Mr Canavan, HC(A)4B

FROM: Richard Armstrong, PS to PS(H)

DATE: 8 July 1992

COPY: Mr Malone-Lee
Mr Scofield, HC(A)4
Dr Rejman, HC(M)2

FOLLOW-UP TO CBLA VISIT: 6 JULY

Following the visit to the CBLA on Monday 6 July there are two issues that PS(H) wishes to follow-up.

NBA

PS(H) supports the creation of a National Blood Authority (NBA) and believes that this is something officials should be working to achieve in the near future. However, he has some concerns that the NBA is planned to be simply a policy orientated authority rather than having direct responsibility for the management and delivery of blood services (i.e., the regional transfusion centres and BPL). PS(H) would wish to have a paper setting out officials thinking on the NBA, how it proposes to work, its relations with RTCs/RHAs and the proposed relationship with BPL.

FUTURE MANAGEMENT OF BPL

PS(H) is interested in moving BPL towards a more commercial relationship in competing for business in England and Europe. He is not however, convinced that the time is right for a complete move away from public control, especially as they have yet to demonstrate financial viability. PS(H) would wish officials to pursue suggestions that BPL could become a trust or an Agency (in time moving towards trading fund status): as well as the option of BPL staying within the control of the NBA. PS(H) is more struck by Agency status than becoming a trust in that it will ensure management and the Board of BPL taking a hardheaded look at their business and the actions they need to take to ensure financial viability. He believes Agency status is a better mechanism by which to make them consider these options.

One issue which was of particular concern to PS(H), and on which he wishes to have more information, is the funding formula agreed between the CBLA and RTCs for providing plasma to BPL. PS(H) is concerned that this is loaded against BPL and wishes to see a rationale of the current costing. The Minister would also like more information on various charges made by each RTC in providing plasma to BPL and how this differs from the "spot market" price for plasma. If plasma was not provided to BPL would there be savings for the RTCs or would the cost occurring to RTCs in obtaining blood remain the same?

When you have provided this information we will arrange a meeting for officials to discuss this matter with the Minister.

GRO-C

p.p. RICHARD ARMSTRONG
414 RH
GRO-C

For Files GEB 5

Miss K Widdocks
DS/PS(H)

From: J Canavan
CAD-OPU2
505 Eileen House
Ext GRO-C

Date: 2 July 1992

cc: Mr Scofield CA-OPU2
Dr Rejman HC(M)2

CBLA

I enclose briefing for PS(H)'s visit to Elstree on 6 July 1992.

Flag A - the programme

Flag B - general background briefing

Flag C - briefing on current issues

Flag D - CBLA's Annual Report - Minister may wish to browse through it

I will be available to accompany PS(H) on the visit.

GRO-C

J CANAVAN

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FLAG A

ITINERARY FOR 6TH JULY 1992

11.00 am	The Rt. Hon. Thomas G Sackville arrives
	Introduction
	Coffee
11.10 am	Mr Wing's Opening Remarks
	Presentations by:
	- Mrs G M Fryers, Marketing Manager
	- Mr R C Walker, Chief Executive
	- Mr R A Wing, Chairman
	- Dr R S Lane, Director Bio Medical Services
11.40 am	Video and tour of site
12.45 pm	Lunch
1.30 pm	Forward plan and discussion
2.00 pm	Leave

ADDITIONAL INFORMATION

Mr R A Wing	- CBLA Chairman
Dr Brian Cromie	)
Mr Hamilton Dempsey	) - CBLA Board Members
Miss K Mellor	)
Dr R S Lane	- Director Bio Medical Services, CBLA
Mrs S M Chapman	- Office Manager, CBLA
Mr R C D Walker	- Chief Executive, BPL
Mrs G M Fryers	- Marketing Manager, BPL

Dr T J Snape	- Technical Director, BPL	) to join
Dr M J Harvey	- R & D Manager, BPL	) for lunch

FLAG B

Background Brief

VISIT BY PS(H) TO THE CENTRAL BLOOD LABORATORIES AUTHORITY ELSTREE ON 6 JULY 1992

1. General

1.1 The Central Blood Laboratories Authority (CBLA) is a Special Health Authority set up in 1982 to manage the Bio Products Laboratory (BPL), at Elstree and the International Blood Group Reference Laboratory (IBGRL) at Bristol.

1.2 BPL is the industrial unit which manufactures and markets therapeutic and diagnostic products in England and Wales made from plasma supplied by the National Blood Transfusion Service. IBGRL is an internationally renowned and World Health Organisation recognised blood group reference and research facility.

2. Capital Investment

2.1 In recent years around £75 million has been invested in CBLA facilities and it is now one of the most modern blood product fractionation plants in Europe. The main capital projects have been:-

- a new manufacturing plant opened in 1987. It cost nearly £60 million.
- new warehouse, quality assurance and engineering block completed in 1991. Cost around £8 million.
- research and development facility opened early 1992. Cost nearly £6 million.

3. The Organisation

Annex A has the organisation chart for CBLA.

Annex B gives the CBLA membership. Those asterisked will be present for the meeting.

Annex C contains brief notes on the management personnel who will be present.

Annex D gives a summary of sales and financial information.

4. Commercial Activity

4.1 The considerable investment was made in the CBLA was in pursuit of the policy of national self-sufficiency in blood products. This policy is interpreted to mean that the volume and range of products should be adequate to meet the clinical demand for home produced products. Clinicians are free to prescribe products from other sources for their patients.

4.2 BPL Commercial Department

Around October 1990, BPL set up a small sales force which is promoting products to individual hospitals. In factor VIII, BPL has more than 70% of the market; their success is prompting a response from the commercial suppliers. In particular Armour have complained to the Office of Fair Trading about unfair competition from BPL (see issues section).

4.3 Licensing Technology from Baxter

In response to demand from clinicians for high purity Factor VIII, BPL has licensed manufacturing technology from the US. Blood product manufacturer, Baxter, is modifying its production facility to manufacture the product locally. For a limited period while these modifications are carried out, the BPL has contracted KABI of Sweden to undertake part of the manufacturing process from plasma supplied by the BPL. This is a new departure, since BPL are importing for the first time a product made from our own UK produced plasma. The high purity Factor 8 (known as 8SM) was launched in March 1991. However sales have been slower to pick up than BPL envisaged and because of the competition among suppliers the price premium for high purity over intermediate purity Factor VIII has been considerably eroded. This situation in the market means that CBLA sales income is running well below budget sales. Volumes are being maintained as the BPL intermediate product is selling in preference to the high purity product.

5. Manufacturing

5.1 BPL is now experiencing some production problems particularly with its sterile filling lines. These problems have caused stoppages in production but sales have usually been maintained from stocks. Present Management believe that the original decision to buy equipment from a variety of suppliers was a mistake. It does not operate as well as a filling line bought from a single supplier and also there have been difficulties in obtaining work under warranty as each supplier attributes faults to equipment from other suppliers. The CBLA are considering how to resolve the difficulty but it is likely that a new filling line will be required (the cost is likely to be £1 or £2 million).

6. Crown Immunity

6.1 Crown Immunity was withdrawn from Health Service Bodies, including the Central Blood Laboratories Authority with effect from 1 April 1991. The main impact for CBLA was to bring its products and manufacturing processes under formal licensing arrangements under the Medicines Act. A number of products and its plant have been licensed and other licence applications are still under consideration by the Medicines Control Agency.

6.2 Transitional arrangements allow BPL to continue to market the products which were on sale before 1 April 1991.

6.3 The removal of Crown Immunity also brings CBLA within the scope of statutory procedures for eg. building, planning and environmental protection.

7. NATIONAL BLOOD AUTHORITY

In a wide consultation, general support was given to the principle of an NBA to combine the roles of the CBLA including BPL, and NBTS Direcorate. However, concerns were expressed about certain operational aspects, in particular the complexities of the proposed contracting arrangements, the structure of the NBA and the proposal that the new Authority should allocate capital to the Regional Transfusion Centres.

In the light of the responses Ministers decided in principle to establish the NBA but to defer its implementation until the concerns over the operational details were resolved.

A technical working group made up of the main NHS interests has been set up. Participants in the working group include a Regional Transfusion Director, a Regional Director of Public Health, the National Director of the NBTS, a representative from CBLA and a Regional Chairman.

The working group will report to Ministers shortly.

The basic idea behind the proposed NBA is to come up with a scheme that works to the benefit of blood services as a whole, so that we have safe, high quality and cost effective blood services.

The present intention is that the BPL will be part of the NBA. However, the CBLA Chairman would prefer it to have independent status outside the NBA. This is discussed in the issues section.