CENTRAL BLOOD LABORATORIES AUTHORITY

Minutes of the twenty sixth meeting of the Central Blood Laboratories Authority held on 23 September 1986 at the Blood Group Reference Laboratory, Oxford.

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

Part 1

63/86 Apologies for Absence

Apologies for absence were received form Dr D P Thomas and Mr Walker.

64/86 Minutes of Previous Meeting

The minutes of the meeting held on 22 July 1986 were approved and signed by the Chairman as a correct record subject to the following amendments: -

Item 51/86 (51.1) - fourth paragraph, third line, delete 'IG' and substitute "IgM'.

Seventh paragraph, third line delete 'Infirmary' and substitut 'Hospital'.

Item 60/86 (60.3) fifth line, delete 'Friars' and substitute 'Fryers'.

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65/86 Matters Arising from the Minutes

65.1(a) Central Committee for R & D in Blood Transfusion - Genetic Engineering Factor IX

Dr Gunson confirmed his hope for progress in this matter. The Director BPL expressed his concern at the very long delay with consequential lack of achievement up to date in this collaboration. He said that no programme had been agreed for an expression stage downstream processing or research. Celltech were the appropriate body to carry out the expression of Professor Brownlee's clone but they had not progressed this at all in eighteen months.

In answer to a question raised by Mr Wing, the Director BPL said that although heat treatment of factor IX limited transmission of hepatitis viruses, production of factor IX from human plasma still posed many difficulties which cloned sourced material would overcome. He emphasised that virus transmission, however, was not the main reason for wishing to progress this particular development.

(b) Commercialisation of Anti-D Reagent - Proposals from Celltech and Wellcome

The Chairman reported that Wellcome were not marketing any blood grouping reagents and had now stated that they had no interest in this field at present.

It was noted that in the case of Celltech, whom CBLA had always regarded as its natural and preferred partners in the biological engineering field, a 5% royalty only on sales of bulk material had been offered, whilst another company were prepared to offer 10%. The Chairman considered the offer of 5% to be inadequate and he had written to Sir James Gowans, Secretary of the MRC, to seek the MRC's view on the importance of the financial return, or whether it would prefer Celltech to be the Licensee for other reasons. The Chairman's letter was circulated to members for information. It was noted that the Chairman's telephone conversation the same morning with Sir James Gowans had indicated that the MRC saw the decision as one for the CBLA.

The Chairman confirmed that Boots-Celltech, understood to have a legal right to all biologically engineered products offered to either partner, had been invited to CBLA at an early date to discuss their interest in a possible licence. It was agreed that the Chairman should negotiate the best terms possible for CBLA. The Chairman said that he would accept this remit and confirmed that he would wish to have the consent of Boots-Celltech before dealing with either partner on a contractual basis.

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In answer to a question raised by Dr Gunson, it was confirmed that supplies of anti-D reagent would continue to be supplied to the NHS through BPL Diagnostics.

The Secretary informed members of discussions he had held with Dr N Hughes-Jones who had indicated the presence of two further anti-D cell lines of equal standard to the anti-D reagent. He asked if it was reasonable to offer any of these to other companies such as Bioscot. It was agreed that in the negotiations with Boots-Celltech an indication of the existence of two alternative cell lines should be made. A licence to all three would require a higher royalty rate. If no agreement was reached on this, other possibilities, including Biotest could be explored.

It was agreed that before any decision was reached about the alternatives, samples of the monoclonal antibodies concerned should be made available to certain RTC's to assess their value in the detection of DV variants.

65.2 Future of Central Committee for R & D in Blood Transfusion

Dr Moore apologised for the slow progress in this matter. He promised to put before the CBLA some proposals at its meeting in November.

65.3 Untested Plasma

The Director referred to the amounts of untested fresh frozen and time-expired plasma currently in stock. It had been agreed with DHSS that this would not be used until ~~the~~ an Advisory Committee, which ~~had been~~ will be set up to consider this issue on a scientific basis, had reported. It was specifically noted that only tested plasma was currently being used for the manufacture of products.

Dr Gunson said that he hoped that the current stockpile at BPL would not need to be written off.

Members received for information a copy of a written reply given in the House of Lords, concerning the distribution of manufactured products from screened donor plasma.

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66/86 Plasma Supply

Dr Moore confirmed that most Regions were up to target. He reiterated the need for Regional General Managers to be aware of the situation regarding factor VIII supply in order that budgets could be fixed appropriately.

He referred to the target levels of plasma supply up to 1990 and the problems of maintaining the flow together with storage at BPL. He felt there was now a need for the Director BPL and Regional Transfusion Directors to discuss this, particularly in the light of the Authority's intention to achieve maximum throughput from available plasma.

67/86 Redevelopment of BPL

67.1 Reports on the redevelopment including the minutes of Project Control Committee meetings held on 25 July and 5 September 1986 (CBLA 86/37) were received and noted.

The Secretary reported that CBLA was at the point of takeover of part of the new building. The Director BPL was looking carefully at the procedure for handover to ensure appropriate accountability throughout the process of transfer.

It was noted that the sum of £52M to complete the new building was now under some pressure; there had been a constant lack of information from MHNE and the possibility of additional fees was aggravating the situation. The Secretary confirmed that DHSS wished to have a high level meeting with MH plc which would include their Chief Executive, the DHSS Deputy Secretary (health and Social Services Policy, the Head of the Health Building Division and the Chairman and Vice Chairman of CBLA.

The Secretary reported receipt of a formal notification from MHNE stating that it was changing its name to Matthew Hall Engineering (Southampton) Limited and that all responsibilities for the new development would be transferred to the new company. He said that he had passed this information to the Authority's solicitors for advice as a precaution to ensure that all obligations and liabilities on the part of the firm under the contract were properly transferred.

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The Director BPL commented on current progress with commissioning. Whilst there were a number of problems, he was especially concerned about the function of Project Co-ordinator at the present time. It was noted that because of other commitments, Mr M Whitney could only spend one day per week at BPL. The Secretary said that he was in the process of arranging with BDP the strengthening of the BDP team on site.

67.2 Warehouse, Q.A. and Engineering Building

The Secretary reported that DHSS were unlikely to change their view that BDP should not act as design consultants in addition to their role as project managers, despite the Authority having previously agreed to BDP carrying out both functions.

The CBLA submission which featured a warehouse capable of holding 540 tonnes continued to be questioned by DHSS. A letter dated 10 September from Mr M A Harris, DHSS highlighting this was circulated to members. A draft reply from the Director BPL to the points raised in the DHSS letter was also circulated. It was agreed that urgent discussions to resolve this matter within the originally agreed policy should continue.

67.3 Pilot Process Plant

It was noted that the various options for Pilot Process facilities for BPL had been forwarded to DHSS. In a letter dated 19 September 1986 circulated to members, Dr Moore had referred to the inconsistency of CBLA's options for research in comparison to its objectives in the Accountability Review.

Dr Moore reiterated DHSS opinion at the Accountability Review meeting in June whereby the Authority should look at a 'make do and mend' option. This would include the refurbishment of the PFL site at Oxford at a cost of approximately £1.5M with a facility for albumin and immunoglobulins alone, built at a lower cost, elsewhere.

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The Director BPL outlined his concern at the views of DHSS regarding the pilot process plant and said that the issue of product licences for BPL products which DHSS wanted to see enforced could not be pursued without a total new facility. He strongly emphasised that a new facility was the only viable option in his view and that a refurbishment of the Oxford site would not be value for money as it would still only have a limited life after any improvements had been made. The Secretary expressed his concern at the delay in reaching agreement because any new facility would be subject to the normal NHS Capricode procedure which, by its nature, had shown itself to be a very slow building process.

After further discussion it was agreed that it would be possible to meet the requirements for product licence applications without new pilot plant facilities and that it would therefore not be possible to achieve the declared objective of operating without Crown privilege. A policy statement from DHSS was required.

67.4 Master Plan

The Secretary said that details of progress made with the Master Plan would be made available to members at their next meeting.

68/86 Finance

68.1 Budget Statement

A copy of a report prepared by the Secretary on the budget (CBLA 86/38) was circulated to members.

The Secretary said that because the cash limit figure for 1986/7 had still to be confirmed, interim budget arrangements were continuing. He said that the statement did show an underspend and he would be willing to answer any questions members wished to raise.

68.2 Losses and Compensation

The Secretary reported that CBLA had now received DHSS approval to write off certain stock items which were reported to CBLA at its March 1986 meeting.

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68.3 Annual Accounts 1985/6

The Secretary reported that the draft Annual Accounts 1985/6 had been prepared albeit without valuations or WIP because of the departure of the Cost Accountant. The new Cost Accountant was due totake up post on 1st October. In the meantime, the Statutory Auditor was looking at the draft Annual Accounts to see if the revised arrangements for their completion met with his approval.

69/86 Production

69.1 Report on BPL products

A copy of the report on the production and issue of BPL Products (CBLA 86/39) was received and noted.

Approval had now been received from DHSS for a reduction in BPL's RIA test to 15p.

69.2 Report on BPL Diagnostic Products

A report on BPL Diagnostic Product Production (CBLA 86/40) was received and noted.

In answer to a question raised by Dr Smithies, the Director BPL said that the most likely cause for a drop in sales value for Anti-D compared with the previous year was the introduction of charging. Dr Gunson substantiated this by stating that some commercial firms had offered a 'financial package' on certain products to hospitals.

It was agreed that the provision of materials for the preparation of NEQAS sets, previously agreed by RTC's, should continue.

70/86 Accountability Review

The Secretary reported that he had written to DHSS asking for more details of their views on the three-year action plan. Action required following receipt of the minutes of the Accountability Review meeting in June was being progressed.

71/86 New Salary Scales and Terms and Conditions

The Secretary said that real progress was being maintained and individual interviews, where necessary, with staff were to be arranged. It was noted that some minor assimilation problems had to be dealt with.

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72/86 Annual Report

Copies of draft Annual Reports for BPL and BGRL were receive and commented upon by members.

Mr Wilson drew attention to the high turnover of staff at BP The Secretary confirmed that the Production rates of pay had been a major problem in retaining staff at Elstree. In addition, competition from the Pharmaceutical industry and t geographical location of BPL were relevant.

Mr Wing commented upon the recall of a batch of anti-varicella-Zoster immune globulin and it was agreed that short report on this should be prepared for members attentio It was also agreed that it would be useful if the Director B could prepare, for each CBLA meeting, a short report highlighting current affairs and publicity in the field of blood products.

Dr R Moore was requested to provide current information on product liability and to include a copy of a recent letter f the Chief Medical Officer DHSS to the PHLS.

The BGRL report was noted and approved. The Director BGRL w thanked and requested to pass on the appreciation of members all BGRL staff for their efforts during a period of extreme difficulty for the laboratory.

The final version of the CBLA's Annual Report, which would include a Chairman's statement, would be submitted to the November meeting of the Authority.

73/86 Implications of Virus Inactivation and BPL Products

A copy of a report on the Implications of Virus Inactivation and BPL Products (CLBA 86/41) was received and noted.

Members were very sympathetic with the views expressed by the Director, BPL in his report and totally agreed that the BPL should attain at least equivalent standard with industry in terms of licence, manufacturing and distribution of product and therefore needed to pursue opportunities for early completion of facilities to augment quality assurance and pil process development and research at Elstree. The approval f these facilities, however, was a matter for DHSS.

74/86 Field Trial - Monoclonal Anti-D

The Director BPL reported that following a meeting a few week earlier between Transfusion Directors, the two laboratory Directors, Dr D Anstee and Dr N Hughes-Jones, this field tri had now commenced. It was noted that RTC's and hospitals ha made a very good response to this.

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75/86 Any Other Business

75.1 Dr A Smithies referred to a meeting of Haemophilia Directors held the previous week and the rapid progress with clinical trials of factor VIIIY and factor IXA was noted.

75.2 Mr Wilson reported that the first meeting of the DHSS Steering Committee set up to look into present arrangements for running the National BTS had been held earlier in the month. He felt that the membership of the committee was well balanced and a second meeting was planned for 2 December. He hoped that the Committee would produce a final report in either May or June 1987.

75.3 The Authority noted that Mr J Redhead had been appointed Assistant Administrative and Donor Services Manager at the Lancaster Centre. Members thanked him for all the hard work he had done for the Authority and wished him well for the future.

76/86 Date of Next Meeting

It was agreed that the next meeting would be held on Tuesday 25 November, 1986 at 11.00 a.m.

The Directors, having completed their contributions, received the thanks of the members and withdrew.

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PART 2

76/86 Matters in Confidence

76.1 Director BPL - Extra Responsibilities

The Secretary confirmed that the report containing proposals for salaries of the four Heads of Functional Directorates and Director BPL for increased responsibilities would be agreed with the Chairman prior tobeing sent to DHSS for approval of salary levels.

It was agreed toextend Dr G Bird's temporary contract as Director BGRL to the end of the calendar year.

76.2 Chief Executive

The Chairman reported that about 70 applications for the position of Chief Executive had been received and that a short list of 12 candidates had been prepared; their curricula vitae were being circulated to the members of the Assessment Panel and it was hoped to conduct interviews of those selected early in November. The applicants included several strong candidates from industry.

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