BLA/1/4

(59)

Mr Harris FAI

BPL REDEVELOPMENT

I attach a draft letter to the Treasury seeking approval in principle to begin incurring expenditure on planning the redevelopment of BPL. I have cleared its content with Mr Hanley and Dr Walford.

26.7.81

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Mr Harris telephoned with one or two minor queries. He will now consider with Mr Ridley-White (A|S) whether to view this as a submission for approval in principle (see para 1) or as a formal Stage 1 submission.

GRO-C

30.7.81.

1. DHSS Ministers have decided that the Blood Products Laboratory (BPL) should be redeveloped within the NHS, and have instructed officials to begin planning and design work for the redevelopment. This letter seeks Treasury approval in principle to begin incurring expenditure on planning the redevelopment of the Laboratory. The project is unlikely to cost less than £17m at Survey 81 prices, and, when completed, will increase the Laboratory's revenue costs from £2.2m to £5m per annum.

Background

2. The National Blood Transfusion Service in England and Wales comprises 14 Regional Transfusion Centres run by RHAs, and 3 central blood laboratories (the Blood Products Laboratory, the Plasma Fractionation Laboratory and the Blood Group Reference Laboratory) run by a Joint Management Committee (DHSS and NW Thames RHA). Scotland has its own blood transfusion service and Protein Fractionation Centre.

3. BPL is essentially a pharmaceutical factory, employing some 125 staff. It receives plasma from Regional Transfusion Centres and fractionates it into various products - notably Factors VIII and IX for the treatment of haemophiliacs, protein solutions for the treatment of burns etc, and normal and specific immunoglobulins for the treatment of certain diseases. Some of BPL's products are not available commercially. The plasma is supplied without charge; at present BPL does not charge RHAs for its products, but this arrangement is to be reviewed. The cost of maintaining BPL is borne on NHS Vote X1-1, Subheads D3-D4.

4. A Laboratory was first established at Elstree in 1952, mainly to salvage plasma from time-expired blood. A new manufacturing unit was commissioned in the 1960s, since when fractionation technology has changed considerably, and the demand for blood products has increased far beyond what could reasonably have been predicted. As a result, the present Laboratory cannot meet the demands for products nor can it comply with modern pharmaceutical manufacturing standards (see paragraph below). Although BPL's production has increased steadily over the years and is currently worth about £11m a year to the NHS, health authorities are obliged to supplement supplies from BPL with expensive and, because of the hepatitis risk, less safe imported commercial blood products at a cost of up to £10m annually.

5. BPL was not purpose built for manufacturing on the present scale. Although it originally conformed with the criteria for medical manufacturing thought appropriate at that time, it now falls considerably short of the standards of good pharmaceutical manufacturing practice applied by the Medicines Inspectorate under the Medicines Act 1968 -standards which successive Ministers have agreed should be observed by NHS manufacturing facilities as well as being required of commercial firms. In 1979 the Laboratory was inspected by the Medicines Inspectorate. The gist of the Inspector's report was that conditions of manufacture at BPL were unsafe and potentially hazardous to patients. The report concluded "If[BPL] were a commercial operation we would have no hesitation in recommending that manufacture should cease until the facility was upgraded to a minimum acceptable level". The Inspectors recommended the complete replacement of the Laboratory, with suitable short-term measures to improve things while rebuilding took place. They pointed out that the Laboratory would have to be redeveloped, since much of its structure would not be useable beyond five years. Ministers agreed that in the interests of patients, closure of the Laboratory could not be contemplated, and they approved a short-term upgrading programme to remedy some of the deficiencies highlighted by the Medicines Inspectorate, and to enable BPL to increase the output of its two major products (Factor VIII and albumin), while consideration was given to the question of redeveloping the Laboratory. The cost of upgrading (almost £2m) is expected to be more than covered by the value of increased production before the present Laboratory is closed.

Redevelopment

Discussions with Industry

6. Last year, the Department investigated the possibility of a British pharmaceutical company rebuilding the facilities and manufacturing blood products on an agency basis for the NHS. Ministers concluded, however, that there was no place for a commercial company in the management of a service which depended upon volunteer donors, and decided that the Laboratory should be redeveloped within the NHS. This was confirmed by Sir George Young in an Adjournment Debate on 15 December, although no commitment was given about the timing of redevelopment.

Planning / design work

7. Some of the preliminary planning work has already begun, and Ministers have agreed to the establishments of a small Policy Steering Group to act on behalf of the Joint Management Committee in planning the redevelopment. The specialised nature of the facility makes it difficult at this stage to estimate with any precision the cost involved. (A cost cannot satisfactorily be based on that of the Scottish plant which is on a much smaller scale and uses a different technology that would not be appropriate for the scale of production required in England and Wales). It would however be unwise to assume that the cost (including fees and equipment) of rebuilding key areas only will be less than £17m at Survey 81 prices spread over the period 1982/1983-1986/87. It could well amount to £25m. Costed design options should be available later this year, and I will write again when these are ready; further work to produce a firm budget cost based on the chosen option and a well-developed design will take 6 months more.

8. A major factor in the cost is the target capacity required of the new Laboratory. For example, demand for Factor VIII is expected to rise from 55 million international units in 1980 to 100 million units by 1985 because of the ageing of the haemophiliac population, and other factors such as changes in the clinical use of the product. I should perhaps explain that we tend to concentrate on Factor VIII demand when estimating the level of production required to enable the NHS to become self-sufficient in blood products because the production technology is such that if we achieve self-sufficiency in this Factor we will achieve self-sufficiency in other products.

9. The 28th World Health Assembly on "Utilisation and Supply of Human Blood and Blood Products" urged World Health Organisation Member States to become self-sufficient in blood and blood products. The principle of self-sufficiency has been fully endorsed by the Government, though Ministers have stated that it must inevitably be a long-term aim. To achieve it, however, would require health authorities to increase six-fold their supply of raw material to BPL, and we are currently studying a range of options in terms of target capacity on which we will be consulting the NHS. We may also be able to make some very limited use of the Scottish plant's capacity. It would seem, nevertheless, that the economy of scale in the production process is such that it is unlikely that we should make directly proportionate savings in the cost of redeveloping BPL if we were to aim at producing only a proportion of the products required by the NHS.

10. We are preparing an initial economic appraisal of the options available to us but a cost benefit analysis prepared at the end of last year, on the basis that redevelopment of the Laboratory to achieve self-sufficiency would cost £25m suggested that the outlay would be paid back (in terms of the replacement of imported commercial products) after six years' operation. We are working on better costings for the plasma supply side of the redevelopment equasion as a matter of urgency, and we will refine our cost benefit analysis as more information becomes available. Given that the Laboratory has to be redeveloped, the main question before us is the optimum target capacity, balancing costs of redeveloping the Laboratory itself and of increasing the supply of plasma against savings to be made by reducing our dependence on imported blood products.

I would be grateful for early approval to proceed with planning on the basis outlined above. Because of the specialised nature of this development, I would be happy to arrange a meeting with those directly concerned if you feel it would be of assistance.

Yours sincerely

D HARRIS