#### CENTRAL BLOOD LABORATORIES AUTHORITY

Minutes of the twenty fourth meeting of the Central Blood Laboratories Authority held on 3 June 1986 in the Board Room, the Crest.

Present: Mr R D Smart (Chairman)

Tase her herlands and Mr A S Jerwood 1830 all

Mr W V S Seccombe

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/PFL)

Dr R Moore (DHSS)

Dr A Smithies (DHSS)

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### 33/86 Apologies for Absence

Apologies for absence were received from Dr H H Gunson, Mr M G

# 34/86 Minutes of Previous Meeting

The minutes of the meeting held on 25 March 1986 were approved and signed by the Chairman as a correct record subject to the following amendments:

Item No 23/86 (23.2) Third paragraph to read: 'On the recommendation of the Secretary, the Authority approved a proposal that the minimal value of inventory items to be recorded, be increased from £250 to £500 in line with Cabinet Office, Stores Management Guidelines'.

Item No 24/86 (24.1) Second paragraph, last sentence to read:
'The Director said that the price of reagents used in all tests
would be lower and so a reduction in the price of RIA tests
would merely anticipate a later change and would enable BPL's
test to compete with the Wellcome enzyme test'.

The minutes of the special meeting held on 22 April, 1986 to discuss the CBLA's Accountability Review were approved and signed by the Chairman as a correct record.

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### 35/86 Matters Arising from the Minutes

# 35.1 Overseas Marketing - Proposed Collaboration with Biotest BPL Patent Situation

A copy of a report from the Director BPL (CBLA 86/31) giving the current patent situation in the proposed collaboration with Biotest was received and approved.

# 35.2 Central Committee for R & D in Blood Transfusion - Genetic Engineering Factor IX

The Secretary reported the receipt of further correspondence from Celltech which had outlined the work required for the collaboration on factor IX and the cost, which, in his view was extremely high. He said that an amount of £50,000 had now been granted by CBLA to Professor Brownlee to enable him to carry on his collaborative research work in the project at Oxford. Whilst the Authority was still looking for a financial commitment from Celltech in the collaboration, the Chairman expressed his doubts about funds being made available by the company because of their present financial situation.

Mr Walker asked if the production of factor IX by genetically engineered methods could be incorporated into CBLA's R & D programme. The Secretary confirmed that this had been placed in the Research and Development plan, and thus in the Accountability Review as part of the Authority's strategy, but, although it was likely to have more money available for R & D in the long term, additional finance would still be required for this particular project.

The Secretary confirmed that Baroness Trumpington, Joint Parliamentary Under Secretary (Lords) was due to visit BPL on 12 June, and this collaboration project was an item to be raised with her.

It was subsequently agreed to review the position on genetically engineered factor IX after the Accountability Review when a further meeting of the R & D Subcommittee or genetic engineering was likely to be held. A special meeting of the Authority to consider collaboration implications was also a possibility.

# 35.3 Future of Central Committee for R & D in Blood Transfusion

Dr R Moore reported that DHSS draft proposals on the future of the Central Committee for R & D in Blood Transfusion had been sent to SHHD for its comments. A reply was currently awaited.

## 36/86 Plasma Supply

Dr Moore confirmed that the revised projection figures relating to plasma use, storage and production provided by BPL had been presented to the last meeting of the National Advisory Committee for the BTS. A major discussion element had been the commissioning of the new BPL and how this would affect the plasma supply requirement. It was noted that a further letter on this matter was now ready to be sent out to Regional General Managers.

## 37/86 Redevelopment of BPL

37.1 Reports on the redevelopment, including the minutes of meetings of the Project Control Committee held on 25 April and 23 May 1986 (CBLA 86/21), were received and noted.

Mr Jerwood referred to the seventh report of the Project Co-ordinator and particularly the new Rev 05 programme outlined therein. He said that disturbing comments/reservations had been made at the last PCC meeting regarding the completion dates of Area D (centrifuge area) in the programme, and, although all the dates had allowed for some slippage, he had asked the officers involved to pursue matters on the action needed for compliance of the dates.

The Secretary said that a complete review of all areas had been undertaken and BDP had their own checklist for room-to-room monitoring.

The Director BPL emphasised his concern that, whilst the equipment would be in the new building, the staff needed to operate it would not. It had been noted at the last PCC meeting that CBLA would be expected to pay for certain MHNE staff being kept on site during commissioning.

As requested at the last PCC meeting the Secretary confirmed that he had prepared for CBLA members a comprehensive financial report on the redevelopment project and he would circulate this accordingly. He said that he was still pursuing with DHSS the question of additional capital finance for the current year.

In reply to a question raised by Mr Wilson, the Chairman confirmed that CBLA members were welcome to inspect the new building at any time. The Secretary referred to certain public relations exercises which members might like to attend and, at the same time, take the opportunity of looking at the new building. It was agreed that the Secretary would therefore provide a calendar of such activities for members' information.

37.2 A summary of BPL Commissioning Planning to date (C A 86/22) was received and noted.

The Director BPL reiterated the position of concern regarding the Authority's inability to recruit maintenance staff for the new building and the fact that DHSS did not recognise that such staff should be treated separately from other NHS maintenance staff.

Members noted the potential problems which might arise with the de-mineralised water because of the omission of the required system by MHNE.

## 37.3 Master Plan - Warehouse and Q.C. Building

The Secretary reported that the Master Plan was being prepared. A formula had been informally presented to DHS which aimed to satisfy the needs of financial and contract control against the expediency of saving time. It was noted that a meeting with BDP and the DHSS Works Division was to be held within the next few weeks.

In regard to the Warehouse and Q.C. Building, the Secretary reported that further information, which had been requested by DHSS in addition to the AIP submission had now been sent.

# 37.4 Opening

The Chairman reported the receipt of a letter from the Private Secretary to the Prime Minister stating that, because of prior commitments, she was unable to open the new BPL building in the Autumn. It was agreed that the Chairman should extend an invitation to Princess Alexandr to perform the opening ceremony.

### 38/86 Finance

### Budget Statement

Copies of the budget statement and Secretary's report (CBLA 86/23) were received and noted.

The Secretary reported that discussions were currently taking place with DHSS to fix an appropriate cash limit for both revenue and capital for 1986/7.

The Director BPL reported upon the very satisfactory position regarding the sale of RIA test kits at the end of the 1985/6 financial year.

### 39/86 Production

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## 39.1 Report on BPL Products

A copy of the report on the production and issue of BPL Products (CBLA 86/24) was received and noted.

It was noted that the new heat treated factor VIII commanded a higher market value than the previous factor VIII product and that there was therefore a general increase in the value of BPL products.

# 39.2 Report on BPL Diagnostic Products

A report on BPL Diagnostic Product production (CBLA 86/25 was received and noted.

The Director BPL confirmed the new format for presentation of the figures in future, as opposed to the old reports on BGRL production.

# 40/86 Commonwealth Serum Laboratories

A report from the Director BPL (CBLA 86/26) was received and noted.

A proposal outlined in the report to adjust the price of BPL Rifor HBsAg downwards to 15p per test in order to retain market interest was approved subject to confirmation by DHSS.

The proposal included information on work proceeding with fluorometric assays for immune quantitation. This type of assay, which could succeed existing methods, should provide increased sensitivity to existing assays and increase the scope of immune quantitation methods available to BPL as part of its plasma quality assurance programme.

As part of the future development, an assay against HIV antibody was neded to augment the BPL immune assay for hepatitis B surface antigen. Approval for this development was granted by the Authority.

The Chairman referred to his recent meeting with Wellcome Diagnostics and emphasised the importance of collaborating with industry, particularly for overseas sales. He said that it would be useful if a portfolio of tests could be defined to use as a basis for negotiation with Wellcome which would be a benefit to both organisations.

### 41/86 Accountability Review

A report from the Secretary, together with a final draft of the Accountability Review, including detailed job descriptions for General Manager and four Directorates (CBLA 86/27) was received and noted.

A number of minor amendments to the documents were agreed befor their final presentation to DHSS on 19 June 1986.

Mr Wilson raised a question about the use of external management consultants in the Accountability Review process. It was agree by the Authority that if the General Manager, when appointed, wished to employ management consultants in any capacity, the Authority would give due consideration to the proposal.

It was noted that the appointments of General Manager and four Directorates would need to be made by a sub-committee of the CBLA and with an outside assessor in attendance.

It was agreed in principle that a fixed three year appointment for a General Manager was inappropriate. A 'rolling' three appointment was considered to be more applicable. DHSS has no yet expressed a view on this issue.

After further discussion the Secretary confirmed that he was still awaiting an agenda from DHSS for the Accountability Revimeeting on 19 June. It was noted that a formal report of the meeting would be made to CBLA at its next meeting on 22 July.

# 42/86 New Salary Scales and Terms and Conditions

The Secretary reported the receipt of the agreed salary scales from DHSS for production staff on grade 0 for which CBLA Officers had been negotiating for over three years. He said, however, that DHSS still had not agreed to make engineering staff a similar special case. The Secretary and Director BPL were congratulated by members for their work in achieving a satisfactory conclusion for process staff.

In answer to a question raised by Mr Wing, the Director BPI confirmed that there was currently a 40% shortfall in the engineering establishment required for the opening of the new building.

The Secretary and Director BPL were encouraged to make as rapi progress as possible in attempting to solve the engineering staff problem.

### 43/86 Bank Signatories

A copy of a proposal made by the Secretary for Dr M J Harvey, Head of Research and Development, and Miss J Richards, Financi Accountant, to be added to the list of bank signatories (CBLA 86/28) was received and approved. With the retirement of Mr L Vallet on 30 May and the departure from CBLA of Mr J Penfold, the revised list of signatories was noted and is as follows: -

Mr W P N Armour Mr A G W Bailey Dr R S Lane Dr M J Harvey

Mr G E Mallory Miss J Richards Mr E D Wesley

## 44/86 Consultant Appointments

The Director BPL referred to the retirement of Mr L Vallet, Deputy Director, after 38 years service with the BPL and said that it would be extremely valuable to himself at this importantime in the redevelopment if Mr Vallet's services could be retained on a consultant basis, preferably for two years in the first instance. It was agreed to retain Mr Vallet as a consultant on an ad-hoc basis on the understanding that it should be for a term of two years. The Secretary and Director BPL would deal with the necessary administrative/financial arrangements.

The members of the Authority wished that the record should include their profound appreciation of the tremendous contribution made to the Blood Products Laboratory and its predecessors by Mr Leon Vallet during 38 years of devoted service to the needs of patients throughout the United Kingdom It was agreed that a copy of this item of the minutes should be sent to Mr Vallet.

The Secretary put forward a proposal that Dr G Bird be granted an Honorary Consultanship after his retirement on 5 November 1986, renewable on a yearly basis. This was agreed.

# 45/86 BPL Diagnostics

A report from the Director BPL on the BPL Diagnostics Division (CBLA 86/29) was received and noted.

The Director BPL said that since being asked by the Authority April to take over Serological reagent production and its associated quality assurance, formerly carried out within BGRL an initial survey and discussions with staff had revealed a number of problems which he had highlighted in his report. He suggested that there was a need for a portfolio of monoclonal products as soon as possible.

A proposal by the Director BPL outlined in the report to build up monoclonal culture facilities at Elstree to accommodate blogrouping and other reagent needs in one unit, as early as possible, was approved.

The provisional budget allocation, giving a shortfall on forecast of approximately £2M was noted. It was regarded as urgent that DHSS should inform the Authority of the final budg allocation for 1986/7.

It was noted that the appointment panel for the post of \_ad of Diagnostics and Reagents Divisions at Elstree and Oxford would need to be chaired by a CBLA member. Arrangements for interviewing prospective candidates would be confirmed as soon as possible.

(Mr Seccombe left the meeting at this point).

The decision of DHSS to transfer NEQAS to NIBSE was noted. The Secretary confirmed that a CBLA reply on this matter was currently being prepared. It would express the Authority's ful support for the intention.

# 46/86 Freeze Driers

Two reports from the Director BPL on Freeze Driers (CBLA 86/30) were received and noted.

# (i) Replacement of PFL Machine (Oxford)

The Director BPL identified the need to replace a fredrier at the PFL despite the fact that replacement of the machine was not anticipated for in the current budget.

It was agreed that the Secretary and Director BPL should have urgent discussions with DHSS on a possible capital allocation for this item. Approval was therefore given for the earliest possible placement of an order with Edwards High Vacuum to secure earliest delivery at a price of £110,000. Single tender action was approved if necessary.

# (ii) Purchase of Pilot Freeze Driers

The Director BPL referred to the problems and risks involved in the transfer of existing freeze drying activities to new machines in the new factory and to the difficulties attending their commissioning and runnin in He said that discussions had taken place between BPL/. staff and Edwards High Vacuum to seek an agreed specification for an experimental pilot-process freeze drier, the cost being in the region of between £80,000 ar £100,000. It was noted that a capital sum had been requested in the research budget for 1986/7.

It was agreed that this equipment should be purchased. The Secretary and Director BPL would also take up this matter with DHSS in capital cash discussions.

# 47/86 Date of Next Meeting

The next meeting would be held on Tuesday 22 July 1986 at 11.0 a.m.

The Director BPL, having completed his contribution, received the thanks of the members and withdrew.

#### PART 2

## 48/86 Matters in Confidence

# 48.1 <u>Director BPL - Extra Responsibilities</u>

The Secretary said that he had received a request from th Director BPL that consideration be given to his receiving an increase in salary for his additional responsibilities since taking over serological reagent product and associated quality assurance.

After discussion it was agreed that consideration should be given to the Director's request in greater detail afte the Authority's Accountability Review had been presented to DHSS on 19 June. If the management structure within the Accountability Review was approved by DHSS there woul be a need to review salaries as a whole.

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