REVISED BUDGET 1978/79 : Forecast Budget 1979/80.

INTRODUCTION

Serum & Vaccines Laboratories

Closure of Lister Institute of Preventive Medicine (LIPM) has affected most aspects of BPL's operation and therefore the current budget proposals; in addition, the immediate period of reorganisation has coincided with the change in directorship.

1. Loading Bay Extension and Stop-Gap

Withdrawal of the Institute's operations from the Elstree site should be complete by July 1979 and, subject to approval, many long-standing constraints which have cramped BPL's development could now be removed. The main changes in the budget proposals relate to the original plans for the loading bay extension and Stop-Gap. Both programmes were developed while BPL was contained within the cramped leasehold on the Institute's site and the potential of each in terms of improved production and workflow was correspondingly severely compromised from the start. Subject to satisfactory negotiations between DHSS and LIPM, BPL should soon be free of these constraints.

In view of these changes and although further delays in planning will cause difficulties, the decision has been taken to abandon the old plans for the loading bay extension and certain earlier proposals for Stop-Gap developments. These two programmes have now been combined into an integrated system which will enable more effective utilization of process areas, greater flexibility of work, provide much needed and properly sited cold room space and will free production areas from bulk storage problems.

The urgent need for these improvements has involved a managerial systems consultant team (approved and financed by DHSS, June 1978) throughout the past four months in conjunction with BPL staff and a recently appointed group of architects. Interim proposals are available in a form which has permitted preliminary cost estimates to be included in the current budget submission and the provisional forecast estimate of £200,000 to be distributed between 1979/80, 1980/81 does incorporate considerable sums (approximately £150,000) already approved for the

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earlier planned loading bay extension and Stop-Gap developments.

Modification of the Stop-Gap programme will mean that significant sums of approved money will not be spent in the allotted financial year, but the decision represents a responsible attempt to obtain a great deal more value for the large capital sums involved and it is important that the revised plans for BPL will not be penalized as a result by budgetary policy. A request is made that approved capital can be carried forward into 1979/80, 1980/81 as outlined in this budget in order that, once the new programme is approved, implementation can proceed without delay.

2. Bacteriology and Small Pool Plasma

A provisional estimate of £40,500 has been included in the forecast estimates for 1979/80. The work in this Department represents the oldest process at BPL (freeze-drying of whole plasma, 14,000 containers p.a.) combined with routine bacteriology carried out in laboratories added during the 1965 extensions. This unit represents the worst section of BPL and is reflected in the continuous problems with staffing of all grades - a new promising Scientific Officer is to leave within one year of appointment after expressing dissatisfaction with conditions of work: Scientific Officers cannot be provided with their own room or with adequate bench space for scientific development.

The worst feature is the combination of bacteriological testing and the production of sterile plasma for therapeutic use within the same section of the laboratory. This is contrary to good manufacturing practice and will not be supported in the event of an enquiry.

Because of cramped facilities the initial bacteriological survey of incoming time-expired plasma is not separated from the sterility-testing of the purified final products, the latter being the most single important part of terminal-process quality control. Cross-contamination of samples occurs during testing and leads to an expensive lengthy process of retesting in order to exclude microbiological contamination of the product-batch.

Finally, closure of LIPM has meant closure of the Institute's media kitchen which provided a media service to BPL costing approximately £5,000 p.a.

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The service is at present purchased from a commercial firm at a cost of £10,000 p.a. until a small media kitchen, appropriate to the needs of BPL, is provided for the bacteriology department. The Institutes own media kitchen cost an estimated £87,500 p.a. made up of £66,000 direct costs, £21,780 overheads p.a., and was totally unsuited to BPL's needs.

An extension to the existing laboratory should be planned and erected at the earliest date. Features should include a media kitchen, separation of plasma pooling from routine testing, separation of final-product testing from initial bacteriological screening and laboratory facilities for scientific staff. An estimated extra 1620 square feet is required for which £40,500 is proposed in the forecast estimates 1979/80.

3. Development of Affinity Chromatography

Dr. Harvey was appointed to BPL approximately one year ago to develop chromatographic means of protein separation, in particular, affinity chromatography of albumin on Cibacron-blue Sepharose. This he has done most successfully and it will be possible next year to separate all the albumin from Cohn Fraction IV (at present incinerated). This albumin has considerable value as a diagnostic reagent and as a support solution in certain tests and it will be preserved for this purpose until the process is licenced to produce albumin for therapeutic use. The affinity chromatography system could salvage an extra 20,000 bottles of PPF each year from current production of Cohn Fraction IV.

At present however no significant budgeted provision has been made to sustain Dr. Harvey's work in research and development and accommodate expansion. To initiate toxicity testing on the Cibacron-blue-Sepharose-albumin system in line with advice from Medicine's Division will cost an estimated £42,000 in 1979/80 and a further £22,446 will be required for capital equipment >£500 in 1979/80.

Apart from these items, no provisional plans exist to provide Dr. Harvey with the necessary expansion in accommodation in the near future to house the chromatographic developments. With no commencement date yet proposed for the much needed Pilot Chromatography Laboratory, there must be concern over the conditions provided for a Senior Biochemist appointed for the purpose of developing Chromatographic separation of proteins on

the production scale.

4. Library

Closure of LIPM means that BPL must now run and provision the library. A curator has been appointed and the list of former journals reappraised. A new selection has been made which covers the wide field of subjects needed by BPL staff. The annual cost will be £5,500 i.e. one half percent of the total budget.

The library is shared by BPL and PFL (Oxford) in that journals are circulated.

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R.S. LANE
Director.

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