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NATIONAL BLOOD TRANSFUSION SERVICE

JOINT MANAGEMENT COMMITTEE (DHSS/NORTH WEST THAMES RHA) FOR THE CENTRAL BLOOD LABORATORIES

MINUTES OF THE 10TH MEETING HELD ON 6 FEBRUARY 1981 AT THE DEPARTMENT OF HEALTH AND SOCIAL SECURITY, HANNIBAL HOUSE, ELEPHANT AND CASTLE, LONDON

PRESENT:

Dr E L Harris (Chairman)
Mr W P N Armour
Mr D G Lee
Mr A Bradshaw
Dr R S Lane
Dr A M Holburn
Professor P L Mollison
Dr G H Tovey
Mr J Harley
Dr D Walford
Mr S Godfrey – Secretary

IN ATTENDANCE:

Dr B A Wills
Mr L J Connor
Mr G J Brechin
Mr H B Hilton
Mr D J Collins
Mrs S C Yuille

INTRODUCTIONS

1. The Chairman welcomed Dr Wills (Chief Pharmacist, DHSS) Mr Hilton (Finance Branch) and Mr Collins (Project Manager, North West Thames RHA).

MINUTES OF THE PREVIOUS MEETING

2. These were agreed.

MATTERS ARISING

a. Progress on BGRL's Move to Oxford

3. Mr Harley explained that it was intended that the Laboratory should move to Oxford in January 1982 and tenders for the conversion of the Harkness Building had been invited. North West Thames RHA had been asked to take on the role of 'employer' in contracts with the architects and contractors, and to provide project management. The Authority had also been asked whether it might draw up an agreement with Oxford AHA(T) on the terms of occupancy covering among other items the payment for services.

4. Dr Holburn said that because of the short-fall in capital for the move, certain major items of equipment, including a sterile suite, could not be purchased. It was explained that because of the financial situation, there was no likelihood of more funds being made available for the move.

5. After discussion it was decided that the RHA and Dr Holburn should meet urgently with the Department to discuss various questions, including the RHA's role as 'employer' and project manager.

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b. Report on the management of the BPL Estate

Renovation of the cottages

6. Mr Collins reported that work on the cottages would be completed by the Spring. The total cost would be £70,000, of which at least £35,000 would be spent in the current financial year.

Lister Crest

7. Mr Godfrey said that Mr Roderick had written to say that he expected the Lister Institute to need Lister Crest at least for the remainder of 1981. Dr Lane explained that this was unacceptable because he needed the Crest urgently to accommodate new staff. In view of this it was agreed that Mr Roderick should be asked to vacate the Crest by July 1981. The Department would write to Mr Roderick.

Subsoil Survey

8. Mr Godfrey reported that the results of the sub-soil investigation had revealed that the sub-soil was conducive to a very economical foundation system, and was therefore ideally suited for the phased redevelopment which was being proposed for the site.

c. Report on BPL's RIA Test

9. Dr Walford reported that BPL was to market its test to Regional Transfusion Centres from 1 March at a cost of 20p per test. Mr Brechin explained that for England and Wales there would be a system of inter-Authority billing, and a cash transaction for tests supplied to Scotland. He foresaw no difficulties in financing the test in the current financial year; eventually the test would become self-financing.

10. Dr Lane said that the virology laboratory for the large-scale production of the test was due to be commissioned in March. He had already received requests for the test from throughout the Blood Transfusion Service including Scotland and Northern Ireland.

11. The Chairman asked the Secretariat to prepare a paper on the RIA test for the next meeting of the Advisory Committee on the NBTS.

SHORT-TERM DEVELOPMENT OF BLOOD PRODUCTS LABORATORY

a. Progress Report

12. Dr Lane reported that the major upgrading work was about to begin. The freeze-drier which had been installed in November was working satisfactorily. Repairs to the fabric of the sterile filling unit were being undertaken, and improvements had begun on the bacterial vaccines laboratory. He said that the cleaning programme which had been instituted was far from satisfactory (he did not think the laboratory was getting a specialist cleaning service) and would have eventually to be reviewed. Dr Lane foresaw major problems in setting up the documentation recommended by the Medicines Inspectors in the BPL's existing premises.

13. Although it had originally been intended to start fractionating plasma from single packs from April this year, the timetable had slipped and Dr Lane feared that the Coagulation Factors Laboratory would not be ready to accept single packs until Spring 1982, although the tear-down machine might be installed earlier. The CF Laboratory was due to be shut down for 3 weeks in November for renovation.

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14. It was agreed that Dr Lane and Mr Collins should meet urgently to discuss the phasing of this work.

b. Reports of Medicines Inspectors' Visits

15. Dr Lane said that he was concerned about the contents of the Medicine Inspectors' reports. He had understood that the intention of the visits had been to look at progress being made with the redevelopment, especially MARPO1, and not to conduct a formal inspection. Dr Wills confirmed that the reason for the visit was to review the progress of certain aspects of the upgrading work and this had been explained to BPL staff by the Inspectors when making the arrangements for their visits.

16. Dr Lane referred to his report which he said was not only a response to the Medicines Inspectors' criticisms but also set out what action had been taken since the formal inspection in September 1979, and what upgrading was still to take place. The short-comings referred to in the Inspectors' reports were being dealt with as far as possible. It was agreed that Dr Lane's report should now be sent to the Medicines Inspectors, who would be invited to discuss it at the next meeting of the Scientific and Technical Committee.

17. The Chairman said that it was of paramount importance for all those concerned to ensure that that remedial action which could be taken at the Laboratory should be taken as soon as possible. It was, for example, essential to fill the 3 key jobs of production manager (Deputy Director Administration), Head of Quality Control (HQC) and Head Engineer. Dr Wills explained that the job description of the HQC had been substantially agreed, although the question to whom he should report had still to be decided. It was agreed that Dr Lane, Mr Smart and Dr Wills should meet to discuss this further.

18. Speaking about the new post of Deputy Director (Administration) Dr Wills said that it required someone with technical knowledge and administrative experience. The Chairman underlined the importance of the post and the need to recruit a suitable candidate as soon as possible. Once the Committee, together with Dr Wills and Mr Smart had agreed on the requirements for the post and a suitable salary, the post could then be advertised. It was agreed that the Deputy Director should be appointed first so that he could be consulted on the appointment of the HQC.

19. Mr Godfrey reported that agreement had now been reached on the grading of the post of Head Engineer at BPL, and the Department's Personnel Division had written to the RHA with its recommendations.

20. Mr Lee explained that the salaries for the 3 new posts could be accommodated within BPL's budget.

LONG-TERM DEVELOPMENT OF BPL

21. The Chairman reported that Ministers had instructed officials to begin work on planning and designing a new BPL, and he referred members to a paper which set out a range of options for project management. The Committee agreed that options 4(i) (NW Thames RHA) and 4(ii) (a commercial firm) were preferable to the remainder.

22. Mr Armour thought that the RHA might be willing to take on the task of project management as outlined in para 4.i, provided that certain conditions on accountability, control and methodology were agreed. He emphasised that this was without prejudice to the RHA's views on the long-term management of the Central Blood Laboratories. He would discuss this with his Regional Team of Officers. If it was considered that the RHA did not have the expertise to provide project management, it could engage a suitably qualified project manager. The Authority, however, was not in favour of

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option ii (which envisaged the RHA (or DHSS) acting as employer to a commercial project management firm) because it could prove difficult for the Authority to exercise firm control.

23. Mr Harley pointed out that options 4(i) and (ii) required a separate input of expertise in pharmaceutical processing, fractionation technology, factory management and sterile production to assist in drawing up the design brief.

24. After discussion it was decided that the RHA and the Department should meet to discuss further the Authority's possible role in project management. However, members agreed that whatever option were chosen (and it seemed likely to be option 4(i) or (ii) a small steering group to provide policy direction would be essential. It was suggested that Mr Smart (Glaxo Holdings Ltd) be invited to chair this group, and other members would include Dr Wills and officials from the Department. One of the primary tasks of the group would be to suggest the composition of the design briefing team. /Members will wish to note that Mr Smart has since accepted chairmanship/.

25. Dr Lane referred to Dr Dunnill's letter of 26 January to the Minister of State for Health, in which he suggested that if a commercial company were to design and build the new BPL it would be completed more quickly, perhaps with a completion date of 1984, whereas it would take longer to re-develop the Laboratory following normal Departmental procedures. Mr Connor thought that this timetable was not feasible.

CASH LIMIT STATEMENT ON THE CENTRAL BLOOD LABORATORIES

26. Mr Lee referred to a paper which set out the schemes being undertaken at BPL and the latest estimated cost over the financial years 1980-81 to 1982-83. The paper also set out a summary of the cash position. Mr Lee also tabled for the Committee's information a paper which set out the cash limit position for the Central Laboratories as at 31 1 81.

27. Mr Brechin said that although the latter paper indicated that the total revenue under-spending at the Laboratories for 1980-81 was likely to be £300,000, this sum would be reduced by approximately £76,800 for superannuation payments relating to the financial year 1979-80.

LONG-TERM MANAGEMENT OF THE CENTRAL BLOOD LABORATORIES

28. Mr Armour said that now that Ministers had decided against commercial management of BPL the RHA was anxious that the future management arrangements for the Central Blood Laboratories should be resolved quickly. The RHA needed to have an answer within the next 2 months because if it were decided to ask the Authority to manage the Laboratories, it would have to take this task into account in its plans for re-structuring the Region as part of re-organisation of the NHS. Mr Armour also pointed out that the staff had expressed a desire to participate in the management of the Laboratories.

29. The Chairman pointed out that the Joint Management Committee had only been set up as an interim measure. A submission detailing the options for long-term management (which the Chairman outlined in strict confidence) was about to be put to Ministers. The views of the RHA would be incorporated in the paper and the Chairman invited other members, especially the Directors of the Laboratories, to send him their views, if they so wished.

MANUFACTURE OF MONOCLONAL BLOOD GROUPING REAGENTS

30. Dr Walford spoke to the paper which described Celltech's proposals for a joint venture with the BGRL on the production of monoclonal blood grouping reagents. The Committee's views were being sought on whether

i there should be a collaborative venture;

ii BGRL should manufacture monoclonal blood grouping reagents, although the NRDC would be in a position to dispose of the licence;

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iii BGRL should take on monitoring and quality control on an agency basic; or

iv any other option should be considered.

31. Professor Mollison thought that an alternative proposal might be for BGRL to make the initial choice of suitable cell lines, and then to undertake such quality control as was felt to be necessary. This would mean that BGRL would not be responsible for bottling or distributing the finished reagents.

32. Professor Mollison also thought that the proposal that the monoclonal blood grouping reagents should be sold to RHAs would cause difficulties in the long run because even if the reagents prepared by Celltech and BGRL were of good quality, many hospitals were likely to want to continue purchasing commercial reagents, not only because existing ones were satisfactory, but it was likely that American manufacturers would soon be in a position to make monoclonal anti-A and anti-B available commercially. BGRL would thus be in the position of trying to sell the British monoclonal antibodies in competition with American firms. Professor Mollison's conclusion was that the BGRL should not become involved in a collaborative venture.

33. Dr Holburn's view was that given access to the appropriate cell lines, the BGRL could produce sufficient blood grouping reagents to satisfy the NBTS and NHS. Already 75% of all reagents used in the NHS were either BGRL's or from the RTCs. If the collaborative venture proposed by Celltech went ahead, it would mean that BGRL would have to promote Celltech's product in opposition to its own.

34. The Chairman said that if it were generally agreed that it would be best not to enter into the sort of arrangement Celltech had initially in mind, some other form of collaboration might be in order. It was agreed that Dr Walford and Dr Holburn should meet Celltech for further discussions. Dr Tovey wondered whether a collaborative venture on HLA antisera might be appropriate.

REPORT ON THE MEETING OF THE SCIENTIFIC AND TECHNICAL COMMITTEE

35. Professor Mollison reported that at its last meeting the Committee had received a report from Dr Dunnill's Technical Working Party. The report highlighted

a. the need for the services of a full-time plant engineer to co-ordinate planning, followed by a specialist architect and a consultant engineer; and

b. the importance of good pharmaceutical practice and safety measures in the re-development of the BPL.

36. Dr Holburn had spoken to a paper on the BGRL's scientific programme, particularly on the manufacture of blood grouping reagents. Dr Holburn would now produce a paper for the Committee, detailing the long-term objectives of the Laboratory.

37. The Committee had discussed Dr Lane's proposals to set up a quality control programme at BPL. It was agreed that having received the advice of the Scientific and Technical Committee, Dr Lane should re-examine the quality control programme structure and the HQC job description in consultation with Dr Wills.

REPORT ON THE FIRST MEETING OF THE ADVISORY COMMITTEE

38. The Chairman explained that the Advisory Committee's first meeting had been an exploratory one touching upon some of the major questions which it would have to consider in depth later, for example increasing the supply of plasma to BPL.

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'TERCHANGE OF BPL STAFF WITH INDUSTRY

39. Mr Harley explained that Minister of Health was keen to encourage appropriate interchanges of staff between BPL and industry to broaden staff's experience. Mr Smart (ABPI) had thought that industry would welcome such an exchange. Mr Harley and Dr Lane had met to discuss this. Dr Lane agreed that his staff would benefit from such a scheme. He suggested that it might begin later in the year when certain of the production laboratories were being temporarily closed down for upgrading. It was also thought advisable to wait until the 3 senior appointments had been made.

ANY OTHER BUSINESS

40. Dr Lane spoke about the collaborative venture between BPL and Speywood Laboratories to manufacture Factor VIII by polyelectrolytes. This form of Factor VIII had been used in trials and was proving to be very satisfactory. However the process which originally involved the use of cryoprecipitate was now using whole plasma. There was some doubt whether the use of plasma was covered in the contract. It was agreed that Dr Lane and Speywood would draft a revised agreement to put to the Department.

DATE OF NEXT MEETING

41. This will take place on 20 March 1981 at 10 am in Hannibal House.

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