30

NOTES OF MEETING ON 21 SEPTEMBER 1994 - SNBTS GENERAL ISSUES.

Present: Mr. G. Tucker
Dr. A. Keel
Mr. R. Panton
Mr. G. Wildridge

1. Clinical Trials Indemnity NQH/5/1

The Department had noticed a rise in the number of indemnities sought for Clinical Trials of SNBTS products, particularly Intravenous ImmunoGlobulin (IVIGg) which appeared to be being considered for unusual conditions in which the use of IVIGg was not standard medical practice. Dr. Keel had raised this issue with DCMO.

Because of the large ongoing number of clinical trials and the fact that some of these appeared to be taking place outwith Scotland whilst still covered by the Secretary of State's indemnity, Mr. Panton would write to SNBTS asking for a summary of ongoing trials to ensure tighter Departmental control.

2. Co-operation with Irish Blood Transfusion Service (Dublin) NQH/4/17

Mr. McIntosh had been enthusiastically pursuing an agreement to contract fractionate plasma supplied by Eire and had written to advise that he felt some agreement would now be possible.

The Department had instructed him to make no commitment before the implications could be considered. There were three areas where further investigation was needed :-

a) SNBTS' Business Case for the proposals - how costs and income had been calculated.

b) Income generation for the SNBTS - this had become increasingly important in dealings with England and this would continue as SNBTS looked to become more involved in contract fractionation.

c) The legal aspects ,especially the question of who bears the liability for the safety of products fractionated by contract.

Mr. Panton would ask SNBTS for more detailed proposals and liaise with Finance colleagues and Solicitor's Office for advice.

3. National Blood Authority. NQH/7/3

It was noted that the announcement of the re-organisation of Transfusion Centres in England had provoked a hostile reaction from the media. The Department had been fortunate in being able to deflect such criticism by not being part of the NBA and by pointing out that the new arrangements would bring England and Wales more into line with thw Scottish model.

The proposed commercial alliance between BPL and Miles was felt to be extremely sensitive politically and might provoke an angry reaction from the public. It remained to see how far D of H and NBA would be able to cope with criticism, but the involvement of profit-making companies using paid donor plasma in such an emotive area was likely to prove difficult to present to the public.

In an effort to expand its overseas markets, NBA also wished to introduce ALT testing for donations. ALT had been used as a marker for abnormal liver function but has been largely superseded by the development and refinement of tests for Hepatitis 'C' - nevertheless some countries still insisted on ALT testing. The general consensus was that ALT testing would; produce no real benefit for patients, ,uneccesarily alarm many donors and also reduce the number of useable donations. If introduced in England, Scotland would be forced to follow suit to avoid allegations of inferior safety standards. The matter would be considered by the MSBT.

The proposed venture appeared to pose only threats to the SNBTS. The choice of Miles was made partly on the grounds that this would give England and Wales greater access to IVIGg and fibrin sealant, both of which are major product developments for the SNBTS. The easy availability of these products to NHS users in England might limit the potential number of users for the SNBTS versions. The fact that Bayer (Miles' parent company) had also developed a recombinant Factor VIII might also fundamentally effect fractionation needs in the longer term.

Since the NBA was clearly committed to becoming more commercial in its operations and that Miles would increase its penetration into the UK market, Mr. Tucker suggested that it would be appropriate for the Department to review the way SNBTS operated and was funded.

In view of the turbulence already being caused by the Peterken review and the potential for political difficulties following the announcement of the Miles partnership, it was agreed that further review of SNBTS should not take place until its future status had become clearer and the reaction to the changes in England and Wales could be assessed.

4. Hepatitis 'C' Lookback NQH/23/1

Glasgow R.I. had written seeking funding for the costs of treatment with Alpha Interferon for patients with transfusion acquired Hepatitis 'C' and Pharmaceutical services had replied to the effect that whoever was in charge of clinical care was also in charge of prescribing. The position of the Department was that the source of the infection was in this case ,irrelevant and that no additional funding would be made available. Mr. Scott, Chief Pharmacist should be copied any further correspondance as necessary.

Dr. Keel had attended a meeting of Hepatologists and their view was that a lookback was necessary as part of a general 'duty of care'. It was noted that SNBTS had still not produced suitably detailed papers on the costs and consequences of a lookback, but that in any case, the issue was no being taken forward by D of H. The Department would continue to monitor the situation.

5. Council of Europe - Membership of Expert Committee on Blood Transfusion. NQC/3/7

D of H had failed to keep the Department informed of the nomination of Dr. Rejman and Dr. Robinson as representatives and had eventually presented a 'fait accompli'.

Mr. Panton would write to Mr. Kelly asking him to ensure that channels of communication were properly used in future and asking that Prof. Cash be kept fully informed of all developments on the Committee.

6. Informed Consent NQ2/10/1

Depite a general move towards obtaining consent prior to various medical interventions, it had been decided that blood transfusion did not fall into this category, largely because it was not considered as a risky procedure and because it was not always possible to obtain consent e.g. when a patient was under anasthetic.

At a conference, Dr. Keel had heard an expert legal opinion that consent had little substance in law and that the general duty of care was of more relevance. This was really a professional issue to be taken forward by the Royal Colleges, but Mr. Henderson, Sols, would be copied papers for his comment.

7. Ethics Committee. NQ3/9/1

The Chief Executive had made his feelings clear on this point at the recent CSA Executive Group Meeting - his view was that the Lothian Health Board Committee should perform this function. It was certainly not appropriate for SNBTS to police itself.