1. Mr Heppell

2. Mr Podger (Mr Peach is Accounting Officer)

3. Mr Langsdon

4. Mr Muir

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REDEVELOPMENT OF BLOOD PRODUCTS LABORATORY ELSTREE

Summary

1. This submission seeks Ministers approval for an increase (from £38.8m to £60m) in the capital cost limit for the new Blood Products Laboratory, Elstree. It updates the submission of 7 August 1986 which is attached as Appendix A.

The laboratory is scheduled for completion in the first part of 1987.

Background

2. The history of the project and the factors which have contributed to the escalation in costs have been detailed in paragraphs 2 to 6 of the submission to Ministers of 7th August (Appendix A). Costs have increased further since that submission.

Current Cost Estimate

3. The cost limit now needs to be raised from £38m to £56.5m. This cost represents the estimate of most likely outcome. It shows an increase of £4.5m over the final cost estimated in the August submission. The latest increase is almost entirely due to reassessments which have been made of the necessary work required to enable the sub-contractors to meet their specifications. There have been no significant changes to the scope of the work.

It remains possible that other essential costs will emerge as the sub-contracts near completion. Although the estimate of final cost should be more accurate as completion approaches, a pessimistic forecast of £60m has been made to allow for unknowns.

CBLA have separately submitted a draft Approval in Principle request for a warehouse, quality assurance, and engineering building costing £7m. These are essential to the full functioning of the factory. Thus the cost of bringing the new production centre fully on-stream amounts to some £63.5m to £67m Appendix B summarises the financial history of the project.

Current Completion Date

Lurrent Completion Date

4. Completion takes place in stages so that CBLA can start commissioning those areas which have been scheduled to be finished first. Commissioning of some parts of the factory has already started and it is anticipated that limited production will begin in the summer of 1987. The build-up to a will begin production levels consitent with self-sufficiency will be dachieved eduring consitent with 1989. Appendix C summarises the delays in completion of the project. The building will still have been completed -2/3 years the earlier than conventional methods would have alllowed.

Recent steps taken by DHSS to improve control of the project

- 5. As the problem of increasing cost has emerged, the Department has had to diverge from the "hands off" remit envisaged by Ministers (see para 4 "hands off" of Appendix A) and become increasingly involved with the details of the project in order to ensure that all possible steps were taken to control costs.
- 6. Most recently this involvement has included a meeting between senior officials, the CBLA chairman and the chairman of the contractor company (Matthew Hall). The meeting was constructive and agreement was reached on a range of procedures for ensuring that the final stage of the factory could be finished as soon as possible. Matthew Hall made out a strong case that the increase in costs was largely due to the complexity of the project which was underestimated at the tendering stage.
- 7. In addition officials now meet regularly with CBLA to ensure that no design amendments are made other than those essential for safe and effective production. Less critical work outside this category will be postponed until the main contract has been completed.
- 8. The fixed fee agreement negotiated with Matthew Hall was based on a completion date in early July. They are now losing money on the scheme. It would be inequitable for them not to get fair remuneration for their work. CBLA are in negotiation with Matthew Hall to agree additional fees. Officials will ensure any settlement has due regard for economy. Allowance for additional fees has been made in the costs at paragraph 3 above.

Benefit of the Factory and its Early Completion

- 9. The financial and other benefits of early completion set out in paragraphs 9 and 10 of the August 1986 submission remain valid.
- 10. The submission of 7 August (paragraph 12) set out a number of options but concluded that the only viable option was to complete the project as quickly as possible. The subsequent passage of time has made any option even less viable.

Cash Limit for 1986/87

12. Expenditure incurred on this project by the end of 1986/7 will be £10million above the authorised cash limit. Ways have been found to accommodate this extra pressure. The cash limit needs to be formally adjusted to reflect this reality.

Cash Limit for 1987/88

13. Sums have been provisionally earmarked within the deposition of HCHS capital to meet the anticipated cost of completing this project. If Ministers approve a formal cash limit will be agreed with CBLA.

Improvements to CBLA management

14. The complexity of the project is the most important cause of the cost escalation. However the Authority could have exercised its role more effectively. During critical stages it was under resourced managerially. Only at the Department's instigation were consultants brought in to strengthen the client team. Steps have been taken to strengthen general management at the CBLA - a new chief executive takes up post on 12 January. Steps are also being taken to strengthen the Authority it self by bringing in new members of hopefully higher calibre.

Audit Interest

15. The National Audit Office have stated that they are likely to examine the project on completion. Public Accounts Committee scrutiny in 1987 or 1988 is therefore a possibility.

Recommendation

16. Officials recommend that the Revised Cost Estimate of £60m accepted. This option has demonstrable economic benefits for the NHS and maintains Ministers' intent to achieve self-sufficiency as soon as possible.

Decision Required

- 17. Are Ministers content that:
 - a) the cash limit for 1986/87 be adjusted; and
 - the necessary funds are allocated in 87/88.

M A HARRIS 1209 HAN.H. EXT GRO-C

29 December 1986

Mr R Davis HBD Dr Moore cc Dr Harris Mr James FA Mr Cashman (O/R) Dr Smithies Mr Goodman HBD

WITN0771066 0003

REDEVELOPMENT OF BLOOD PRODUCTS LABORATORY ELSTREE

Summary

1. This submission seeks Ministers approval for a substantial increase (from £38.8m to £52m in the capital cost of the new Blood Products Laboratory, Elstree. The laboratory is now scheduled for completion early in 1987.

Background

2. In 1982 Ministers decided that the UK would become capable of achieving self-sufficiency in blood products, with substantial savings to the NHS, by the major redevelopment of the Blood Products Laboratory (BPL) at Elstree.

A new production unit, with three-times the manufacturing capacity was needed. Ministers decided that, because of the urgency of getting the new unit into production to achieve self-sufficiency—and NHS savings as soon as possible, commercial contractual procedures could be used. Five companies were invited to submit proposals. The feasibility study prepared by contractors Matthew Hall Norcain, (MHN) without the benefit of detailed design work, concluded that the plant could be built for £22.6m at November 1981 prices on a design, manage and construct basis.

The then PS(H) (Mr Finsberg), after deleting contingencies provision, gave the Central Blood Laboratories Authority (CBLA) approval to go ahead with a budget of £21.1m (November 1981 prices). Inflation indices would raise this budget figure to about £27m at 1986 prices.

3. There was a considerable risk in entering a fast track "design, manage and construct" contract with a fixed budget and a commitment to start building before either the design or its cost was firm. If the budget cost is paramount, the scheme may not meet the design objectives. If, on the other hand, the designers stick closely to the specified functions of the scheme, then the budget cost can only be regarded as tentative until the outcome of detailed design and costing is known. As the design stage is likely to continue well into construction, cost-monitoring techniques are difficult to apply. Fast-track procurement methods are quite normal in the pharmaceutical world, but unique for the NHS. Time is not usually so critical to NHS projects, and contracting is done after completion of the design.

- 4. On the direction of Ministers, CBLA were given the task of managing the project and the Department's role was intentionally minimal. Within this remit, progress and cost were monitored but effective cost control had largely to be left to the Authority. The considerable development of services, design, and specification of process equipment and plant during the construction stage made cost control extremely difficult.
- 5. In September 1984 Ministers approved an increase in project costs to £35.5m. This increase had arisen due to the incorporation into the original design brief of the latest available technology for flexible operation and automation. The increase in building and equipment costs was expected by officials to be accompanied by a decrease in revenue costs. At that time it was understood that design work was 95% completed and that the estimated costs were therefore realistic. CLBA had also sought funding for ancillary warehouse and quality control facilities but in view of the escalation of costs in the main project, no funds were made available.
- 6. During 1985 it became apparent that although no further expansion of the scheme was taking place, the cost was still rising and slippage of the completion date was occurring. The inability of the management of CBLA to control all aspects of such a complex project was becoming a matter of increasing concern. At the Department's prompting they took on, in August 1985 a firm of project management consultants (BDP), to coordinate all management aspects of the scheme. In September 1985 officials approved a revision to the cost limit from £35.5m to £38m which at the time appeared to be a realistic estimate of the final cost. The subsequent investigations by BDP have revealed for the first time the extent of the cost escalation and the slippage in completion date: details which CBLA had not been able to fully extract from MHN themselves. Detailed monthly cost reports during 1986 have shown continuing increases in estimated costs due to:
 - a. Essential modification by the contractor to designs in order to meet the specification and the reintroduction of essential equipment previously omitted to make immediate savings. Appendix 1 gives examples.
 - b. Revision by the contractor of previous estimates of quantity and cost of materials and equipment.

- c. Delays in actual construction because of the complexity of the plant and difficulties with special building techniques. These delays give rise to claims by sub contractors for extra payment for their work. Special measures such as weekend working may be needed to contain the programme . slippage.
 - d. Additional MHN fees.
- 7. As the inability of CBLA to control costs has emerged, the Department has been forced to diverge from the remit envisaged by Ministers and become increasingly involved with details of the project. CBLA have been put under considerable pressure from the Department to increase the effectiveness of their project management and to limit the escalation of costs.

Current Cost Estimate

8. CBLA have made a formal submission for the cost limit to be raised from £38m to £52m to take account of all known and projected requirements essential to completion. This cost represents the present estimate of most likely outcome. A small amount of design work is still outstanding and cannot yet be finally costed. However the delay in completion has led to problems with critical sub-contractors, the full effect of which is only now emerging.

Allowance for possible disruption to the programme by this and other unknowns gives a £55m pessimistic forecast. Appendix 2 gives details. CBLA have separately submitted a draft Approval in Principle request for a warehouse quality assurance and engineering building costing £7m (see paragraph 5 above). These are regarded as esential to the full functioning of the factory but the start of the work may be delayed for funding reasons. Thus the cost of bringing the new production centre fully on-stream amounts to some £57m to £62m. Appendix 3 summarises the financial history of the project.

Current Completion Date

9. Progress against current programme suggest that the factory will start processing plasma during the first half of 1987. Commissioning of some parts of the factory has already started and it is anticipated that limited production will begin in the summer of 1987. The build-up to production levels consistent with self sufficiency will follow. Appendix 4 summarises the delays in completion of the project.

Financial Benefit of Factory

10. When completed, the new factory will make blood-products with a commercial value of about £45m p.a. for the NHS. In addition, by the time self sufficiency has been achieved, CBLA anticipates sales of excess production outside the NHS to be worth £10m p.a. The running costs of the new factory and support services, including the supply of plasma will then be around £35m p.a. There would therefore be a net saving of around £20m p.a. to the NHS. Although the CBLA estimates may be too optimistic, it nevertheless still looks possible to payback the capital investment in 5 years.

The Importance of Early Completion

- 11. There are several reasons for BPL being completed speedily
 - i. By 1980 it was clear that BPL was not capable of meeting Medicines Act requirements. Since then it has been relying on Crown Immunity to stay in operation.
 - ii. There is considerable potential for saving money on imported blood products and there is potential income from the sale of product surplus to NHS need (see above).
 - iii. The problem of Hepatitis and (more recently) AIDS contamination of imported Factor VIII. All imported Factor VIII is now heat treated and considered safe, but there is some evidence that the BPL product remains superior to these commercial alternatives.
 - iv. The Blood Transfusion Serviæ has geared up to increase plasma suplies. Large stocks are building up. Further delays beyond those already apparent would increase storage problems. Regions expected to offset the cost of plasma collection against the supply of 'free' Factor VIII from BPL. Instead they are supporting the costs without any benefit.

Options Appraisal

12. The available options have been considered and where appropriate costed [Appendix 5]. The preferred option is to accept the revised cost estimate of £52m. This option will lead to completion of the building in the shortest time and at the lowest cost. The benefits to the NHS of early completion will accrue sooner.

Further expenditure to the order of £6m will be required in 87/88 for Warehouse, Quality Assurance and Engineering buildings.

Availability of Finance

13. It is estimated that the CBLA will require £16m in 1986/87 to meet revised expenditure demands. This is some £10m more than the present allocation, and there is no ready provision to fund the excess. There is a distinct possibility that a large part of the deficit can be met by brokerage with the Regions. It would require later repayment through central top-slicing of health authority capital, probably in 1988-89. Where possible, all reasonable means of spreading the costs by deferring expenditure into the next financial year will be considered short of deliberately delaying the project.

Audit Interest

14. The National Audit Office have stated that they are likely to examine the project on completion. Public Accounts Committee scrutiny in 1987 or 1988 is therefore probable.

Recommendations

15. Officials recommend that the Revised Cost Estimate of £52m should be accepted. This option has demonstrable economic benefits for the NHS and maintains Ministers' intent to achieve self-sufficiency as soon as possible.

Decision Required

16. Ministers are invited to approve the revised cost estimate of £52m and to agree that, as far as possible, the necessary steps should be taken to make the extra provision required so that the CBLA's 1986-87 cash limit can be set to allow the project to proceed on schedule.

EXAMPLES OF INCREASED COSTS ARISING FROM EXTENDED SCOPE OF WORK

Extra Work

In order to ensure that the factory meets the required specification for its function, the scope of work has increased substantially from that assumed initially. The details of these increases are recorded on variation orders. The total value of these variation orders to May '86 was £6.9m.

Examples of these orders are

11

Increased requirements regarding sterilising ovens	£30,000
Revision to air conditioning	£118,000
Water treatment plant	£33,800
Ground floor cold rooms	£272,000
Packaging lines	£350,000
Standby Diesel Generators	£230,000
Factor 8Y Heat Treatment Equipment	£392,000

BLOOD PRODUCTS MANUFACTURING UNIT: ELSTREE

ANALYSIS OF COST INCREASES

	WORKS	CONTINGENCIES	FLUCTUATIONS	FEES AND	TOTAL	**************************************
	E	£	£	EXPENSES E	£	evene Egyman ARO
MHNE estimate April Report No 1 (1983 ra no allowance(for incosts)	ates with	Nil	Ni1	3.950	27.630	
Allowance for increance included in Cost Re	a		*3.100		3.100	
Additional Work:				Wys		
Variations ordered Rework Allowance for extra Pyrogen-free and des systems Additional allowance identified work	work to min. water e for	•500 •500)			
Allowance for items from Cost Report No	•)			
Claims:		00000	}			
Provision in Cost R No 33 Reserves/Overrun General Contingency Allowance for restr uneconomic working CBLA Costs (apporti	3.500 1.770 ictive and practices	1.000	}	3.250 0.750	18.520 1.000 1.000 0.750	APPENDIX
	37.950	3.000	* 3.100	7.950	52.000	N
Add for pessimistic forecast mid 1987 c		Inc	Inc	Inc	3.000	
	40.950	3.000	* 3.100	7.950	55.000	
•		Tanana and				

Finar	ncial History of I	Project	£m	
1.	11th Nov '82	Treasury Approval for £22.6m Ministers withheld contingency CBLA authorised	21.1	
2.	19th Jan '83	Works 13.8 Equipment 4.6 Fees 2.7		
.5		21.1 (Nov '81 prices)	21.1	
3.	15th April '83	Contract signed with MHNE		
4.	May '83	Construction started		
5;	Aug *84	CBLA request £38.7m (incl. 3.45 for Warehouse/QC building)		
		21.1 original authorisation 4.2 inflation 1.6 construction 3.6 equipment 4.8 fees 35.3		
6.	21st Sept '84	Submission to Ministers for £38.8m		
7.	28th Feb '85	CBLA authorised (No warehouse/QC building)	35.35	
8.	Aug '85	Submission to Ministers for £38m (Approved by K. Stowe)		
		Works and Equipment 31.0 Heat treatment 0.4 Fees 6.5		
		<u>37.9</u>		
9.	-	CBLA authorised	38.0	
10.	Feb '86	Fees fixed at £6.9m		
11.	July '86	Estimated Cost £52m Pessimistic forecast £55m (excluding warehouse/QC buildings)		

Slippage of Project

Date	Projected Completion
Nov *82	July '85
Nov *84	Dec 185
July '85	June '86 including commissioning
July '86	Early '87

Summary of Options Appraisal

The following options have been considered.

1. Abandon the project:

This is the most expensive option and is not viable. It would involve abandoning self sufficiency entirely since the present plant cannot continue much longer. The new plant is in any case in a semi completed form and writing off the present level of investment would be difficult to justify.

2. Complete within previous cash limit by redesign:

This is not possible; spending has already reached £36m. The design philosophy is too far developed to enable radical change to be made.

3. Clear site and employ new main contractor:

There would be considerable financial penalties and the time to completion would be considerably extended.

4. Exert legal pressure on the main contractor to obtain redress:

CBLA have been advised by their legal advisers that there is little scope in the original contract for any penalty.

5. Reschedule the project to delay completion until mid 1987:

This option is marginally more costly than acceptance of the revised cost estimate. However, it would be difficult to achieve a controlled delay of the programme. Loss of control could lead to greater cost penalties.

6. Defer expenditure on QA, Warehouse and Engineering Buildings:

The time-scale of consultation with CBLA on this issue have effectively limited likely expenditure in 86/87 to $f_2^{\perp}m$. However expenditure on these essential facilities will be required in subsequent years.

7. Accept revised cost estimate:

This is the cheapest alternative. It will also ensure the most speedy commpletion of the factory and self sufficiency . in blood products for the NHS.

Finan	cial History of F	Project	£m
1.	11th Nov '82	Treasury Approval for £22.6m Ministers withheld contingency CBLA authorised	21.1
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		original authorisation 4.2 inflation 1.6 construction 3.6 equipment 4.8 fees	
6.	21st Sept '84	Submission to Ministers for £38.8m	
7.	28th Feb '85	CBLA authorised (No warehouse/QC building)	35.35
8.	Aug 185	Submission to Ministers for £38m (Approved by K. Stowe)	
		Works and Equipment 31.0 Heat treatment 0.4 Fees 6.5	
		37.9	
9.	17th Sept '85	CBLA authorised	38.0
10.	; Feb '86	Fees fixed at £6.9m	
11.	July '86	Estimated Cost £52m Pessimistic forecast £55m (excluding warehouse/QC buildings)	55.0
12.	Dec '86	Estimated Cost 56.5 Pessimistic Forecast 60.0 (excluding warehouse/QC buildings)	60.0

Slippage of Project

July '86

Nov '82

July '85

Nov '84

Dec '85

July '85

July '85

Early '87

WITN0771066_0016