

CENTRAL BLOOD LABORATORIES AUTHORITY

Minutes of the twenty-first meeting of the Central Blood Laboratories Authority held on 20 November, 1985 in the Board Room, the Crest.

Present: Mr R D Smart (Chairman)
Dr H H Gunson
Mr A S Jerwood
Mr M G Storey
Dr D P Thomas
Mr C Walker
Mr G A Wilson
Mr R A Wing

In Attendance: Mr W P N Armour (Secretary)
Dr A M Holburn (Director (BGRL))
Dr R S Lane (Director (BPL))
Dr R Moore (DHSS)
Mr A J Williams (DHSS)
Dr A Smithies (DHSS)

The Chairman welcomed to the meeting Dr R Moore who was succeeding Mr A J Williams as DHSS observer. The Chairman thanked Mr Williams for his past assistance to the Authority.

Part 1

92/85 Apologies for Absence

An apology for absence was received from Mr W V S Seccombe.

93/85 Minutes of Previous Meeting

The minutes of the meeting held on 18 September, 1985 were approved and signed by the Chairman subject to the following amendments: -

Item 79/85 (79.2) sentence to read:

'On the receipt of further information, Mr Williams would report back to the Authority at its November meeting.'

Item 80/85 - First paragraph, second sentence, delete the words 'debate in October' and substitute the word 'interest'

Item 81/85 (81.1) fourth paragraph to read:

'Mr Jerwood confirmed that in order that the contract did not overrun unnecessarily, it was hoped that MHNE fees would be closed down at a final sum of £6.6 million.'

Item 81/85 (81.2) last line, after the word 'design' add:
'and also the current BPL buildings'

62/197

94/85 Matters Arising from the Minutes

94.1 Charging for BGRL Products

A report prepared by the Secretary outlining the replies received so far from RHA's (CBLA 85/49) was received and noted.

The Secretary confirmed that the majority of Regions supported the Authority's proposals on recharging but would speak further to Dr Gunson in regard to those unsupportive RHA's. Dr Gunson referred to the North Western Region which, like Oxford, felt that the District Health Authorities should deal directly with CBLA.

Mr Wing raised a question about the advantageous terms negotiated by West Midlands RHA for material prepared by the Scottish NBTS and marketed by Bioscot. The Secretary confirmed that this was a competitive arrangement and he referred to the current difficulties in collaboration with the Scottish CSA for free future access to its developments with private companies such as Bioscot. Mr Walker confirmed that the East Anglian RHA had rejected the proposals purely on a cost basis. The Secretary said that a written response had been sent to East Anglia explaining in detail BGRL's position.

It was agreed to finalise the re-charging exercise as quickly as possible, bearing in mind BGRL's financial situation, probably before the CBLA met again in January, 1986.

94.2 DTI Biotechnology Unit - Downstream Processing

Mr Williams said that DHSS, in all probability, would have to advise DTI thoroughly on the Authority's activities. A meeting in the near future therefore between DHSS and DTI was likely.

94.3 Bioscot - Supply of Anti-Thrombin III to PFC

Mr Williams said that the difficulty in collaboration with Scotland in this matter was a question of policy rather than a legal concern. The Secretary confirmed that this topic would be discussed again when CBLA and CSA representatives met again in the new year.

94.4 Rapid Anti-D

The Chairman reported that there remained a lack of interest from the commercial side in regard to anti-D. He was hopeful of a change in attitude however, in the not too distant future.

94.5 Overseas Marketing - Proposed Collaboration with Biotest

The Director BPL reported that preliminary work had been completed in this proposed collaboration and a consignment of four samples had been sent to Biotest. Biotest would report back after inspecting the samples.

The financial benefits to the Authority of the proposed collaboration were outlined by the Director BPL. It was noted, that at the present time, a confidentiality agreement, only, was in existence, and the next step would be to secure a commercial agreement with Biotest which would be laid before the Authority before engrossment.

The situation with regard to patents was discussed. It was noted that the Deputy Director of BPL was currently reviewing this and it was hoped to produce a report for the CBLA's next meeting.

The Chairman referred to the possibility of having to use a specialist patent adviser in this proposed collaboration rather than use MOD. It was agreed to keep the question of patents under review.

The Director BPL was asked to continue his liaison with Biotest.

95/85 Plasma Supply

Mr Williams reported an unchanged situation in regard to the expected plasma returns from Regions. He said that DHSS would have to closely monitor the figures already promised from RTC's.

Dr Gunson said that RHA's were currently looking at next year's plans and the matter of plasma supply was now at a critical stage. The Secretary expressed his concern that the problem Regions, in terms of supply, remained a concern and he thought that DHSS would have to continue to exert as much pressure as possible on them.

The impact of AIDS on blood donations was discussed. Dr Gunson said that donations had decreased initially but the situation had been reversed and donations had now actually increased.

96/85 Redevelopment of BPL

The minutes of the meeting of the Project Control Committee held on 15 November, 1985 (CBLA 85/50) were received and noted.

Mr Jerwood gave an outline of the Project Co-ordinator's synopsis on the project to date, which was circulated to members. This was part of the Project Co-ordinator's comprehensive report, currently being finalised, which would be passed to members on completion. Mr Jerwood referred to two particular disturbing issues highlighted in the synopsis, namely the final cost of the project, which in BDP's opinion was now unlikely to be under £43 million and an estimated completion date of July 1986. MHNE had indicated that a further injection of finance into the project could accelerate the programme. The Secretary said that MHNE would have to demonstrate to CBLA how this could be achieved.

The Secretary reported upon a meeting he had held with Mr G Walden, Special Projects Director, MHNE, the previous day to discuss the project delay and MHNE fees. It was noted that Mr Walden would not accept the delay factor; he still believed the project could be completed by the end of March 1986. In answer to a question raised by Dr Gunson, the Secretary and the Director BPL, both supported BDP's view on the timing of the project. It was subsequently agreed that the Secretary should write to Mr Walden requesting written confirmation of his personal commitment to a March 1986 completion.

Mr Storey questioned MHNE's professional competence in the project as a whole and expressed the opinion that the matter should be pursued in the courts after project completion. He subsequently asked if the necessary evidence would be available to pursue such a claim. The Secretary confirmed that Deloitte's, auditors were gathering evidence on the claims side as well as determining MHNE's liability. Mr Williams said that CBLA would receive the support of DHSS in any criticism it was likely to make about MHNE. Mr Storey's motion, to pursue a claim against MHNE once the project was completed, was fully supported by Authority members.

Dr Thomas expressed concern that the extra finance needed for the redevelopment might create difficulties in obtaining further cash in the future for new buildings such as an R & D facility.

Mr Williams emphasised the need for DHSS to be provided with information about the official opening of the new building as early as possible.

In reply to a question raised by Mr Williams about fixed fees, the Secretary confirmed that he was about to secure this at a sum of £6.7 million for completion of work. He would send written confirmation to DHSS about this.

Mr Williams reported that the National Audit Office, which generally looked at projects similar to that of BPL, had carried out an exercise on the redevelopment. It was noted that it did have some points to discuss and a NAO representative would approach the Secretary to discuss these. Mr Williams said that the NAO did send interim reports to the PAC and he felt that in all probability this would happen with the BPL project.

97/85 Finance

97.1 Budget Statement

Copies of the budget statement and Secretary's report (CBLA 85/51) were received and noted.

97.2 Forecast Estimates 1986/87

A copy of the revised and forecast estimates 1986/87 and Secretary's report (CBLA 85/52) was received and noted.

The Secretary reported that, because of timing difficulties, the estimates had, on this occasion, been presented in the first instance to DHSS. Mr Williams said that at the present time he was unaware of the Authority's cash limit for the next financial year.

Mr Wing expressed the view that it would be helpful if members could have more specific details of the staff budget with a breakdown of figures. The Secretary agreed to provide this information.

The Chairman, whilst accepting the change in procedure on this occasion, said that the Authority should receive a copy of the estimates prior to their submission to DHSS. It was agreed therefore that the Secretary would prepare a timetable and mechanism for presentation of the figures, firstly to CBLA and then to DHSS.

The estimates for BGRL were discussed. The Director BGRL outlined the reasons for an additional five technician posts and the general rise in expenditure for the laboratory. Mr Williams emphasised the need also, in future, for written explanations to accompany the estimate figures. This was agreed.

97.3 Annual Accounts

The Authority noted that with the agreement of the Statutory Auditor certain minor amendments to the Annual Accounts had been made. These were available to any members who wished to see them.

98/85 Production

98.1 Report on BPL Products

A copy of the report on the production and issue of BPL products (CBLA 85/53) was received and noted.

Dr Gunson asked about the reasons for the fall in the plasma volume processed. The Director BPL explained that 150 tonnes of plasma could not now be handled through the Factor 8Y process. He stressed, however, that the optimum handling of plasma was being undertaken which would assure the best yield.

98.2 Report on BGRL Products

A copy of the report on BGRL production (CBLA 85/54) was received and noted.

The Director BGRL referred to the large increase in new products at BGRL, which it was noted would not continue until the resources that would be made available for the laboratory were known.

The impending departure of the Head of Quality Control at BGRL was noted.

The Director BGRL confirmed that the targets for human materials would not be met within the present financial climate; raw materials were running out at a faster rate than resources were being obtained to purchase monoclonal reagents. It was noted that Celltech was now pressing for an answer from BGRL on whether it wished to purchase additional monoclonal stocks.

After discussion it was agreed that the Director BGRL would prepare a report for the next meeting of the CBLA on how he saw the future consequences for BGRL in the present situation of underfunding.

99/85 Pilot Development and Research Requirements at BPL

A copy of a report from the Director BPL outlining Pilot Development and Research requirements at BPL (CBLA 85/55) was received and noted.

The Chairman on behalf of CBLA members expressed his appreciation to Dr M J Harvey, Head of Research and Development at BPL for his valuable contribution in the production of the report.

In view of the comprehensive nature of the report, it was agreed that a special meeting of the Authority would be held before the next normal meeting to consider the report in detail. It was agreed that a similar report should be prepared by the Director BGRL for his laboratory to be considered at the special meeting. The Secretary confirmed that similar assistance in its preparation would be made available to the Director BGRL, from Deloittes.

100/85 New Salary Scales and Terms and Conditions

100.1 Progress

The Chairman confirmed that he had met Mr C France, on 3 October, 1985. Mr France was entirely aware of the Authority's problems in establishing a viable pay structure, but the constraints of civil service procedures made it impossible to move unless all proper steps had been taken.

It was noted that DHSS maintained that a job evaluation was the best way to proceed. The Secretary confirmed that whilst a further job evaluation was impractical, senior staff at BPL were being asked to update the previous job evaluation undertaken in the light of how they foresaw operations in the new factory. Mr Williams emphasised the need for the Authority to present a reasoned argument why a bonus scheme at BPL was not feasible. In regard to craftsmen, the Secretary confirmed that taking the case to the MAP panel would be a repetition of the situation which occurred with the management side of the ASC and therefore would not be beneficial. It was agreed that the arguments expressed by CBLA would be presented in writing to DHSS as a matter of urgency.

100.2 Staffing

A report from the Secretary on staff recruitment at BPL (CBLA 85/56) was received and noted.

The Secretary expressed concern over the current position and he said that the situation was worsening with the continuing loss of trained staff. In answer to a question raised by Mr Williams, it was confirmed that approximately 50% of staff leaving were in the process grades. The remainder were mainly junior technicians. Whilst it was accepted that there would always be some kind of staff turnover, the Director said that the lack of a proper pay structure for seven years at the laboratory had aggravated the situation.

After further discussion it was agreed that evidence of the current problems should be produced for inclusion in a report to DHSS as a matter of urgency with the intention of putting this before Ministers.

101/85 Amersham International

A copy of a report prepared by the Director BPL outlining the interim situation in regard to new collaborative projects between BPL and Amersham International (CBLA 85/57) was received and noted.

It was noted that a draft confidentiality agreement, which would enable the collaborative discussions to take place, had been presented to BPL by Amersham for the Authority to sign. The Secretary confirmed that the agreement was being amended slightly in CBLA's interests and he would sign the document on the Authority's behalf.

102/85 Welsh Regional BTS - Review

The Director BPL reported the receipt of a letter from the Welsh Office inviting him to review the NBTS in Wales and to advise on the achievement of self-sufficiency. It was noted the review would take a minimum of ten days and so the Director was seeking a view from the Authority on the advisability or otherwise of his accepting the invitation.

The Chairman expressed the view that the Director's time, at this stage in the redevelopment, was critical and therefore regrettably, he should decline the invitation. Authority members supported this view.

It was agreed however, that if the Welsh Office provided further information on their review, the Authority would try to give assistance by suggesting names of possible alternatives to conduct the assessment.

103/85 Central R & D Sub-committee on Genetic Engineering and Recombinant DNA Technology

Dr Gunson reported that the Sub-committee on Genetic Engineering and Recombinant DNA Technology had held its first meeting on 11 November 1985 under the chairmanship of Professor L Luzzatto to discuss progress in Factor IX development.

It was hoped to put forward further proposals in this area of development to the Authority at its next meeting in January, 1986.

69/204

104/85 Development of Monoclonal Antibodies

A report prepared by the Secretary on the Development of Monoclonal Antibodies (CBLA 85/58) was received and noted.

The continuation of the comprehensive research programme for monoclonal antibodies was agreed. Whilst the pursuit of collaboration agreements with the interested companies was also agreed, this should be primarily with a UK Company. The pursuit of collaborative arrangements with non UK companies would be considered as a second resort.

It was agreed to pursue with Boots Pharmaceutical Company possible collaboration for anti-D.

105/85 Any Other Business

105.1 The Secretary confirmed the sealing of a document concerned with the transfer of patent rights from the DHSS to CBLA in regard to the purification of albumin by affinity chromatography on an immobilised triazine dye.

106/85 Date of Next Meeting

The next meeting would be held on 28 January, 1986 at Elstree at 11 a.m.

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

69/205

CENTRAL BLOOD LABORATORIES AUTHORITY

GRO-C

Chairman:
R. D. SMART, C.B.E.

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12 November 1985

To: Members of the Central Blood Laboratories Authority

Dear Member,


Attached herewith is a copy of the agenda for the next meeting of the CBLA on 20 November 1985, at 11.00 a.m.

If possible, I would be grateful if you could arrange to arrive at Elstree between 10.30 and 10.45, which will allow time for members to have their photographs taken prior to the meeting, in order that identification badges can be prepared.

A buffet lunch will be available at 1.00 p.m. as usual.

Yours sincerely,

GRO-C

 W P N ARMOUR
Secretary

64/206.