Reference 116

BLA 1/1

Extract from J.M.C. minutes 6/2/81

SHORT-TERM DEVELOPMENT OF BLOOD PRODUCTS LABORATORY

13/01

a. Progress Report

13. 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.

14. 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.

15. 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 - JMCCL(81)1
JMCCL(81)6 - tabled

16. 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.

17. Dr Lane referred to his report (JMCCL(81)6) 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.

18. 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; Dr Wills' view was that the HQC should report to the Deputy Director/Production Manager. It was agreed that Dr Lane, Mr Smart and Dr Wills should meet to discuss this further.

19. Speaking about the new post of Deputy Director (Administration) Dr Wills said that it required someone with technical knowledge and administrative experience. There was unlikely to be an equivalent post in the NHS. 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.

20. 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.

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