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CENTRAL BLOOD LABORATORIES AUTHORITY

Minutes of the fourteenth meeting of the Central Blood Laboratories Authority, held on 26 September, 1984 in the Board Room, The Crest.

Present:
Mr R D Smart (Chairman)
Dame Phyllis Friend
Dr H H Gunson
Mr A S Jerwood
Dr G A Stewart
Dr D P Thomas

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

PART I

64/84 Apologies for Absence

Apologies for absence were received from Professor A Bloom, Dr E L Harris and Mr M G Storey

65/84 Minutes of Previous Meeting

The minutes of the meeting held on 18 July, 1984 were approved as a correct record and signed by the Chairman.

66/84 Matters Arising from the Minutes

66.1 Central Committee for R&D in Blood Transfusion

Mr Williams reported that Dr Harris had discussed this matter with the Scottish Home and Health Department and in the light of Scottish views, the DHSS had accepted that the Committee, whilst retaining the same membership, should be a sub-committee of the National Advisory Committee on Blood Transfusion who would have to confirm its acceptance to this.

Dr Gunson confirmed that the next meeting of the Central Committee for R&D in Blood Transfusion was due to be held in November.

The Chairman emphasised the importance of having a feedback from the Committee to the CBLA through Dr Gunson, whilst the Secretary confirmed that his department would be pleased to continue providing the administrative assistance to the Committee.

66.2 Logo

The Director BPL reported that the logo design was still with the outside agency but would be sent to the DHSS for appropriate clearance in the next few days. The design would therefore be presented to the November meeting of the Authority.

67/84 Plasma Supply

A copy of a letter dated 10 August 1984 from Mr J A Parker, DHSS, to Regional Administrators on the supply of plasma to BPL together with a report from the Director BPL on the plasma supply curve 1984/5 (CBLA 84/42), was received and noted.

The Director BPL expressed concern that the plasma curve did not indicate sufficient momentum in the growth of fresh frozen plasma stock. He said that discussions had commenced with a contractor for storage of the plasma, although in the current financial year the FFP stock had only increased by 1,500 kg against a targetted 10,400 kg. Dr Gunson said that some regions had started to respond but only the Trent and NE Thames regions were progressing satisfactorily.

Members expressed their appreciation of Mr Parker's letter to Regions and Mr Williams confirmed that some replies to it had been received.

The Director BPL referred to a recent meeting he and the Secretary had held with officers of the West Midlands RHA. Dr Lane reported on the last meeting of the National Advisory Committee on Blood Transfusion when it had been evident that Regional Treasurers were not being made fully aware of all the facts in the argument for ensuring that sufficient plasma was made available to BPL. It was agreed that Mr Williams would follow up this point.

Dr Thomas suggested that some form of contingency planning might be necessary if the required plasma supply looked in jeopardy. The chairman expected the DHSS to explain to Regions the consequences they would face in this event, which might mean their being charged for products.

After further discussion it was agreed that Mr Williams would keep the Authority informed on the progress of the plasma supply programme and if the situation worsened, contingency planning would be implemented. The matter would be received again at the Authority's November meeting.

68/84 Redevelopment of BPL

A copy of a report on the Redevelopment Project (CBLA 84/43) was received and noted.

The Secretary reported that design work would be completed by the end of the year and it was expected that the building would be watertight by the beginning of November.

In answer to a question raised by Mr Williams about tender prices for mechanical equipment and piping installation, the Director BPL confirmed that the prices using provisional bills of quantities received, ranged from £1.3 M to £2.0 M whilst the control estimate figure was £1.9 M. MHNE had given an assurance that the control estimate figure would not be exceeded.

Mr Jerwood reported that since becoming Chairman of the Project Control Committee he had met with all the Management Officers concerned, which had proved to be valuable. He confirmed that all measures to monitor costs in the Project closely were being taken.

Mr Williams confirmed that Ministers were still discussing the cost implications of the new development at Elstree whilst cash limits for the current year were imminent.

69/84 Finance

69.1 Budget Statement

Copies of the budget statement and Secretary's report (CBLA 84/44) were received and noted.

It was agreed that the Secretary would in future provide information in regard to anticipated receipts in addition to the "underspending to date" figure.

69.2 Report on BPL Products

A copy of the report on the production and issue of BPL products (CBLA 84/45) was received and noted.

Dr Gunson said that the requirement for Factor VIII was now in excess of 100 M units per year and he felt therefore that there was a need to give attention in the future to cloned products. It was noted that he and the Director BPL were due to meet the Vice-President of Travenol Laboratories in October to enquire about possible research collaboration in regard to cloned products. A progress report on the enquiry would be made at the November meeting of the Authority.

69.3 Report on BGRL Products

A copy of the report on BGRL production (CBLA 84/46) was received and noted.

The Director, BGRL reported that the production of Saline Anti-D had been discontinued due to non-availability of raw material.

In the following discussion, the Director BGRL referred to problems that had occurred in a batch of Anti-D grouping reagents which had been known to contain Anti-BGA antibodies. Despite this problem the product had been sent out against the advice of the Head of QC, BGRL.

Mr Williams confirmed that a DHSS hazard notice would be issued to the NHS about the batch of Anti-D reagent in question.

The Director BGRL said that the laboratory was constantly seeking to identify problems and eliminate them and Anti-D reagents did, on occasion, contain Anti-BG^a antibodies. He had subsequently made a judgement on this occasion that the product should be distributed.

70/84 Non-A Non-B Hepatitis - Intravenous Immunoglobulin

Copies of reports on safety tests in chimpanzees and studies with Immuno AG, Vienna (CBLA 84/47) were received and noted.

After discussion it was agreed that the proposed chimpanzee studies to establish the safety of the product, both for home and overseas distribution, should be carried out provided they were economically viable. It was also agreed that, following discussions with Immuno AG, Vienna, investigations of the product should continue in a collaborative research study using chimpanzees in the Immuno colony.

71/84 BPL and BGRL Overseas Travel

A copy of a further paper on Overseas Travel (CBLA 84/48) was received and approved.

The Secretary would inform members of the budget figure for Overseas Travel.

72/84 Research and Development Projects - Six Monthly Review

A copy of a report prepared by the Director BPL (CBLA 84/49) was received and noted.

It was noted that the Director BPL would, at the end of the year, identify those projects which were concluded and their financial implications.

73/84 SAPU

The Secretary reported that the Director BGRL and himself had met representatives of the Common Services Agency on 30 August, 1984 to discuss relationships between the Scottish Antibody Production Unit (SAPU) and the Blood Group Reference Laboratory.

It was noted that a professional dialogue had been initiated between SAPU and BGRL and Dr Holburn and Dr A C Munro, Head of SAPU, would be preparing a joint paper for their next meeting identifying areas where collaboration might prove useful.

74/84 Anti-D Immunoglobulin

A copy of a report prepared by the Director BPL on Anti-D Immunoglobulin (CBLA 84/51) was received and noted.

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The disposal of the stock of Anti-D immunoglobulin in the form of freeze-dried Fraction II intermediate was formally approved. (This followed a hold placed on use of this fraction 9 months earlier, after a report of illness in a Trent Region plasmapheresis donor.)

75/84 Intravenous Immunoglobulin - Contract Manufacture

A copy of a report by the Director BPL on the production of Intravenous Immunoglobulin by external manufacture under Contract (CBLA 84/52) was received and noted.

The Director BPL said that letters had been sent out to enquire interest in tendering for production of iv immunoglobulin and five companies had now replied expressing a wish to tender. Preparation of formal invitations to tender was now in hand and Messrs Coward Chance had been consulted. Mr Williams emphasised the need for tenders to be drawn up in line with EEC procedures.

76/84 Plasminogen Manufacture - Discussions with Beecham Pharmaceuticals

A report of the Director BPL (CBLA 84/53) was received and noted.

Dr Lane reported that a meeting had been held on 3 September with Beecham Pharmaceuticals to consider the purification and supply of plasminogen in relation to supply requirements, specification, safety of product and costs. After discussion

the Chairman said there was a need to ask a reasonable price for this manufacture, which would be slightly favourable compared with the current market. A further report would be made to members in due course.

77/84 BGRL - Head of Reference and Research

The Director BGRL confirmed that there had been no obvious candidate for the position of Head of Reference and Research and therefore it was proposed to appoint a part-time consultant in Research, for BGRL. Dr D Anstee of Bristol had expressed a wish to take up this post which would create the advantage of integration with Dr Anstee's unit in Bristol. It was noted that, as part of the proposal, a Principal Scientific Officer would also be appointed to assist Dr Anstee.

Dr Gunson expressed his support for the proposal and whilst it was approved in principle, it was agreed that the position should be reported at the next meeting of the Central Committee for R&D in Blood Transfusion, inviting any comments it wished to make.

78/84 National Association of Health Authorities - CBLA Membership

A copy of a report by the Secretary (CBLA 84/50) was received and noted.

It was agreed, on the recommendation of the Secretary, that it was not appropriate for the CBLA to become a member of the National Association of Health Authorities.

79/84 Any Other Business

79.1 The Secretary reported that the old BPL chemical building had been demolished.

79.2 The Director BPL referred to the meeting the following day in Manchester of the British Blood Transfusion Service Society.

79.3 The Director BPL enlarged upon a further meeting he had recently held with the Director of CAMR, Porton Down.

80/84 Date of Next Meeting

The next meeting would be held on 28 November, 1984 at 2.00 pm and the possible absence of the Chairman on that date was noted.

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

PART II

81/84 Matters in Confidence

81.1 The chairman expressed deep concern about the actions of the Director BGRL in sending out a batch of Anti-D grouping reagent, which was known to contain Anti-BGA antibodies, against the advice of the Head of Quality Control.

It was subsequently agreed that Dr G A Stewart and Dr D P Thomas should carry out an audit of QC procedures within CBLA facilities starting with BGRL.

The Secretary was asked to write to the Director BGRL explaining the need for a detailed report outlining the events leading up to this incident and informing him that an audit of QC procedures within the manufacturing laboratories would be carried out.