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IN STRICT CONFIDENCE

MINUTES OF A MEETING ON 3 MARCH 1980 AT THE DEPARTMENT OF HEALTH AND SOCIAL SECURITY, HANNIBAL HOUSE, ELEPHANT AND CASTLE

Present:

Dr Diana Walford - Chairman	Dr P Dunnill
Dr W Wintersgill	Dr G H Tovey
Dr B Wills	Dr H H Gunson
Mr J Flint	Mr R D Smart
Mr J Harley	Mr J Prydie
Dr R S Lane	Mr T E Dutton
	Mrs S C Yuille

Dr Walford explained that following the Medicines Inspectors' Report on the Blood Products Laboratory, Ministers had asked that all options for the future production of blood products, including commercial participation, should be investigated. The purpose of this meeting was to discuss the technical and policy briefing for Supply Division, who were required to take the lead in discussions with industry.

Dr Wintersgill was to chair a working group to steer the talks. It was accepted that there were particular problems related to commercial involvement, for example, there was the hepatitis risk if imported plasma from paid donors was brought into contact with UK-donated plasma; commercial partnership could have an adverse effect on the volunteer donor system; there might be difficulties in persuading commercial fractionators to undertake research and development in this country. All these questions would have to be carefully examined in deciding the nature and extent of any possible arrangement with industry. Dr Dunnill said that in his view the NBTS ought to have a Government-run and independent laboratory, on similar lines to Amersham, with its own board of directors.

Members, discussing the proposed points of policy in Paper 1, thought that there were several matters which should be considered to be non-negotiable.

PLANT

Members agreed that self-sufficiency in blood products should certainly be the aim, and accepted that the amount of albumin and Factor VIII needed would be the determining factors in deciding the size of the fractionating capacity of a new plant. Mr Smart reminded members that in the long run it would be proportionally cheaper to fractionate larger quantities of plasma. Members accepted that 400 tonnes of plasma total capacity with 60% (250 tonnes) plant occupancy was probably about right. A plant of this size could produce the 90 million international units of Factor VIII which would be required by 1985. In negotiations, industry should be given target production values for individual products which they should not exceed and which should be produced from a stated quantity of plasma. Industry would have to be made aware of the problems relating to the supply of plasma from the NBTS. On the question of fall-back capacity members thought that because of its problems, Liberton Protein Fractionation Centre might not be a suitable alternative producer and it was generally felt that fall-back capacity within the new plant itself might be the only feasible solution.

It was agreed that, where required, the formal licencing and other requirements of the Medicines Act must be met.

SITE

The site of a new plant could be a matter for negotiation; industry might not find the Elstree site appropriate if it meant, for example, having to move their staff.

PRODUCTS

It was agreed that, if industry were to fractionate all the NBTS plasma, they should be required to manufacture the entire range of products which were currently being prepared at the BPL.

On the question of which specifications should apply, it was agreed that the products must meet any specifications laid down by the NHS or the EP or BP specifications, as appropriate. Mr Flint would ascertain whether industry or the Department would be the product licence-holder.

TECHNOLOGY

The method of fractionation should be negotiable; (in 5-8 years' time, fractionation by genetic engineering could be the more effective technology).

(No mention should be made to industry of the fractionation by poly-electrolytes - the collaboration between BPL and Speywood was confidential).

RESEARCH AND DEVELOPMENT

Members agreed that it was essential that the industrial manufacturer should have research facilities on site and that research projects should be agreed between the NBTS/DHSS and industry.

SOURCE PLASMA

Dr Gunson said that central co-ordination was vital to ensure the supply of plasma and to increase the supply for the fractionator. Increasing the donor panel to 40 per thousand population was an easy matter, although increasing the panel to 50 per thousand would be more difficult and costly. If however the panel were to be increased to 60 per thousand, this would be very expensive and would mean a surplus of red cells. In his opinion, therefore, plasmapheresis was the only alternative and Centres with a 3-4 million population were ideally suited for this method of plasma collection. Another alternative would be to increase the number of bleeds per year, for example, male donors could be bled 3-4 times annually. Such frequent bleedings might however deter the firms, whose staff provided 40% of all donors. Also, once such firms knew that blood was being fractionated by a commercial enterprise, they might ask to be paid for their staffs' time.

Dr Gunson thought that whatever form of blood collection was adopted, funds would have to be made available for increased collection. Mr Harley assured members that this point would be made in the submission to Ministers.

Members agreed that the four conditions set out at the top of page 2 should be considered mandatory.

On the question of the use of foreign plasma members agreed that because of the risk of contamination, imported plasma from paid donors should not be processed in the same plant as UK plasma. However, if industry were to function at economical capacity, there might be no alternative but to allow it to fractionate imported plasma from overseas unpaid donors such as that which might be provided by voluntary transfusion services. The two types of plasma and finished product would have to be kept separate at all stages and there might have to be separate quality control arrangements. It was thought that monitoring such arrangements would not be easy.

SALES

Members agreed that the price of the products should reflect the fact that the manufacturer had not had to pay for the starting plasma and that all prices should be agreed with the relevant Government body.

If industry was able to sell any products overseas, there should be a requirement that such sales should be confined to other voluntary organisations, for example, the Red Cross.

STAFFING

It was agreed that industry should be asked to consider the questions raised in Paper 1.1. The question of who paid redundancy payments was one which merited special attention.

March 1980 DHSS