FILE 29

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PS/Minister for Health and Community Care

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COMPENSATION FOR HAEMOPHILIACS INFECTED WITH HEPATITIS C: BBC ENQUIRY

Background

1. The BBC is planning to run a story tomorrow on claims for compensation from haemophiliacs who have contracted Hepatitis C as a result of receiving infected blood clotting agents (not to be confused with blood transfusions) in the late 1980s/early 1990s from the Scottish National Blood Transfusion Service (SNBTS). The haemophiliacs appear to be claiming negligence by the NHSiS, on the basis that sufferers in Scotland were exposed to risks for a year longer than those in England. They are seeking a debate in Parliament on the matter.

2. Claims for compensation from haemophiliacs - and from NHS patients who received similarly infected blood transfusions – have been pursued against all the UK Departments of Health for some years. In Scotland there are around 20 claims currently pending in court (there are over 120 known cases of infection in Scotland). Our advice has been that the blood transfusion services were not negligent in administering infected blood and blood products because the infections occurred before tests and treatments to make blood and blood products safe from Hepatitis C could be practically introduced.

3. As a result the UK-wide government position has been not to accede to claims for compensation, on the basis that 'no-fault' compensation should not be paid. For ease of reference I attach a copy of a note recently submitted to Ministers which outlines the policy issues surrounding the claims and the line which has been taken (the note covered a green folder reply which not been yet been sent). The Government has treated this as an issue on which all the UK territories need to keep in step, given the pressures which a change of policy in any one territory would place on the other parts of the UK.

Situation with regard to blood products

4. The haemophiliacs' claims concern the blood clotting products manufactured by SNBTS as a specific treatment for patients suffering from haemophilia. These

products are heat treated in order to kill any viruses which may be present in the blood. It is claimed that in Scotland the heat treatment required to kill the Hepatitis C virus was not introduced until a year after it was applied in England, and that this constitutes negligence on the part of SNBTS.

5. The chain of events is as follows:

- December 1984: SNBTS introduces 68 degree heat treatment to kill HIV virus, then the prime safety need for blood products. Hepatitis C was not designated at this time as a separate virus and no test was available to determine at what heat it would be killed (68 degrees was later found to be insufficient to kill the Hepatitis C virus). No heat treatment introduced in England.

- 1986: English Blood Service introduces 80 degree heat treatment; hot enough to kill both HIV and Hepatitis C viruses.

- April 1987: Following re-engineering of its product, SNBTS introduces 80-degree heat treatment, *as soon as practically possible to do so.*

- 1988: Early clinical studies give first evidence of heat thresholds for deactivation of Hepatitis C.

6. This chronology makes clear that although there was a period between 1986 and 1987 when Scottish products were not as safe from Hepatitis C as English products, this was not due to any negligence on the part of SNBTS. SNBTS had already introduced some time before England the priority safety measure - anti-HIV heat treatment - and, given the state of knowledge at that time, could not know what the required heat treatment was to kill Hepatitis C. Once the 80-degree heat treatment had been introduced by England it was adopted by SNBTS as soon as it was able to re-engineer its product.

7. Furthermore it was not feasible for Scotland to import the safer English product between 1986 and 1987 because not enough of this product could be produced for domestic English consumption, let alone for distribution elsewhere in the UK. In fact, 68% of the main Factor VIII product used in England in 1986 was imported from overseas (almost certainly without being heat treated against Hepatitis C, thus making it as unsafe as the Scottish product). By contrast Scotland was self-sufficient in product and could guarantee its safety from Hepatitis C from the time SNBTS introduced the higher heat threshold in 1987.

8. Having said this we will investigate these events with SNBTS more thoroughly in the next few weeks to confirm for ourselves that the correct action was taken.

<u>Line to take</u>

9. We propose that the following line be given in response to the enquiries from the BBC:

'The actions taken by the NHS in Scotland in the 1980s to ensure the safety of blood products administered to haemophiliacs do not suggest that there was any negligence on the part of the health services, given the state of knowledge at that time about protection against Hepatitis C and the practical difficulties of introducing a Hepatitis C-safe product any sooner in Scotland.

This suggests that compensation for this set of patients, tragic as their case may be, would not be appropriate, as compensation should only be paid where the NHS or individuals working in it have been at fault.

Of course it is open to the Scottish Parliament to discuss the matter and the Executive would have no objection to these issues being aired in debate if Members so wish.'

Situation with regard to blood transfusions

10. A quite separate set of issues surrounds claims made by patients (non-haemophiliacs) infected via blood *transfusions*. These should not be confused with the claims against blood products from haemophiliacs and are not strictly relevant to the current BBC enquiry. They are mentioned here in order to make the Minister aware of a shift in policy in England being seriously considered with regard to these claims.

11. Recent legal advice in England judges that the Department of Health would in fact probably be held liable in court for the failure to introduce screening for Hepatitis C as quickly as it should have done for some patients. This is because the anti-Hepatitis C screening test for transfusions was available in May 1991 but was only introduced in a few blood centres in England between then and September 1991, when it was made universally available. Advice is that the Department would probably be held liable for any infections incurred during the period between May and September 1991.

12. The Department of Health is therefore preparing to recommend to Ministers that these cases be settled out of court. This will represent a considerable shift in policy which will require careful presentation and will have implications for the other UK territories, assuming that the same time lapse in applying the test occurred throughout the UK (the Scottish National Blood Transfusion Service is currently looking into the circumstances in Scotland). We will therefore request that we are fully consulted before any decisions are taken by Department of Health in England, and will brief Ministers accordingly. We will also be submitting in the next few days a revised draft reply to GF CE/1069/99, taking account of the considerations underway in England.

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