Dr Ian Hudson MCA/ES

From: Michael Adam
SOLC5

Date: 12 April 2001

Cc: Dr Tsang MCA
Dr McGovern HSD2
Mr Lister HSD2
Mr Harvey PH6
Ms Aitken SOLC2
Mr Roberts SOLC4
Ms Sandby-Thomas SOL

File: B17

TREAT OFFICAL LETTER: vCJD AND THE SAFETY OF BLOOD PRODUCTS

1. I understand that you have been in discussions with Rachel Sandby-Thomas about a 'Treat Official' letter from GRO-A dated 15th February 2001. A follow-up letter was sent to Lincoln Tsang dated 28/3/01.

2. For the benefit of colleagues the correspondent has asked, in terms, whether he/she has received pooled plasma that contained a donation from a donor who was subsequently diagnosed as having had vCJD. MCA's research into this matter indicates that he/she did in fact receive pooled plasma from one of the affected batches.

3. You have submitted to us a draft letter advising the correspondent that this is the case. Given that this is 'Treat Official' correspondence, you are understandably anxious to process this as quickly as possible. However, I have the following concerns.

4. Firstly, I doubt very much whether MCA should be responsible for replying to GRO-A. This seems to me to be a matter for HSD2, who, as I understand matters, have already addressed this issue in the context of other patients.

5. My understanding is that they received advice from SOLC2 (David Dunleavy) on the potential responsibilities towards patients in this type of case, and we would obviously expect the Department to adopt a consistent approach. Matters may, however, have moved on from when David gave his advice – the Department's view on the ethical position may have changed and the advice may have predated the coming into force of the Human Rights Act – so his advice will need to be reconfirmed with Gill Aitken. It is also possible that PH6 and SOLC4 will need to have an input into this answer, as they deal with vCJD issues more generally. Unless DH's response to this type of query is now settled, I suspect Alan and Charles may want to raise this case with the DCMOs.

6. From a SOLC5 perspective, I have two further additional comments. Firstly, consideration will need to be given to the possible application of section 118 of the Medicines Act 1968 in this area. If DH believes that it has a duty to advise the

correspondent what has happened, this duty should be articulated, be it only internally. Secondly, if we do assume responsibility to tell GRO-A what has happened (as I presume we will), DH may be assuming a duty of care towards him/her in relation to the manner of that notification – and will, in any event, want to ensure that the notification is not done in a manner that could be construed as negligent.

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