

-> JAC (for info) 10/4/87
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10/4/87 21-23 Mths
Plus C.I.A.B. discussion

**BLOOD TRANSFUSION SERVICE: MISCELLANEOUS ISSUES
NOTE OF MEETING ON 31 MARCH 1987**

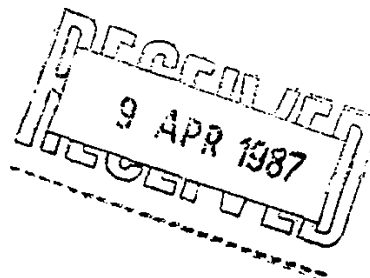
Present:

SHHD

Mr D Macniven
Dr A McIntyre
Dr J Forrester

CSA

Mr J Donald
✓ Prof J Cash



1. The meeting had been arranged at Mr Macniven's suggestion to allow ~~informal~~ discussion of a range of current BTS topics.

Relationship with CBLA

2. Mr Macniven's letter of 21 January and Professor Cash's reply of 26 January were used as a basis for discussion. Mr Donald would take a convenient opportunity to meet the new Chief Executive of the CBLA. Mr Macniven elaborated on the considerations which the BTS would want to take into account in selecting a firm to commercialise BTS developments. These included the competence and location of the firm and the likely pay off to the NHS in terms of royalties etc.

Handling charges for blood and blood products

3. Mr Macniven's letter of 15 January and Professor Cash's reply of 26 January were used as a basis for discussion. Professor Cash explained why he felt it was necessary to make a greater input to DHSS's decision on handling charges. The last revision of the price list had come out late; separate lists had been produced at different times for CBLA and NBTS products; the list of products on the last occasion had contained errors (eg a single product included under 2 different names and at different prices) and did not include products available from the SNBTS but not from CBLA; and, on the occasion of the last price increase, the handling charge for Albumin had increased by the surprisingly high figure of 58%, without explanation. Mr Macniven agreed to pursue these points with DHSS, with a view to increasing the Scottish input to pricing decisions.

4. The future level of handling charges was discussed. The meeting forecast that there might be an economic argument for charging less in Scotland than in England; the Lapsley and Mitchell study seemed to be suggesting that Scottish handling costs were lower than the present handling charges, while it was possible that CBLA charges would have to be increased to take into account the capital cost of the new plant at Elstree. The pros and cons of a differential price were discussed and the general view was that differential pricing was not desirable. Mr Macniven would take an opportunity to raise this prospective problem with DHSS.

Albumin supply problems in England and Wales

5. Dr Forrester was concerned, in view of the recent CBLA letter asking for SNBTS assistance in meeting a prospective short fall of Albumin production south

of the Border, that the SNBTS should not assist the English service at the expense of Scottish patients. (He was aware that the needs of the Scottish private private sector could not at present be met, because of a shortage of plasma.) Professor Cash explained that the CBLA proposal was that they would provide plasma, which would simply be fractionated at the PFC. Sufficient capacity existed at PFC for this purpose and the proposal would neither improve nor harm the Scottish supply position.

Endowment funds

6. Mr Macniven gave his initial reactions to the proposition, contained in a recent letter from Professor Cash to Mr Donald, that the CSA should be empowered to set up its own endowment funds. Mr Macniven explained that the CSA could have access to central endowment monies (eg the Scottish Hospital Endowment Research Trust), so long as the normal conditions were met. But he confirmed that the CSA, unlike Health Boards, had no power to set up its own endowment fund. Professor Cash and Mr Donald explained briefly why they thought that it would be desirable for CSA to be put on the same footing as Health Boards. It was agreed that Mr Donald would write setting out the case in more detail, particularly in view of the fact that the CSA had operated for many years without an endowment fund.

AIDS issues

7. Professor Cash elaborated on his letter of 3 March to Mr Donald (which he had copied to Mr W K Reid) in connection with the Social Services Select Committee's visit to Edinburgh. It was recognised that, while there were differences in practice south and north of the Border as regards donor literature and other matters, these were largely a question of clinical judgement. Dr McIntyre regarded it as unlikely that the Health Departments would intervene to standardise practice.

Aberdeen Blood Transfusion Centre

8. Mr Macniven apologised for the fact that consideration of the BTS approval-in-principle submission had been delayed due to pressure of business consequent inter alia of Mr Murray's unexpected and lengthy sick leave. Following the discussion which Mr Macniven and Dr Forrester had had with Dr Urbaniak (and the latter's follow-up letter), only one piece of information was now required: more details of the benefits to Grampian Health Board of the "preferred option". The Department had been pursuing this with the Board but with as yet incomplete success. Mr Donald agreed to take this point up with the Grampian Health Board General Manager.

Private blood collection agencies

9. Mr Macniven noted that he had recently received a letter from Mr Mutch, expressing the BTS Sub-Committee's strong concern about the current proposal to set up a private blood collection service at Gloucester. He asked for an elaboration of the Sub-Committee's concern, bearing in mind that the Gloucester proposals apparently restricted to autologous services which were not at present offered by the NHS. Professor Cash explained that, according to the regional blood transfusion Director in Bristol, the Gloucester proposal was not in fact restricted to autologous blood collection. Furthermore, he foresaw pressure from the private medical sector for broader blood collection services, because of severe dissatisfaction with the service available from the NBTS. Although the (small) private medical sector in Scotland had no reason for dissatisfaction with the

SNBTS services, the establishment of private blood collection facilities south of the Border would probably have the effect of encouraging the export of Scottish blood, in competition with the SNBTS's volunteer donor arrangements. Mr Macniven said that he found this elaboration very helpful.

Extension of compensation arrangements for clinical trials

10. Dr Forrester and Mr Macniven explained that, while present action was delayed by Mr Murray's absence, the intention was to pursue two issues. The priority task was to extend the compensation arrangements for non therapeutic trials, to cover the products listed in Professor Cash's recent letter to Mr Murray. Dr Forrester was hopeful that such an extension was achievable. But the second task (the extension of compensation arrangements to cover the "named patient only" period of clinical trials, as requested by Dr Ludlam) was a great deal more problematic, and would be pursued less urgently.

Product liability

11. Mr Donald and Professor Cash pressed for stronger action to persuade the European Community to reverse the decision that product liability should extend to blood products (learning the lessons of the recent US experience). Mr Macniven referred to Mr Morison's recent letter to Mr Donald on this subject, which explained the substantial difficulties which had persuaded SHHD and DHSS that it would not be fruitful, even if it were desirable, to pursue this issue.

Product licences

12. Dr McIntyre explained that the DHSS were about to launch a review of the work of their Medicines Inspectorate. The review would consider the extent to which licences should be issued to Crown bodies such as the SNBTS. Professor Cash emphasised the considerable importance the SNBTS attached to its ability to apply for a product licence. While it was true that the writ of the Medicines Inspectorate would run to SNBTS procedures whether or not product licences were involved, it was his experience that application for product licences led to greater attention by the Inspectorate. He welcomed such attention because, however diligent SNBTS management were, it was important for their procedures to be thoroughly audited by an independent inspectorate conscious of practices in the broader industry.

Patents

13. Professor Cash and Mr Donald noted increased attention to patent infringements: the SNBTS had had 2 cases in the past year and the CBLA had one case at present. A question which would have to be addressed at some time in the future would be whether the SNBTS should pay royalties for producing patented products on a non-commercial basis.

Export of blood products to Eire

14. Professor Cash explained that the SNBTS had been approached informally by the Eire Government to export blood products (replac~~ement~~^{ment} the current commercial source). In the course of a brief discussion, it was noted that the proposal raised political, financial, contractual and practical questions which would have to be addressed, if, as Professor Cash suspected, it were formalised.

PFC staffing

15. Professor Cash noted that 2 key staff at the PFC had recently resigned, to take up industrial posts at Livingston. They would not be easy to replace and their loss was a further indication that salaries were uncompetitive.

SHHD/IVD
April 1987

Distribution:- Those present
Mr Morison, SHHD
Mr Calder, SHHD/Pharm
Mr Baxter, SHHD/IVE