From: Dr A Keel
Room 364
St Andrew's House
18 February 1999

Mr John Aldridge
Mr Mike Palmer

Copy to: CMO – for information (minute only)

MSBT: MEETING TUESDAY 16 FEBRUARY 1999

1. This was meant to be Dr Metters' final meeting of MSBT prior to his retirement. In the event, he had been asked to deputise at short notice for CMO England abroad, and the meeting was chaired by Mike McGovern. John Forsythe (Renal Transplant Surgeon from RIE) yet again did not attend and no apologies were given. As far as I can recall he has only attended one meeting since his appointment, and I would be grateful for CMO's view on whether/how this should be raised with him. He appears to be contributing to the MSBT Sub-group which is currently revising Guidance on Microbiological Safety of Tissues and Organs using Transplantation. However, I do not feel we are getting full value from him as far as the main Committee is concerned.

2. The following is a brief summary of the main agenda items.

(i) FDA Meeting, 18 December 1998

A Sub-group of the FDA met in December to consider the implications of deferral of UK donors in the light of the potential for them to be carrying nvCJD. Dr Metters attended the meeting, but as far as I am aware has not formally communicated the outcome to the other Departments of Health. I had already gleaned through SNBTS that the FDA had agreed in principle that such donors should be deferred, although this might result in a 10% decrease (1,000,000 units) in the amount of blood available for transfusion in the US. The Sub-group are now looking in more detail at the logistics of such a decision, which apparently the American Red Cross are opposing. A final decision is likely in March, and if the US decide to go down the deferral route, Canada will probably follow suit. It was noted that this will no doubt get adverse press coverage in the British media which will need to be managed.

(ii) DNV Risk Assessment

It was announced that this would be made public on Thursday 18 February – Mr Palmer's submission refers.

(iii) Blood Products Manufactured from non-UK plasma

Papers from BPL and PFC had been circulated, and indicated that Scotland are lagging about 4 weeks behind in terms of the changeover to non-UK products. It is clear that, notwithstanding the extensive discussion at the October meeting of MSBT, BPL do not intend to be nearly as rigorous as PFC in ensuring withdrawal of UK plasma products. BPL have simply issued a letter (copy attached) asking customers to

return any unused UK products. In contrast, Elspeth McIntosh from SNBTS has compiled a comprehensive register of the location of all products which will need to be replaced.

There followed a discussion about normal human immunoglobulin which for me brought sharply into focus the risks which BPL will be running in not taking greater steps to ensure withdrawal of all UK stocks. Normal human immunoglobulin is given as short-term protection against Hepatitis A for those travelling to endemic areas. The preferred method of protection is by active immunisation, and a perfectly satisfactory vaccine exists for this purpose. Nonetheless, significant amounts of immunoglobulin are still being used, partly because vaccination is much more expensive, and partly because some travellers do not give sufficient foresight to their travel arrangements. Apart from anything else neither BPL nor PFC has as yet sourced hyperimmune plasma abroad to continue manufacturing this product. The question therefore arises whether they should bother, particularly as current expert advice is that the product should not be used for travel protection, and other indications may also have a question mark over them. (The Advisory Group on Hepatitis is going to be asked to advise specifically on its use in outbreak control.) It was agreed that the Departments of Health should probably issue a "Dear Doctor" letter pointing out that the product should not be used for travel protection, and that the NBA and SNBTS will no longer be manufacturing it, although there are a number of commercial suppliers of the product. DH England will provide a first draft.

Of relevance is the fact that this product has a long shelf life (approximately 3 years). If BPL do not pursue withdrawal of the product more actively than they appear to be planning, then it is perfectly feasible that GPs in far flung, or not so far flung, parts of the country could continue to use the existing supplies, with obvious ramifications if the risk of transmitting nvCJD by blood product turns out to be less than hypothetical. I think BPL might have been pushed further on this had Jeremy Metters been chairing the meeting. In the event, their proposals for product withdrawal in general really went unremarked.

Anti-D supply was also discussed under this heading. Again Scotland are lagging 4 to 6 weeks behind BPL's proposed release data. Angela Robinson maintained that patients in England had been refusing Anti-D because of the theoretical risk of nvCJD. However, she did not have any hard data to substantiate this, and certainly SNBTS and the Department have heard nothing to suggest that this is happening in Scotland. However, I have asked Brian McClelland to supply us with data on Anti-D usage, to see if there has been a decrease in the use of the SNBTS product since the CSM announcement.

(iv) NvCJD: Transfusion Medicine Epidemiology Review (TMER)

A more accessible form of the report of this review than was presented at the previous meeting was tabled. A total of 10 recipients of products from donors who subsequently developed nvCJD have been identified. One of these recipients has died, and of the 9 remaining only 3 are of an age group eligible to donate (the remaining 7 are over 60 and have never donated). The NBA have taken steps to identify these 3 potential donors throughout England and Wales, so that they can be deferred if they turn up to donate, although obviously the reason for the deferral will

not be disclosed. I have written to Ian Franklin to check that SNBTS also have a system in place for deferring these 3 individuals in the event of them turning up to donate in Scotland.

(v) Viral Inactivated Plasma

You may recall that production of this product has been giving NBA major problems over the past few months. SNBTS are now producing small quantities of methylene blue (MB) inactivated plasma to supply current demand, which apparently is low. It was clear from Angela Robinson's approach that because of the NBA's operational difficulties, she would have liked MSBT to advise that the organisation no longer needed to produce such a product. In the event she was given a clear message that this would not be satisfactory. However, rather worryingly the whole thing was dressed up as concern about the potential toxicity of MB inactivation. Dr Robinson alleged that the German blood transfusion service (Paul Erlich Institute) may be about to suspend the Springer process, (which uses MB) because of worries about its potential toxicity. No hard data was presented. She also mentioned that Octopharma are pursing BPL via the OFT because the former reduced the price of their product. BPL has been marketing this very hard, but have had little interest from clinicians! Clearly not satisfied that MSBT would not change its advice in this area, Dr Robinson took the opportunity to point out that Scotland are apparently the only country using the MB method – this remark was left hanging in the air. Again I have asked Brian McClelland to look into the German situation, and try and get some hard data on the alleged toxicity of MB, as a matter of urgency.

3. Finally, the attached HSC Circular on Provision of Recombinant Factor IX for new patients and children under the age of 16 was tabled. This was issued in England on 22 January, but I knew nothing about it prior to the meeting. The main message is that extra money will not be made available centrally in England for provision of this product. Would it be worth drawing the Circular to the attention Trevor Jones?

GRO-C

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