

Mrs Delfgou PS (PS(L))

FILE GEB 5
From: J Canavan EHF1A

Date: 8 March 1991

cc: Mr Malone-Lee
Mr Dobson
Dr Pickles

Visit to CBLA, Monday 11 March

I enclose briefing for PS(L)'s visit to CBLA on Monday.

This comprises background material on the people, the organisation and current activities (at A) and briefing with speaking noted on the Touche Ross report, which is the main issue for discussion. There will also be a presentation on the work of the commercial Dept. and a short speaking note is provided on this (at B).

Mr Malone-Lee and Dr Pickles will be accompanying the Minister on the visit.

GRO-C

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PS(L) VISIT TO
CBWA. 11/3/91

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SECTION A

Background Brief

VISIT BY PS(L) TO THE CENTRAL BLOOD LABORATORIES AUTHORITY
ELSTREE ON 11 MARCH 1991

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 distributes therapeutic and diagnostic plasma products for use in England and Wales. IBGRL is an internationally renowned and World Health Organisation recognised blood group reference and research facility.

Annex A has organisation charts for CBLA and NBTS.

Annex B shows the difference between cellular products used in hospitals and plasma products which are fractionated; and shows BPL's main product lines.

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

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

Annex E is the itinerary for PS(L)'s visit.

2. BPL Building Projects

Manufacturing Plant (Phase I) - the new plant is now fully operational at a final cost in the region of £58 million.

Quality Assurance (Phase II) - comprises the new Warehouse, Quality Assurance Building and Engineering Block, all but complete, at an estimated cost of around £8 million.

Research and Development (Phase III) - work has only recently started on clearing the site for the new Research and Development facility, for which PS(L) gave approval at the end of last year to central funding of around £0.6 million to start the work.

3. Sales and Finance

3.1 Sales Figures

	1989/90	Budget 1990/91
	£ million	
Coagulation Factors (Factor VIII and IX)	£20.2 m	£26 m
Albumin	£9.7 m	£7.2 m
Immunoglobulins	£3.4 m	£4.6 m
Diagnostics	£1.7 m	£2.0 m

3.2 Finance

Budget 1990/1991 (from CBLA budget statement)

Total income £40 million

Main costs:

Plasma	£22 m
Manufacturing costs	£11.7 m
Commercial Department	£0.8 m
Research and Development	£2.1 m
Finance and Administration	£3.0 m
BGRL	£0.7 m
CBLA	£0.4 m

DH Cash Limit:

Revenue	£7.1 m
Capital	£4.6 m

4. Commercial Activity

4.1 Commercial Department

Around October 1990, CBLA set up a small sales force which is promoting products to individual hospitals. In the current year, nearly 70% of sales are distributed through RTCs, but this is likely to diminish in future and it will become increasingly important for BPL to promote to the users. In factor VIII, BPL have about 70% of the market; their success is prompting competitive response from the commercial suppliers. In particular in recent months Armour have been behind a number of PQs attempting to obtain information about the economics of CBLA and to try to show them in a bad light.

4.2 Baxter

In response to demand from clinicians for high purity Factor VIII, BPL has licensed manufacturing technology from Baxter and is modifying its production facility to manufacture the product locally. For a limited period while these modifications are carried out, and to meet demand as quickly as possible, 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 will be importing for the first time a product made from our own UK produced plasma. BPL expect to start marketing the high purity product in March. This early entry into this market will be particularly unwelcome to Armour who were the sole supplier of high purity factor VIII.

4.3 Scotland

CBLA also offered to manufacture the high purity factor VIII under licence from Baxter for Scotland, but the Scots have decided to license technology from French fractionators on the basis that a two way exchange of technology would provide a better deal for Scotland.

5. Crown Immunity

Crown Immunity is to be withdrawn from Health Service Bodies, including the Central Blood Laboratories Authority with effect from 1 April 1991, and its main impact for CBLA is to bring its products and manufacturing processes under formal licensing arrangements. BPL already have:

- product licences for two albumins and
- full manufacturing licence for the Elstree site

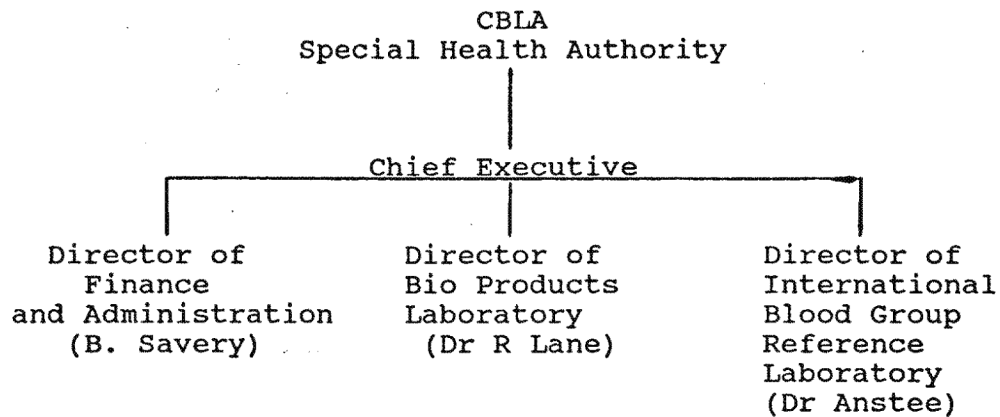
and other licence applications are still under consideration by the Medicines Control Agency.

Transitional arrangements will allow BPL to continue to market the product provided they were on sale before that date and they be covered by the transitional arrangements.

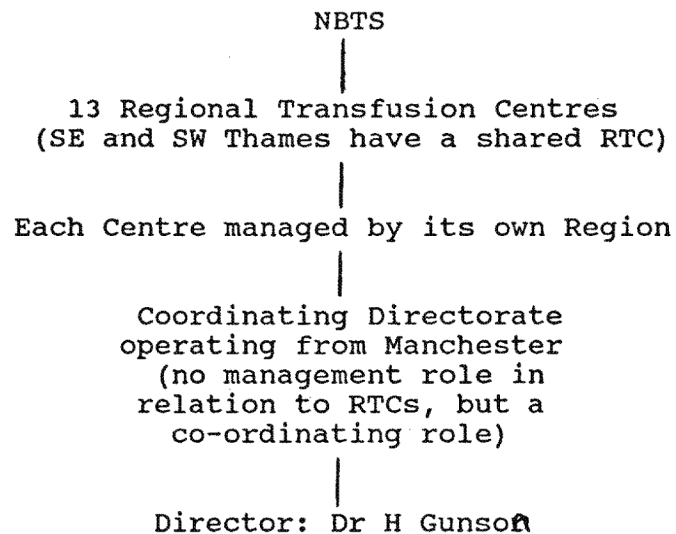
The removal of Crown Immunity will also bring CBLA within the scope of statutory procedures for eg. building, planning, and environmental protection.

ORGANISATION CHARTS

1. CBLA ORGANISATION

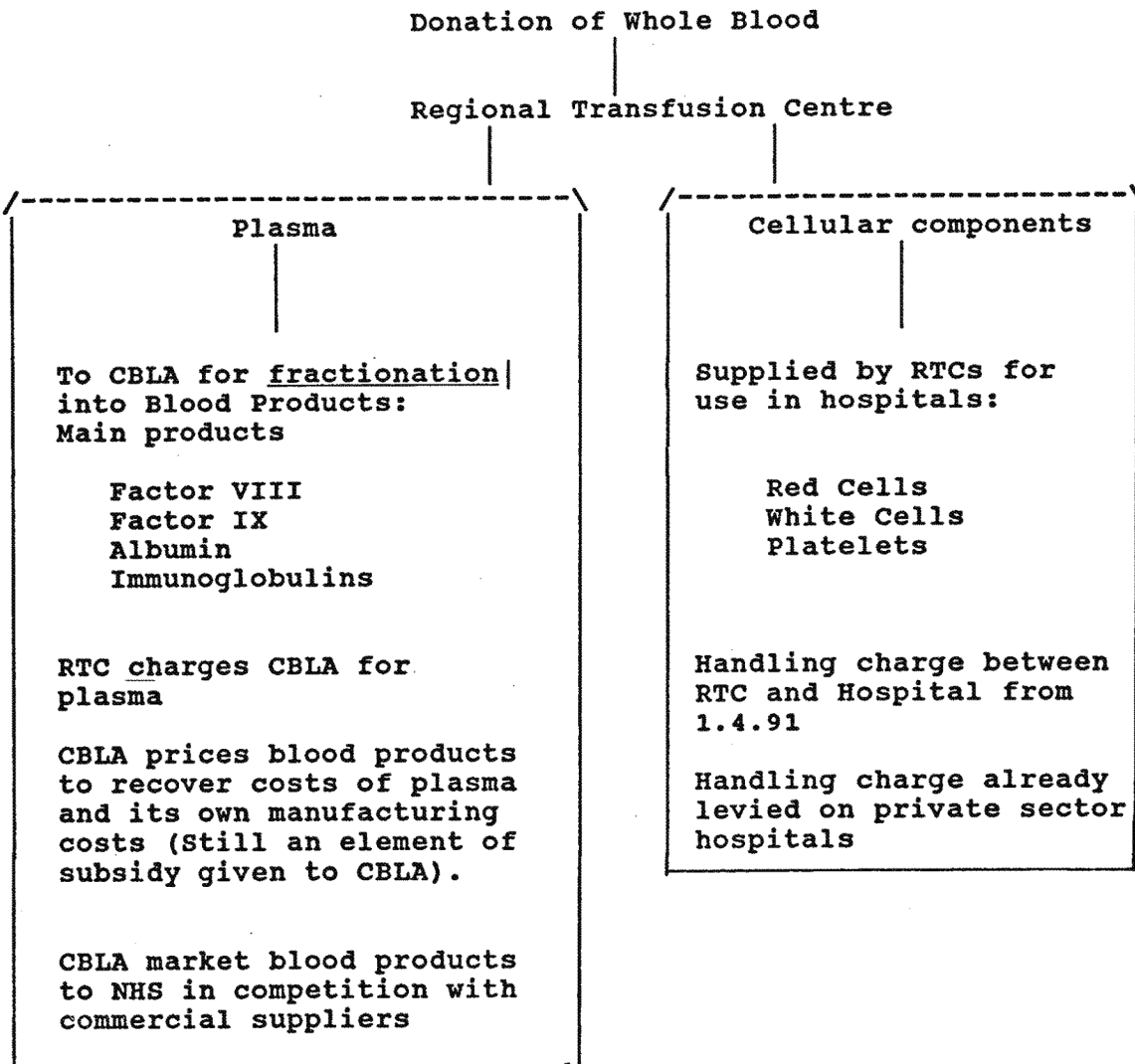


2. NBTS ORGANISATION



BLOOD PRODUCTS

This chart shows the distinction between cellular products used in hospitals and plasma products which are fractionated.



CBLA MEMBERSHIP

The members who will be present for the meeting are asterisked

* Mr Ronald Wing (Chairman) - aged 64. Non-executive p/t Chairman of Sanofi UK Ltd. Former President and Vice President of ABPI (Association of the British Pharmaceutical Industry). Former member of East Yorks DHA.

* Dr Roger Brimblecombe, former Research Director with Smith Kline and French, now consulting, age about 60 years. Broad knowledge of of therapeutic research internationally.

* Dr Brian Cromie - aged 61. Qualified medical doctor and ex Executive Director of Hoechst and ex Chairman of Arthur Cox. Has served on the Medicines Commission.

* Sir Colin Walker - aged 56. Chairman of East Anglian RHA and Managing Director of a farming company.

* Mr Hamilton Dempsey - aged 60. Former Advertising Director of large pharmaceutical company. Present Chairman of Advertising Design Associates (medical and scientific division of largest medical and technical agency in the country).

Dr Peter Kernoff. Director of the Haemophilia Centre at the Royal Free Hospital.

Sir Vernon Seccombe - aged 61. Former Chairman of S Western RHA. Present Chairman of Plymouth DHA and former proprietor of an electrical contracting company. Wide experience of NHS.

Miss Katherine Mellor - aged 44. A Solicitor with John Elliot and Co, Manchester. Former President of Manchester Law Society. Specialises in commercial law.

MANAGEMENT PERSONNEL WHO WILL BE PRESENT

Mr Bernard Crowley, Chief executive of CBLA, started January 1987. An experienced pharmaceutical industry manager who was previously a President of Merck, Sharp and Dohme.

Mr Barry Savery, Director of Finance and Administration of the CBLA started in June 1987. An accountant by training, Mr Savery has come from a commercial background.

Dr Richard Lane, Director and General Manager of the BPL, is medically qualified, and an expert on plasma protein fractionation.

Mr Terry Snape is the Factory Manager, appointed May 1988, previously Head of Quality Control BPL, Elstree, and PFL Oxford.

Dr M J Harvey is the Research and Development Manager, appointed in 1980, he joined BPL as a Senior Biochemist in 1977.

Mrs Gaynor M Fryers is the Commercial Manager, appointed in September 1987, previously Head of Production at BPL Diagnostics, Oxford.

Proposed Itinerary for 11th March 1991

11.00 am	Lady Hooper arrives
	Coffee
	Mr Wing's Opening Remarks
	The Touche Ross Report
12.30 pm	Walk about Phase II New Warehouse, QA Building, Engineering Block.
1.15 pm	Lunch
2.30 pm	Presentation - Mrs G M Fryers New Commercial Activities
2.50 pm	Round up
3.00 pm	Minister Departs

Additional Information

Mr R A Wing	-	Chairman
Mr B J Crowley	-	Chief Executive
Mr B J Savery	-	Director of Finance and Administration
Dr R S Lane	-	Director and General Manager BPL
Dr T J Snape	-	Factory Manager
Dr M J Harvey	-	Research and Development Manager
Mrs G M Fryers	-	Commercial Manager
Dr B Cromie)	
Mr H Dempsey)	Members of the
Dr R Brimblecombe)	CBLA Board
Sir Colin Walker)	