

(29)

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 W Wintersgill
 Dr B Wills
 Mr J Flint
 Mr J Harley
 Dr R S Lane

Dr P Dunnill
 Dr G H Tovey
 Dr H H Gunson
 Mr R D Smart
 Mr J Prydie
 Mr T E Dutton
 Mrs S C Yuille

Dr Walford explained that following the Medicines Inspector's 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} going to take the lead in discussions with industry.

Dr Wintersgill was to ^{chair} set-up a working group to steer the talks, but the group would first consider the feasibility of industrial participation, and if it was possible, it then had to be decided what part industry could take in the production of blood products for the NHS. It was accepted that there were ^{particular problems related to} cogent arguments against 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; ^{and} 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 whether ^{the nature and extent of any possible arrangements with industry} industrial participation was a feasible proposition. Dr Dunnill said that in his view the NHS 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} those which ^{should be considered to be} were non-negotiable.

PLANNING

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 factor in deciding the size of the fractionating

relating to the supply of plasma from the NBS

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 ^{probably about} was 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 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 ~~it was essential~~ that, where required, the formal licencing and other requirements of the Medicines Act ^{must} ~~should~~ be met.

SITE

The site of a new plant could be a matter for negotiation; industry might not find it ~~an advantage to build on the Elstree site~~ ^{if it meant, for example, having to move their staff.} ~~if it meant, for example, having to move their staff.~~

PRODUCTS

It was agreed that ^{if industry were to fractionate all the NBS plasma, they should} ~~industry should be asked~~ ^{be required to} 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} ~~come up to the~~ specifications laid down by the NHS ^{or the} ~~this~~ EP or BP specifications as appropriate. ~~could be either EP or BP.~~ 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} preferred 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 NBS/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} commercial firms who ^{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 4 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} ~~on~~ moral grounds, ~~because of the World Health Organisation~~ ^{Resolution} and also because of the risk of contamination, imported plasma ^{from paid donors should not be processed in} ~~should not be used to manufacture~~ ^{these to function at economical} products for the NHS. However, if industry had ~~space~~ ^{capacity} there might be no alternative but to allow it to fractionate ^{imported plasma from} ~~foreign plasma for~~ overseas unpaid donors ^{such as that which might be provided by} re-export, on condition that the plasma was obtained through overseas voluntary transfusion services, like the Red Cross, and the finished products were sold back to such organisations. ^{two} The types of plasma and finished products 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.

Pls Yvonne for information:
- the Red Cross also buys in plasma
but members didn't seem
to be aware of this

SALES

the manufacturers had not had to pay for the starting plasma

~~the donors who provided it had not been paid,~~
Members agreed that the price of the ^{products} plasma should appropriately reflect ~~the fact the~~
~~its free supply,~~ 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} ~~had to 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.

DHSS

March 1980