL referred to the income received from RIA tests. He said that in view of the recent HTLV 3 test produced by Wellcome, which had linked to it an eliza test for hepatitis B, the RIA test produced by BPL might not be required in the future, which would result in a loss of income. He did, however, confirm BPL's aims to produce its own enzyme linked test for hepatitis and a letter of intent had been sent to CSL, Australia about this. A response from CSL was currently awaited. The Director said that the price of material used in the enzyme test would be lower and so a reduction in the price of RIA tests would merely anticipate a later change and would enable our test to compete with the Wellcome enzyme test.

Dr Gunson expressed concern that RTC budgets could contract if the price of RIA tests was lowered.

The Chairman referred to impending talks with Wellcome and expressed the view that any price reduction should be held in abeyance at the current time. In the event of this idea proceeding a price of 12-15p. was agreed.

24.2 Report on BGRL Products

A copy of the report on BGRL production (CBLA 86/17) was received and noted.

25/86 Accountability Review

A report from the Secretary, together with the Executive Summary, draft Corporate Plan and discussion papers (CBLA 86/18) were received and noted.

The Chairman expressed his congratulations to those responsible for producing what he considered to be a very good and comprehensive report. He invited comments from the meeting on the report.

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The Director BPL referred to the proposals concerning the management structure and questioned the idea that the style of 'Griffths' as operated by other NHS Authorities was appropriate for CBLA. He felt that there was not a clear enough definition of Directorial responsibility for BPL.

Members expressed a general comment in favour of CBLA operating in a commercial type manner and therefore, having an industrial type structure which would i intment of a General Manager.

Dr Gunson expressed concern clear definition and role for BGRL within the Re lack of interface with the BTS. He referred to th ISS enquiry on the BTS and felt that the Accountab ould take account of this.

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It was agreed that a speci he CBLA would be held on Tuesday 22 April, 1986 at 11.00 to s: -

(i) The Management Structure
(ii) The operational plan for the three years 1987/8/9

It was also agreed that discussion should take place with DHSS prior to the special meeting regarding Dr Gunson's point about CBLA's interface with the BTS.

26/86 New Salary Scales and Terms and Conditions

The Secretary reported upon progress made in regard to staff on scale O. The matter would now be debated at ministerial level. P Division at DHSS was still concerned about a possible 'knock on effect' to the rest of the NHS in respect of the ancillary scales.

The Secretary confirmed that the situation regarding maintenance staff still had a number of problems which required attention.

27/86 Meeting with the Scottish Health Service, Common Services Agency, 21 February 1986

The Secretary reported upon the normal six monthly meeting of the Chairman, the Director BPL and himself with representatives of the Common Services Agency.

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Members expressed a general comment in favour of CBLA operating in a commercial type manner and therefore, having an industrial type structure which would include the appointment of a General Manager.

Dr Gunson expressed concern about a lack of clear definition and role for BGRL within the Review and also a lack of interface with the BTS. He referred to the forthcoming DHSS enquiry on the BTS and felt that the Accountability Review should take account of this.

(Mr A Jerwood left the meeting at this point)

The objectives and strategy were accepted by the Authority, but after further discussion it was agreed that there were areas in the Accountability Review which required specific discussion at a special meeting of the Authority.

It was agreed that a special meeting of the CBLA would be held on Tuesday 22 April, 1986 at 11.00 to discuss: -

(i) The Management Structure
(ii) The operational plan for the three years 1987/8/9

It was also agreed that discussion should take place with DHSS prior to the special meeting regarding Dr Gunson's point about CBLA's interface with the BTS.

26/86 New Salary Scales and Terms and Conditions

The Secretary reported upon progress made in regard to staff on scale 0. The matter would now be debated at ministerial level. P Division at DHSS was still concerned about a possible 'knock on effect' to the rest of the NHS in respect of the ancillary scales.

The Secretary confirmed that the situation regarding maintenance staff still had a number of problems which required attention.

27/86 Meeting with the Scottish Health Service, Common Services Agency, 21 February 1986

The Secretary reported upon the normal six monthly meeting of the Chairman, the Director BPL and himself with representatives of the Common Services Agency.

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Particular attention was focussed upon the avoidance of duplication of effort by England and Wales and Scotland. Dr Moore said that DHSS was taking the initiative in attempting to meet with the SHHD more frequently.

28/86 Sealing of Documents

A report from the Secretary outlining documents signed and sealed on 10 March 1986 (CBLA 86/19) was received and approved.

29/86 B G R L

A report from the Secretary on BGRL (CBLA 86/20) was received and noted.

The Secretary reported that Dr G Bird had been appointed Director of BGRL (replacing Dr Holburn) until his retirement on 7th November, 1986. A Management seminar, as well as meetings with BGRL staff, had been held to discuss the future of the laboratory.

The recommendations outlined in the Secretary's report were approved taking into account Dr Gunson's comment that more emphasis was needed in regard to the laboratory's reference work. The intention to move BGRL from Oxford to Bristol in the long term to link up with the similar work already carried out there was noted.

As a point of principle, it was agreed that the Deputy Director (Diagnostics), and the Head of Quality Control, would report to the Director BPL immediately.

The Secretary's report was approved as follows: -

1. The laboratory will continue to change to monoclonal reagents as and when these are developed to the point at which bleeding special donors can no longer be justified. These will be charged out to the NHS and BGRL will become a major supplier on a global basis.

2. The production section of the BGRL will transfer to Elstree when suitable space becomes available in Elstree Building 25 (the existing production unit) and will come under the control of the Director, BPL who will appoint a Deputy Director (Diagnostic).

3. The Authority affirmed the continuation of its central reference activities (including the WHO activities), first at Oxford and later, at a time to be determined at Bristol.

4. The Authority agreed to the specific definition of the R and D aims under the new arrangement, which are: -

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(a) to develop the existing monoclonal based diagnostic reagents.

(b) to carry out research in the diagnostic reagent field with a view to maintaining leadership in this field.

5. To appoint a Deputy Director (Diagnostics), a Head of Quality Control and a Director of R and D at the BGRL.

6. NEQAS. Subsequent to the move of the production processes from Oxford, with its management change the unit should remain within the BGRL.

30/86 Any Other Business

30.1 Dr Gunson reported that discussion had taken place at a meeting of the Advisory Committee for the BTS a few weeks earlier about the future of the Central Committee for R & D in Blood Transfusion. He said that it had been agreed that a further approach should be made for the Committee to embrace the UK.

In view of the disagreements over the nature of the Committee and to which body it should report, Dr Gunson said that he had offered his resignation from the Chairmanship of the Committee.

Dr Moore said that DHSS was currently in the process of drawing up a report in conjunction with SHHD which would be outlining a number of options and terms of reference for the Central Committee.

The Chairman confirmed that the CBLA had always found the output from the Central Committee to be most useful and emphasised the need for continuing liaison. The Authority would be happy to continue to provide a Secretariat for the Committee.

30.2 The Secretary reported the receipt of a letter from DHSS which endorsed the earlier view of CBLA, that it should seek both manufacturing and product licences, when the new BPL building was in operation. It was noted that FDA approval would be required in markets other than the United States and that failure to achieve it would severely limit the potential for the export of surplus products from Elstree.

It was agreed that it was essential to have the FDA licence in addition to Medicines Inspectorate approval.

30.3 It was agreed that the Chairman, following discussions with DHSS, should extend an invitation to the Prime Minister to open the new BPL building on a date in the Autumn which met her convenience.

31/86 Date of Next Meeting

The next meeting would be held on Tuesday 27 May at 11.00 a.m.

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