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RESTRICTED POLICY

Mr Charles Blake, SOLB4

From: Roger Scofield, CA-OPU

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Copies (cover note and annex G only)
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HEPATITIS C - CLAIMS FOR NEGLIGENCE AND THE LOOK BACK EXERCISE

Summary

1 This paper seeks to set in motion a process of discovery of relevant papers and records in order to ascertain whether the Department, the National Blood Authority (NBA) or any other party has acted negligently as regards the safety of the blood supply and in caring for the interests of patients who may have been inadvertently infected with Hepatitis C virus through blood or blood products. It seeks advice on the general vulnerability of the parties concerned to such claims and specific advice on a number of issues arising from the Hepatitis C lookback exercise.

Background

2 My submission to PS(H) dated 22 December 1994 (Annex A) set out a programme of work in response to our acknowledgement that a number of people had been inadvertently infected with Hepatitis C as a result of treatment with blood or blood products. The response included reviewing our position on negligence; preparing a package of actions we could take to ensure that such people were traced, counselled and where appropriate treated. Support should also be given to self-help programmes which provided good value for money and research might be undertaken to improve our knowledge of the natural history of the disease and the best treatment options.

3. Since then we have publicly announced the lookback exercise (Annex B), including advising GPs and relevant consultants of the background (Annex C), and set up a helpline for anxious members of the public (12,000 cases since 11 January and now falling off).

4. The Panorama programme on Hepatitis C put out on 16 January sought to show that the Department/Blood Transfusion Service had been negligent in not introducing tests for Hepatitis C as soon as they were available: nor had they sought to trace those who

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might have become infected as a result. The Deputy Chief Medical Officer sent an open letter to the Editor of Panorama (Annex D) refuting these allegations and stating that the programme would have alarmed many patients quite unnecessarily.

5. The Ad Hoc Working Group held its first meeting 20 January (minutes at Annex E) and guidance on the first steps of lookback (identifying the donors and the units of blood provided to hospitals) has been sent to the Blood Transfusion Service (attached at Annex F).

6. Some further work will be undertaken in advance of the next meeting 24 February, after which we hope to be able to send out

i. model letters to Haematologists in charge of blood banks

ii. a proforma to record all significant information relevant to the lookback exercise

iii. guidance on the remaining stages of the lookback exercise

iv. guidance on counselling, and

v. guidance on treatment options.

7. In response to a starred question in the Lords from Lord Ashley (31 January) PS(L) reiterated the Government's position that

i. there was no question of negligence, and

ii. there was no intention of making payments to those infected.

8. A further starred question from Lord Ashley asking if the funding and role of the MacFarlane Trust can be extended, is due for answer 21 February 1995.

Possible Past Negligence

9 Having got the major part of the response package moving, we now need to address the issue of negligence. Writs have been served against individual Regional Transfusion Centres for negligence in supplying infected blood. The cases considered occurred during the "window period" 1989-1991, ie after the first tests for Hepatitis C were available, and before all donations were routinely tested in this country.

10. We have asked the NBA for full details. It is understood that they have not yet entered any detailed defence. However the case would be as follows:

i) Screening was introduced in September 1991. The first anti-hepatitis C tests were reported in the literature in March 1989 but did not become available until later that year.

ii) These first tests had too large a number of false positive and false negative results and no satisfactory confirmatory tests were available. Expert advice was that these tests should not be introduced because of these deficiencies.

iii) The Department of Health funded several trials of the first and second generation anti-Hepatitis C test kits. Screening was introduced in late summer 1991, following advice from the Advisory Committee on the Virological Safety of Blood (AVSB). Satisfactory kits became available together with confirmatory tests. The screening kits now available are even more accurate than the second generation kits.

11. The Panorama programme made much of the Polymerase Chain Reaction (PCR) test which it was claimed had been used in Belgium since 1990. The expert Committee, which advises Ministers on the safety of blood, discussed at the time the course of action pursued by the Belgian authorities. Their view was that the screening test should not be introduced at that time because of deficiencies, particularly in the detection of false negatives. Having a good confirmatory test, whether Recombinant Immunoblot Assay (RIBA) or PCR,is of no use if true positives are missed by the initial screening. Also there are major problems in respect to quality control for PCR.

12. Whilst these are the only writs received so far, solicitors are pulling together as many cases as they can and may well enter a group action against the NBA, the Department or the Advisory Committee.

13. A case might be brought which alleges failure to mount a lookback exercise once tests were available and infected donors could be identified and recipients who had been exposed to infection might be traced.

14. The defence which we have given publicly to this is that:

i) Until recently it was considered that look back to identify recipients of blood transfusion who are at risk would be technically difficult; and as there was no effective treatment, to inform people they were at risk, when there was nothing that could be done about it, would increase distress, reduce insurability etc, without any medical benefit.

ii) The long term effects of the disease were also unclear and it was not easily transmitted.

iii) The position is now clearer and a means of treatment has become available. There is now some confidence that many, but not all, recipients of blood infected with Hepatitis C can be identified and Interferon alpha has been licensed for the treatment of chronic hepatitis C. This may be of help to some people.

iv) For this reason the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) at its meeting 15 December 1994 advised Ministers to undertake a look back exercise.

15. It is important to note that so far as we know, the UK is the only country to have introduced an HCV specific lookback exercise.

16. The role of the expert committees needs to be considered in all of this. The NBA's case will be that they are only permitted to carry out tests which are specifically ordered by the Secretary of State. SofS in turn is guided by the recommendations of the expert advisory committee on blood safety. On the face of it the NBA cannot be faulted in this.

17 However, the Medical Director of the National Blood Transfusion Service was also a member of the Advisory Committee on the Viral Safety of Blood (ACVSB) at the time the key decisions were taken and Dr Angela Robinson, the present Medical Director of the NBA, is a member of the committee's successor body, the Advisory Committtee for the Microbiological Safety of Blood and Tissues for Transplantation (MSBT). The committee could presumably be challenged in respect of the advice it gave.

18 The NBA can also refer to paragraph (d) of article 7, in the EC Direcetive 85/374/EEC on which the Consumer Protection Act is based. There is also the question of whether blood is a product (and so liable under CPA) or a service and so capable of negligence. Blood products after 1988, when CPA was inntroduced, would probably be regarded as products and most have been treated with viral inactivation procedures.

19. Another key question could be the access we had to information from elsewhere in the world. The information relating to the position in other countries is not completely clear. The best information we have available at present is that the first country to introduce universal screening was Japan in November 1989. It should be noted however that HCV is believed to be a major cause of liver disease and cancer there, and it is thought likely that between 2 and 4 million people are infected. France introduced screening in either December 1989 or March 1990. We understand that Luxembourg and Italy introduced screening in April 1990, although in Italy it was on a voluntary basis. Holland introduced it in May 1990. The test was licensed in the USA in May 1990 but it is not known when it was introduced. Testing was introduced in Belgium in July 1990.

20 We have no further information on when other countries introduced screening although it was much later in central and eastern Europe. It was brought in in Bulgaria in July 1994. This list was drawn up a couple of weeks ago, using information available to us <u>now</u>. It is likely that we had very much less information at the time. Questions might be asked about what we did to find out what was being done elsewhere; and with what results; and what assessment we made of that information.

Discovery of Papers

21 I have asked Tom Kelly in CA-OPU and Dr Rejman in HC(M) to draw up a sequence of events and to assemble the key papers, including records of the ACVSB and the MSBT. I understand that Dr Harold Gunson did quite a lot of work on this before retiring from the NBA and I have asked Dr Robinson to get hold of this information for us.

22. From a handling point of view, the NBA are coordinating centrally any writs brought against individual RTCs. We assume that when formed, the NBA took over liabilities as well as assets and hence are answerable for the action of their predecessors. Whilst there could be differences in position between the NBA and the Department, the SofS would presumably be the ultimate defendant in both cases. I suggest that so far as possible, we work openly with the NBA and their legal advisors in this matter but I should appreciate advice from you on this before I discuss this exercise more fully with them.

Lookback Exercise

23 Before going too far ahead with the lookback exercise, we would like to discuss with you, both the general way in which we are proceeding and a number of detailed points about the extent of the exercise in the light of "taking reasonable steps"; about confidentiality of donors, recipients and samples; and about the status of the guidance given to the field. At Annex G I have set out a number of specific questions. Others are likely to arise as the exercise progresses and guidance is developed for the field.

Next Steps

24 The papers provided as Annexes to this minute (not copied to, or needed by, copy addressees) constitute a substantial record of actions so far. Before going too far ahead with the discovery process, it might be useful if we had a quick meeting to ensure that we are on the right lines and targeting the right issues. We might also have a separate meeting with NBA officials to ensure that we are keeping together. My secretary will be in touch with yours to fix a suitable date.

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ANNEX G

QUESTIONS TO BE CONSIDERED ON THE PROPOSED LOOK BACK EXERCISE

1 Does the exercise as now constituted - including tracing, counselling and, where appropriate, treating those affected, provide a reasonable response to the duty of care which you agreed SofS should demonstrate?

2 Should we contact donors who are identified as being anti-HCV positive but who have not subsequently come forward to give blood?

3 Are there issues of donor consent involved? and if so does the public health defence apply?

4 Should GPs or other consultants be told that a patient is, or may be, Hep C positive, without specific authority from the individual?

5 Can samples be tested for genotyping without specific authority from the patient? This may be helpful in determining treatment options but might also be used to show positively if someone was infected by a specific sample of blood or whether they contracted the infection from elsewhere.

6 What is the status of the guidance which it is proposed should be issued to the field so far as look back procedures, counselling and treatment options are concerned?

7 Are there any problems associated with the model letters?

8 There are large numbers (several millions) of blood samples at the South of Scotland RTC and at the North London centre. These date back before 1991. Should these be tested? To do so would be very expensive with little likelihood of finding more than a very few positive results. It is understood that Scottish lawyers have advised their Ministers that cost should not be a factor.

8 Having agreed that there is a duty of care with regard to blood recipients put at risk because of hepatitis C, is the Department's position on HIV vulnerable? Should a look back exercise be mounted there also?