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SELF SUFFICIENCY IN BLOOD AND BLOOD PRODUCTS

? BEC req prior hearing

Discussion Paper for SNBTS Directors

JDC/1/90/TDs/DGM

INTRODUCTION

Directors will recall that in the early 1980s a paper was put to the BTS Sub-Committee in which we requested authority to forward plan on a basis that it was the Government's policy that the SNBTS should be targeted towards self sufficiency in blood and blood products. The BTS Sub-Committee and the Management Committee concluded that they were not competent to make this decision and sought policy approval from SHHD. SHHD subsequently conveyed to the Agency that they did not wish to make a policy statement on the matter.

The lack of policy on this issue of self sufficiency in blood and blood products and appropriate and timely policies associated with the loss of Crown immunity have proved to be the major factors in the deteriorating operational position of the SNBTS in the latter half of the 1980s.

On July 5th, 1989 (see Appendix 1) there emerged the first formal policy alert that SHHD wished the SNBTS to develop a programme of self sufficiency in blood and blood products. The stage is now set for the Service to take this matter one step forward, for we now require a series of operational (policy) definitions of self sufficiency in order to develop the appropriate strategies.

There are likely to be a number of questions which require answers before detailed strategy planning commences but at the present time there seem to me to be a limited number which, if answered fully, will probably cover most issues. These are addressed below.

THE MARKET PLACE

An important first question which follows the command, "Go ye and become self sufficient" in the context of a national health service, is to define the market place and to ascertain whether the market place (NHS customers) is inexorably party to the implementation of this policy. Put in rather blunt terms, does national self sufficiency mean in Scotland that provided the SNBTS makes a product available (subject to satisfactory quality) then hospitals must not obtain supplies of that product from outside sources unless SNBTS supplies were exhausted (i.e. self sufficiency strategy had failed)? An answer to this question is essential for it is critical to the development of future SNBTS strategies. If an assumption is made that the answer is "Yes" then the Agency will have to give careful consideration to establishing a series of product quality groups - with significant and effective client representation - so that it can give AHB General Managers, and the many prescribing clinicians, appropriate assurances. Recent activities have revealed that such formal quality peer reviews may prove to be key elements in future litigations and, moreover, there may be a need to more clearly define the legal consequences of such arrangements, for it seems to the author that there may be a significant shift from AHB to CSA. It follows, from the above, that I am assuming that the market place, for the SNBTS, in the context of self sufficiency, is Scotland: perhaps this too needs consideration and clarification.

cf. [illegible] document re. monopoly

THE SCOTTISH HOME AND HEALTH DEPARTMENT

A vitally important element in the complex operational jigsaw of self sufficiency (and assume this is in a strict Scottish context) will be the role of the SHHD. Current evidence (derived from discussions associated with the HIV/haemophilia litigation) would

suggest that both SHHD and DoH are keen to pursue in the courts what, on matters of evidence, seems a lost cause, because they wish to secure the position that such Government departments **have no legal duty of care.**

Directors will be aware that on several previous occasions SHHD have declined to comment on proposed product targets. There can be no doubt this sustained negative managerial approach has ultimately and overwhelmingly depressed the drive and enthusiasm of many senior SNBTS managers. There must be some form of a "Main Board" for this self sufficiency exercise and it is far from clear whether SHHD wishes or is able to fulfil this function. We need clear decisions on this matter in order to develop appropriate strategies. On the other hand it is difficult to envisage the "Main Board" outside SHHD because the key function of any Main Board is the control of investment allied to policy.

It is suggested this matter is pursued, with some urgency and determination, with the Chief Executive.

PRODUCT SELECTION AND QUANTITY

It is an interesting fact, known certainly to the Agency's General Manager and myself, that BPL managers claim they are now self sufficient in factor VIII and albumin. Self sufficiency has been defined by the Chief Executive of the CBLA (with, he claims, approval of DoH) as simply meeting the market demands. He, and presumably his Board, are quite content if (as it does) they meet 50% or 10% of the market needs and the other 50% or 90% comes from donors outside the UK. It would appear that England and Wales have rejected the concept of **national** self sufficiency and espoused the emerging philosophy of European (EC) self sufficiency. It seems certain that the introduction of cross charging for plasma

products in England and Wales was closely allied to this philosophy. Recent developments, the accruing of unwanted stockpiles of factor VIII and albumin and BPL, may suggest that this hybridised and extended version of self sufficiency is inherently destabilising, almost impossible to control and manage and potentially really quite dangerous - to blood donor attitudes.

These preliminary remarks under this section are important because SNBTS managers must know, as they devise their several self sufficiency strategies, whether their policy is "go for gold" (100% self sufficiency) or something else. We had an all too brief macho period of self sufficiency for factor VIII. The macho was infectious and did much, I think, for the morale of the Minister, the GM, the NMD, Directors, very many of our staff and perhaps even donors and donor recruitment - "we were winners and we kept telling a lot of people we were winners". But, is it appropriate that we plan now to "go for gold" again, or would it not be more managerially prudent to ensure there was always an active alternative supplier, however cost effective our operation?

These crucial policy matters need very careful and formal consideration by the Directors in the first instance and thereafter, I presume, by the Agency and SHHD. There would be some substantial advantage in considering this topic on a product by product basis, but it would be essential to obtain improved financial management arrangements so that if we decided we went for 90% of the market then the AHBs were not penalised and left to pick up the tabs for the other 10%. This current fiscal policy against the background of "free SNBTS products" to AHB, is proving to be highly detrimental to both the Agency and the SNBTS (see below). There has been much correspondence over the last 12 months but, as usual, no managerial decisions.

PFC: THE MANUFACTURING BASE

It would be appropriate to conclude that in the days when national fractionation facilities were in the business of producing a stable range of 4 products the tasks in front of PFC were relatively straightforward - all 4 products were produced at PFC. In those days PFC did an excellent job. Times have changed, the rate of change is escalating and there is now an urgent need to ask the question, "Is self sufficiency for the SNBTS primarily about **plasma** self sufficiency?". Should we continue to expect PFC to provide from the plasma collected in Scotland the full range of products required by the SHS? If not, then what mechanisms should be established to decide what products are required, how might they be acquired from sources outside PFC and how will we, as the managers of self sufficiency, exercise appropriate control over such a devolved state?

It should be emphasised that Bob Perry and his colleagues have already taken the initiative with this concept; discussions are taking place with BPL about a single UK rabies immunoglobulin product manufacturing location. But has not the time arrived when we should be giving consideration to more substantive examples - say factor VIII and factor IX concentrates and more? It would be of considerable interest, and possibly of great operational advantage and long term benefit to patients in Scotland, if we began discussions which asked the question, "Why not transfer all factor VIII, factor IX and albumin production to BPL and PFC prepare all immunoglobulin products for the UK?". Such a development would inevitably bring the SNBTS and NBTS together and it is certain that the resultant **UK** initiative could have profound long term beneficial effects. There can be no doubt that it would put future product development on a sounder base than at any time, both with respect to achieving targets and in terms of cost effectiveness.

or non UK ? attempts suppliers above

cost effectiveness. In the context of the recent EC Directive it is my view that this sort of development is now imperative. Consideration of operational liaison with fractionation facilities outside the UK should also not be excluded.

RTC: PLASMA PROCUREMENT

(unlike PFC, make "all your own

I would suggest that whereas there is no absolute requirement to insist that PFC meets all the implications of self sufficiency this should not apply to RTCs. There will be, for the foreseeable future, a sustained need to encourage active participation of our blood donors and it would not be prudent to develop significant external support systems for either cellular products or plasma.

FISCAL ARRANGEMENTS: CROSS CHARGING

Reference has already been made to the current and potentially serious problems when AHBs are expected to fund "SNBTS deficiencies". This issue must be taken up with the Chief Executive and, I suggest, that the proposal which should be submitted is that SNBTS should undertake all purchases of externally sourced plasma products on behalf of Health Boards. They would be supplied through RTCs and paid for by the SNBTS.

Directors should be aware that throughout the EEC - and perhaps even the developed world! - Scotland is unique in not having introduced cross charging arrangements to hospitals and GPs for blood and blood product supplies. It is my view that the arrangements we have are best suited to the nature of the service we traditionally have given to the SHS. Nonetheless, it is also my view that the implementation of EC Directive 89/381 may force us to introduce a system of cross charging for at least plasma products.

If this interpretation is correct then we need to know sooner rather than later, not least to brief our staff but also the blood donors in the most appropriate manner.

There are some who believe that this market force approach (cross charging) is the one which will ensure a cost effective and efficient type of service, because you can, at last, they believe, manage it yourself. This certainly is broadly in line with our current government's philosophies. Looking across the world, there is, however, no evidence to support this hypothesis. Most of our sister organisations have been as spectacularly poorly managed as ours and have been a good deal less successful. It seems probable that the reasons for this are threefold; cross charging introduces an ethos in which the factor of common interest to supplier and client is money and, as such, is a polarising exercise; cross charging in all parts of the world known to the author involve governments actually setting prices - not the manufacturer; cross charging involves substantial additional revenue costs - to administer. Charging for products also commits the supplier "to market" products and thus the notion that BTS staff have a professional responsibility to caution against excess use (affects hospital care costs and patient safety) is unacceptable in this sort of market ambience. There is much evidence of this in France, of late: they assure me that positively encouraging increasing demand is the only way they can increase funding for R & D - they are using fibrin glue in France like there was no tomorrow! It's madness, for it provides an opportunity for "creative vandalism" within health services between separated marauding groups all supposed to be serving patients!

You will be aware of the grave developments at BPL. The prices fixed by HMG for BPL factor VIII and albumin have been substantially undercut by their commercial competitors - result:

large unwanted surpluses at BPL and cash flow problems because of fixed commitments to purchase RTC plasma.

Directors will need to give these matters very serious and I believe urgent consideration, because this issue, I suggest, will very soon surface and it may be of some assistance for SHHD to know of Directors' views before final deliberations take place. But, make no mistake - self sufficiency is largely about money - and management!

PRODUCT DEVELOPMENT

Directors deserve, and will get, a separate and substantial document on this topic but I suggest it is important for us to clarify many of the points raised above before we embark upon a major product development programme. Of particular importance will be decisions about the proposed manufacturing options and what impact, if any, the team formed in Scotland might have on product development South of the border.

STAFF ATTITUDES

Reference has already been made to the depressed state of the drive and enthusiasm of some of our senior managers, as a consequence of the lack of direction and communication from a "Main Board". There is another view perceived to be evident among middle managers - that the Directors (but most of all that NMD) cannot be described as depressed. "They still spend most of their time exhorting middle management to countless objectives that have not got "Main Board" support and therefore are never appropriately resourced". "A bunch of headless chickens, but worst of all that headless cockerel (soon to become a capon!)".

There's a lot of truth in the cris de coeur from our middle managers. Self sufficiency was made our operational policy by the SNBTS Directors, in isolation, in 1980. We achieved our objective in 1984 without any targeted additional resources, particularly staff resources. In this period total plasma input to PFC rose 114%. Total HIV-1 donation testing was introduced throughout the SNBTS in October 1985 without (with the exception of Aberdeen) any additional staffing resources (c.f. NBTS). The same applies to CMV donation testing. Since 1980 the production of platelet concentrates has increased by 46%, again with no increase in staff resources. Much the same applies to PFC. And all the time HQ has demanded increased facts and figures from hard pressed technical and A&C staff! And now SHHD demand efficiency savings.

Many of the workers out there, who have delivered for the last 10 years an ever increasing return on the Agency's investment in salaries and wages, are not so much depressed as exhausted and Directors need to consider this fact in any further plans for self sufficiency. There is a need to return to the Lapsley and Mitchell report and the associated O&M studies and it is to be hoped that future management developments will consider the complex ramifications of this investment to further improve the effectiveness of those members of staff whose increasing exhaustion, one senses, may have reached a point of being counterproductive. This, I would suggest, is particularly important as we plan for self sufficiency against a rapidly expanding horizon of total quality management (the latter hitherto almost totally ignored, not least because the "Main Board" did not consider it cost effective in an era of Crown Immunity).

But beyond all this will be a need, and rightly, to persuade our colleagues that the prescribing doctor and the patient must

have some locus in determining what self sufficiency is. Soundly based government doctrine this.