IN CONFIDENCE

Reference .....

Dr Oliver

FUTURE SUPPLIES OF BLOOD PRODUCTS

I visited Kabi AB, Stockholm on 18-19 June 1979: a comprehensive report is in the final stages of preparation by Mr J S Sloggem, Supply Division who accompanied me. I do not intend to reiterate what is in that report. This visit, coupled with my imminent remove from Med SM4, has prompted me to set down some of the problems as I see them of future supply of blood products and possible solutions.

As you know I was interested to visit Kabi because of their involvement in the manufacture of blood products and their interest in extending Kabi activities outside Scandinavia. They wish to build a plasma fractionation plant and approached us earlier to discuss the possibility a) of building such a plant in the UK and b) fractionating UK plasma on our behalf. HS2A, Supply Division and Med SM4 had discussions in April 1979 with representatives of Kabi AB: a note of that meeting is attached.

It is accepted that in order to meet the anticipated demand for the principal plasma fractions (factor VIII and protein solutions - mainly albumin) new plant, in addition to that already available in the UK, must be acquired. With this in mind plans for the further development of the Blood Products Laboratory have been drawn up. In addition to increasing production it will be necessary to upgrade existing plant to meet the requirements of the Medicines Act. Needless to say any new plant will have to be built to the same specification.

There are a number of alternative schemes for making plasma derivatives available in sufficient quantities to meet the demands of UK clinicians and some urgent discussions will be necessary.

To meet the estimated demand several possible alternative schemes have been described - others may become apparent:

1. to invest sufficient money in the BPL, Elstree to build up its capacity to meet the level of demand for factor VIII and albumin - production of other fractions at 'self-sufficiency' levels will follow for almost all plasma derivatives.

2. to re-examine the capacity, present and potential, at PFC, Liberton and to see whether this could be developed to meet UK demands.

3. to seek a UK firm willing to undertake work under contract for the NHS and 'without profit'.

4. to enter into a joint venture with a foreign or UK commercial enterprise.

5. not to invest in UK plant for the production of the major plasma derivatives (factor VIII and albumin) but to rely entirely on commercial sources, with the exception of PFL, Oxford and PFC, Liberton who will continue at their present level of production.

Option 1

In a paper prepared for the Scientific and Technical Committee (STC) of the main Joint Management Committee for the Central Laboratories (JMC) and elsewhere Dr R S Lane presented in detail his case for extensive investment in the BPL, Elstree. He is supported by Mr R D Smart, a member of the STC in his paper. The arguments, given the money to invest, appear convincing but I would question whether there is sufficient expertise within the BPL, even within the NHS, to plan, build and commission a plant on the required scale. If this option is taken up either staff of suitable calibre and experience should be recruited

to BPL or a firm with the necessary expertise should be contracted to plan, build and commission new plant.

Option 2

I have been convinced for a considerable time that it is essential to make a coordinated UK approach to solving the 'self-sufficiency' problem. Criticism has been levelled by the Directors of BPL (past and present) at the plant at PFC, Liberton and on occasion at the major products. Nevertheless Scotland is better provided with protein solutions and factor VIII (there is reported to be little purchase of commercial factor VIII) than England and Wales. The Medicines Inspectorate have not yet visited or reported on PFC, Liberton but if the PFC proves to be satisfactory, or more readily brought up to the required standards, then we should consider further investment there, and manufacturing the major components at PFC, Liberton. The Director, Mr John Watt has experience of designing plant and developing new methods of fractionation in addition to the more conventional methods used at BPL.

Whatever option is pursued DHSS must examine the potential of PFC, Liberton. We have already invested in the plant and perhaps should invest further. (DHSS has already invested £400,000 (of the total cost of £1.7 million) in the PFC, Liberton.)

Option 3-4

Great value is placed on the good-will of blood donors. Indeed without their 'gift' there would be no Blood Transfusion Service as we know it and we would be forced to rely on paid donors. The hazards associated with the latter schemes are well documented: most notably the experience of the USA which has swung almost completely from a paid donor scheme to a voluntary system, the main exception being large-scale collection of plasma by plasmapheresis of paid donors by commercial manufacturers of plasma derivatives.

If an enterprise outside the NHS undertakes to fractionate plasma on behalf of the NHS then it is believed by many that the good-will of donors will be lost to a significant extent and the BTS will suffer. This consequence is debatable.

It is possible that this situation could be avoided if a 'nationalised' UK firm could be interested in fractionating plasma exclusively for the NHS. With careful publicity this could be made acceptable to blood donors. However at present no UK firm appears to have the expertise, nor the interest, to enter the field of plasma fractionation.

An alternative might be to interest a foreign firm: some have already expressed an interest. Perhaps the most worthy of consideration is Kabi AB, a firm already working closely with its own government, effectively 'nationalised' in this area of its activity, and from a respected country with high standards of medical care and ethics but, as has been pointed out as a disadvantage, outside the EEC.

You will see from the report of our April 1979 meeting with Kabi and Mr Sloggem's report the main arguments put forward by Kabi in presenting their case for a joint venture with the UK.

Again with careful preparation, I believe this or a similar scheme could be presented in an acceptable way to the British blood donor.

One must ask what will be the future of the BPL, Elstree and PFL, Oxford if this option is pursued. It is possible that Kabi would be interested in acquiring a) the site at Elstree and b) some of the staff (including the director and senior researchers) but not the majority of the buildings. 'Minor' products production, for example the immunoglobins, could remain in the best of the existing plant and possibly some R and D. It is the declared policy of

Kabi, and no doubt any other firm in a similar situation to invest significant resources in R and D.

Option 5

In the long term this is unacceptable. Previous Ministers have declared their intention that the UK shall be 'self-sufficient'. This policy is in line with WHO principles accepted by all nations with advanced medical care, and would probably be the intention of present Ministers.

In practical terms I believe prices would inevitably rise once 'commerce' realised we had dropped out of competition with them. The price per unit of factor VIII concentrate is held at an artificially low level in the UK (compare for example prices of the same material in Europe): in effect the 'loss leader' principle exists. The price of factor VIII could double or treble if the NHS did not maintain its endeavour to become independent of commercial sources.

Summary

To pursue any of the above options will bring major problems to which there are no easy solutions. Some have been touched upon in this paper. Expenditure of several million pounds would solve a few, but the greater problems, would remain: the attitude of blood donors to what they might interpret as exploitation; the lack of expertise in the centres in which we might invest; the attitude of clinicians who look for increasingly large volumes of therapeutic materials - some clearly have a responsible attitude to their use, others as in many other fields of clinical practice wish their demands to be met without question or payment.

However in summary I believe self-sufficiency can be reached one way or another if the problems can be overcome: blood donors will cooperate when difficulties are explained to them (cf the acquisition of blood/serum for laboratory quality control); expertise is available in the UK and Europe for planning and building and running new fractionation plant; clinicians attitudes can be changed by education and by example or in the last resort by the constraints of limited resources.

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