

A. A Departmental Minute dated 17 March 1975, and approved by Dr Owen, reads:

1. Immediately after the decision was taken in December last to invest £0.5m of special finance in AHG concentrate production, provisional targets of plasma production were drawn up for each of the 14 Regional Transfusion Centres. These were then circulated to Regional Transfusion Directors and discussed with them at a special meeting on 19 February. The target had now been revised and we shall be asking Regional Health Authorities next week to indicate the amount of money required for extra staff, equipment, transport, and adaptation of accommodation. A copy of our draft circular letter is attached (Appendix 1 needs some revision). We shall process these returns as speedily as possible.
2. The time-table for starting up this programme is likely to depend on the time taken for:-
 - (a) Delivery and installation of three Sharples Centrifuges at Blood Products Laboratory. The quoted delivery period is six months; this is evidently the key factor determining the speed with which we can get on; we shall pursue this to see if we can shorten the period.
 - (b) Adaptation of premises at Regional Transfusion Centres and Blood Products Laboratory; at the latter laboratory recruitment and training of staff may be a problem.
 - (c) There is a **possible** risk that delivery and installation of certain other items of equipment, e.g. freezers for plastic bags and refrigerated vehicles, may also add to the time taken; this will not be known until information is received from the suppliers.

B. A Minute by Dr Owen dated 11 July, and apparently requested by him in consequence of his briefing for that answer, reads: "and ??? as a result of our discussions"

1. Dr Owen has commented on PQ 3474:- "Once again we are a 2-3 years timescale. I have asked if we can improve on this. Can I have a note?"
2. This is the timescale which Dr Owen gave in a reply to a PQ from Mr John Spence on 22 April. Since then, as a result of our discussions with regions, we have given them targets which would produce plasma from 337,000 blood donations. This is some 20% more than the total of 275,000 recommended by the Expert Group on haemophilia but figure must be regarded as the minimum.
3. All regions, except two, have now indicated when they expect to achieve their share of the target of 337,000. The position may be summarised as follows:

The two regions which we are at the moment uncertain will provide another 45,000 donations i.e. 13% of the target.

4. The main reason why the programme cannot be completed earlier is that in four regions extensive alterations have to be made to the Transfusion Centres before they are in a position to provide more plasma. In one case the work will take six months, in two cases one year, and in the fourth 21 months. There is no scope for reducing these periods. Arrangements are in hand to purchase centrally those items of additional laboratory equipment requested by RTCs. First deliveries are expected within 2-3 months and the programme is unlikely to be held up on this score. We are having difficulties about the date of delivery of three Sharples Centrifuges for the Blood Products Laboratory but we are pursuing this and hope to resolve the matter soon.

5. We are taking steps to clarify the position of the two regions whose ability to contribute to the programme is at present uncertain. From the point of view from the NBTS it is desirable, if it is at all possible, that all regions should take part. If the two regions in question can be brought in we hope that they will be able to achieve their target by about the end of 1976. However, if they cannot participate we will have to consider allocating the funds provisionally earmarked for them to other regions able to provide more plasma than they have at present undertaken to do.
6. It is difficult to be precise in estimating a date for achieving self-sufficiency, not least because not all are agreed as to what constitutes self-sufficiency, some Haemophilia Centre Directors envisage prophylactic treatment whereas the department's programme is based upon home treatment of those patients for whom treatment at home can be recommended. It remains to be seen whether RTCs will be successful in persuading clinicians to accept a steadily increasing proportion of blood in this form of concentrated red cells; this may be a possible limiting factor. AHG concentrate has not previously been prepared in the NHS on the scale envisaged and this in itself will almost certainly give rise to some problems.
7. However, accepting these qualifications, the figures in paragraph 3 suggest that we can improve on the previous estimate of achieving self-sufficiency within 2-3 years. We can now say that we expect to be self-sufficient within 2 years or, alternatively, that within about a year we will be able to meet some two thirds of present requirements and become self-sufficient in 1977.

C. In a Management Note, Dr Owen commented: "This is excellent and I recognise that everyone is doing everything possible. I believe we should keep up the pressure. Can I be kept informed on the Centrifuges and also the two regions – why are there difficulties

and what can be done? I would not easily accept that they should not contribute."

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Even had there been no interruption of the manufacturing process, the volume of plasma resulting from the injection of funds could not have been processed. In May 1979 there had been a General Election and a change of government. The incoming government spent some time in exploring the possibility of commercial involvement in the future of BPL, but appears to have rejected the option on grounds both of cost and of danger that commercial companies might wish to introduce payment to donors.

The problems escalated. In July 1979, the Medicines Inspectorate visited BPL. They reported that the buildings were never designed for the scale of production envisaged. They commented:

"If this 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."

BPL was rescued by Crown Immunity. Among their recommendations the Inspectorate advised:

"Under no circumstances should production of any product be increased under the existing manufacturing conditions."

The government decided to introduce a complete redevelopment programme at Elstree, but meanwhile, interim measures were undertaken to increase production. At a meeting in Glasgow of the Haemophilia Centre's Directors Organisation on 30 September 1980, it was stated that £1million had been authorised by ministers to improve the facilities, and that BPL aimed to double

the existing output. In the event the sum set aside was augmented to £1,300,000. The work began in July 1981, and it was completed in November 1982.

However, the improvement in facilities was accompanied by a restructuring in management, which does not appear to have been carefully considered, possibly because it was intended only as a temporary measure. In October 1979, responsibility for management by the Lister Institute was terminated, and as an interim arrangement, the Department of Health assumed direct responsibility. A draft paper by an official in February 1981 included a disturbing criticism.

"The chief difficulties over these temporary arrangements are that management is too diffuse with too many people exercising a fragmented responsibility; management is insufficiently and not continuously coordinated; at RHA level particularly the task of management is largely an addition to the normal work of those who are carrying it out; and that those responsible have very little experience in the management of facilities of the kind concerned. Responsibilities are vested in the department for which it is not equipped; and which had in principal be elsewhere. Consequences of these difficulties are, for example, that the Directors of the laboratories are required to work without adequate policy guidance and without sufficiently expert monitoring of their laboratories performance, but it is often difficult to reach fairly elementary policy decisions and to ensure that they are implemented; and that attention to the management of the laboratories may have to be dropped from time to time in order to deal with other pressing matters". The paper was severely redacted by superior officials before submission to ministers.