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NBTS CENTRAL LABORATORIES
BPL : BLOOD PRODUCTS PRODUCTION

NOTE OF A MEETING HELD ON 25 OCTOBER 1977 AT THE BLOOD PRODUCTS LABORATORY

PRESENT:	BPL	DHSS
	Dr Maycock (Chairman)	Mr Parrott
	Mr Bailey	Mr Dutton
	Dr Lane ✓	Dr Waiter
	Mr Vallet	Mr Cleasby

1. Dr Maycock explained that the original stimulus for the meeting was the arrival at BPL of letters from Sheffield RTC and West Midlands RHA containing proposals both of which would involve BPL in processing greater quantities of plasma into Factor VIII concentrate. Although BPL could process one extra plasma pool per week this would be carried out in unsatisfactory accommodation which the Medicines Inspectorate would be likely to condemn. It had therefore been decided that the scope of the meeting could usefully be broadened to consider future production problems at BPL generally.

2. The Department thought that the meeting would be a useful occasion to take stock of BPL's current situation and to crystallise the possibilities for future planning. At this stage, however, there could be no commitment by the Department to any specific solution.

3. Dr Lane saw 3 principal determinants:

a. The continuing pressure, both from the field and the Department, to produce more Factor VIII concentrate. BPL had almost reached the limit of its present production capacity, and, as a prerequisite, RTCs would have to increase the supply of plasma.

b. The implications of the recommendations of the Working Group on trends in the demand for blood products (the "Trends" working group), which pointed to a substantial expansion of the existing production of Factor VIII and albumin over 5 to 10 years.

c. The application of the Medicines Act to the NBTS and the probability that a number of processing units in RTCs and in BPL would not meet the standards being demanded by the Medicines Inspectorate, particularly in relation to open systems for handling blood and plasma.

He suggested that developments at BPL should be closely integrated with those at RTCs: for example, BPL might consider looking to the geographically close Thames RTCs alone for plasma supplies, perhaps with plasmapheresis units being funded centrally as BPL satellites; similarly, BPL could mitigate the effects of the Medicines Act in the Regions by redeveloping its production facilities to enable RTCs to send single packs of plasma there, thus obviating the need for sterile areas for plasma pooling at RTCs. At BPL, the redevelopment ~~to be envisaged~~ would take place in 3 phases:

I - Factor VIII production (with support services, including R & D) and the proposed chromatographic separation pilot plant would be relocated outside the present BPL building.

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II - Albumin production would be moved from the existing building.

III - The existing BPL shell would be re-equipped to include units for bacteriology, pharmacology, physiology and quality control.

The cost of this work would be offset by savings accruing from the fact that less sophisticated facilities than at present would be needed at RTCs. Effective implementation of such a scheme would require a high degree of national coordination.

4. Mr Parrott explained the Department's thinking on future planning for BPL. It was clear that the current constraints on expenditure and the relationship existing between the Department and NHS field authorities were not conducive to the successful implementation of radical, expensive solutions to blood products production problems. Although the Department fully accepted the desirability of having the activities of RTCs coordinated among themselves and with the central laboratories, it would not be possible to instruct RHAs how to develop their RTCs. However it was agreed that whatever happened at BPL would tend to influence RHA planning of their own services. Progress would most probably be achieved by concentrating on what needed to be done at BPL and a phased redevelopment solution, such as that put forward by Dr Lane, seemed to be worthy of further examination. The need to expand blood products production, provided this was done on the basis of low-cost, selective development, was now being accepted by the Department, and the importance of maintaining a separate production unit for England and Wales and of not relying on the Scottish PFC at Liberton had recently been affirmed. The Department would therefore welcome further development of these ideas by BPL leading to the preparation of realistic development plans, based on agreed production targets.

5. The meeting agreed that planning would have to be based on the assumption that the RTCs would be able to deliver the plasma required to meet future demand. Over the past 11 years, the average annual growth in donations collected by the NBTS was 3·1% which, if this trend continued, would provide the NBTS with 2·4 million donations by 1985. This would just be sufficient to yield 200 gm of albumin annually per 1000 population (as recommended by the "Trends" working group), provided that RTCs could issue 80% of their blood to clinicians as concentrated red cells.

6. The Department wondered whether some immediate action should not be taken in view of the fact that even the first phase of the rebuilding would take some years to complete. It was suggested that BPL should examine the possibility of contracting out certain non-specialist operations (eg packing, labelling) so as to release space within the existing building for increased production, and there might be other similar possibilities.

7. In further discussion, the following points were made:

7.1 The main BPL products were expensive: the Factor VIII concentrate alone was worth £1·3 million annually.

7.2 It was not necessary to maintain routine production and R & D in the same unit, and there was the possibility, in theory, of locating a blood products "factory" in a place other than Elstree. There were, however, thought to be advantages in keeping the supervision of both elements under a single medical director at a common site.

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7.3 The present area leased by BPL (about 1/8 of the whole Lister Institute 36 acre site) was too congested to allow further building there. Any new construction at BPL would therefore involve the leasing of more land from the Institute, and informal soundings with the Governing Body by BPL would precede any formal approach.

ACTION

8. It was agreed that BPL would draw up a list of options for future development, bearing in mind the constraints outlined in paragraph 4 above. The production targets were 50 million iu of Factor VIII annually, and 200 gm/1000 population of albumin annually. A possible solution involving redevelopment at Elstree is outlined as an Annex to this note.

November 1977

RPC
DHSS (HS2A)

cc those present
Mr M A Harris
H1/B13/2
H1/B15/02
H1/B12/6

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ANNEX

A POSSIBLE SOLUTION FOR PHASED REDEVELOPMENT AT BPL

IMMEDIATE ~~Provided that the Expert Group approved the proposals and~~ the pilot scheme for chromatographic separation, including associated R & D laboratories, storage, and quality analytical control. ~~The possibilities of releasing extra space for production (6 above) would be studied.~~

PHASE I Factor VIII. Increased production and support services, including the processing of consequential albumin and the associated cryosupernatant

PHASE II PPF/albumin.

PHASE III Reworking of existing BPL shell, including provision for bacteriology, pharmacology, physiology and administration.

The plans would take account of the production requirements for other products.

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