Mrs Marsden 3/1/95
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hep008

RESTRICTED - POLICY

To Mr Hollebon PS(H)

From Roger Scofield

Date 22 December 1994

see attached copy list

HEPATITIS C - THE GOVERNMENT'S RESPONSE

SYNOPSIS

1 This paper seeks to identify the action which should be taken by the Department to assist those who have been infected with hepatitis C (HCV) as a result of blood transfusion or the use of blood products for the treatment of haemophilia. It includes a recommendation to undertake a "look-back" programme to identify those at risk. The submission is being made in parallel with proposals to strengthen the position on the NBA's plans for the future of the National Blood Service.

BACKGROUND

2 About 3000 people with haemophilia and about a further 3000 people who had blood transfusions prior to September 1991 are believed to have been infected with HCV as a result of NHS treatment. The Department has denied negligence and Ministers have refused calls for compensation. A note is provided at **Annex A** which describes the transmission of hepatitis C and explains the timing of the introduction of testing for the virus. It also estimates the numbers of recipients infected.

Pressure for action

3 It has been known for at least five years that some people will have been infected through NHS treatment and we have expected at any time a campaign to be mounted along the lines of that for HIV. In recent weeks there has been increased media interest and a series of EDMs, an adjournement debate, and a large number of PQs and PO cases. Writs have been taken out against a former regional transfusion centre and we are aware of others being prepared.

4 In addition to the concerns of those directly affected certain solicitors are seeking to establish themselves in the field of medical negligence, local MPs are pressing the cases of their constituents and the Swiss drug company Roche have recently been granted a licence for the first drug approved for use in the treatment of hepatitis C.

Panorama programme

5 Panorama are proposing to screen a programme on HCV and blood transfusions 9 January 1995. This is likely to claim that many people may have been infected through blood transfusions but remain unaware of it. They will be pressing for Government action

to identify those at risk and asking why action was not taken earlier to screen blood donations. A number of staff from the Blood Transfusion Service in England, Scotland and Eire have been interviewed for the programme. It is known that some feel strongly that action should be taken to identify patients at risk. Whilst there are satisfactory answers to the main claims, (eg. see para. 2 of Annex A and paras. 11 and 12 below) the programme is likely to bring increased pressure from MPs, the media and the public for action to be taken.

Haemophilia Society

6 In September the Haemophilia Society, which represents the interests of about 4500 members who have haemophilia, issued a statement saying that they were not proposing to pursue any financial claim against the Department but they did wish to see a series of actions taken to ensure that those affected received the best treatment possible. Following a conference the Society modified their position to call for financial help for those suffering from actual illness.

The legal position

7 The Department's lawyers have not yet taken Counsel's advice on whether any case exists for negligence. Officials have taken the line throughout that everything has been done that could have been and that they acted on the advice of the Advisory Committee for Virological Safety of Blood (ACVSB - the predecessor of the MSBT) which was set up specifically in order to provide Ministers with advice on blood safety. It is planned to assemble the key documents and to seek Counsel's opinion in the New Year. Meanwhile action is in hand to ensure that any writs taken out against any component part of the transfusion service are co-ordinated by the NBA centrally.

8 Meanwhile our lawyers have advised that Secretary of State may have a duty of care to do whatever can reasonably be done to identify, inform, counsel and treat any who may have become infected as a result of NHS treatment. This is not entirely clear; nor is it an absolute duty but in circumstance where:

* SofS acknowledges a broad responsibility for public health and the care of those in need of medical treatment;
* and is in the habit of issuing warnings concerning action to be taken to safeguard health and of seeking to identify those who are in particular danger of suffering ill health;
* and if there is action that can be taken to identify those who may be at risk;
* and having identified them there is action that could be taken to assist them;
* then if no such action is taken the SofS might have a case to answer.

ACTION THAT CAN BE TAKEN

9 There are a number of actions which can be taken short of financial assistence. They include:

i) identifying those at risk, informing them and providing appropriate counselling and care;
ii) ensuring that appropriate treatment is available for them;
iii) undertaking research into the best forms of treatment and management of the disease.
iv) support of any self-help initiatives.

These will be considered in turn.

Identification of those who are at risk

10 The majority of those who were being treated for haemophilia prior to 1985, (after which blood products were routinely heat treated) are assumed to have been infected. They are nearly all under the care of haemophilia centres. Some individuals have been found to have contracted HCV and this has been traced to blood transfusions they have had prior to September 1991. After that date all donations of blood were tested for HCV.

11 It is possible to identify others who may be at risk because they received blood from donors who it was subsequently found were HCV positive. This process is known as "look-back". Until recently it was considered that lookback 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 without any benefit.

12 The position has changed on both counts. There is now some confidence that many, but not all, recipients of blood infected with hepatitis C can be identified and some treatment regimes using interferon alpha have been licensed. The Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) at its meeting 15 December agreed to advise Ministers of the four Health departments that:

i. In MSBT's view there is a duty of care towards those infected with HCV as a result of NHS treatment. It follows that procedures should be put in place to identify those patients at risk;

ii. Whatever is done should be done equally and uniformly throughout the UK;

iii. Guidance should be drawn up as soon as possible:

a) on procedures for identifying those at risk, and

b) While it was for the medical practitioner responsible for each patient identified as at risk to decide what should be made known to the patient about his/her risk status, and to decide whether

and what treatment should be advised, guidance on the counselling and treatment options would be desirable."

13 The MSBT further advised that if Ministers agree to a "look back" programme an ad hoc Working Party should be established to provide the necessary guidance. The Working Party would be drawn from members of the MSBT and the Advisory Group on Hepatitis.

14 The position is futher complicated as earlier in the month officials in Scotland, having carried out a pilot research study and satisfied themselves that a look-back exercise on Scottish patients would be feasible and practicable advised their Ministers that they had a clear legal duty to undertake such a programme, whether other Health Departments did so or not. It is understood that Lord Fraser has decided to instruct the SNBTS to go ahead with such work immediately since he considers that any delay could put Ministers into a legally untenable situation. He will be writing to PS(H) and other Health Ministers. For one part of the UK to proceed to a look back on its own would be untenable. It is vital if the risk to legal challenge is to be minimised to maintain maximum commonality between policies throughout the UK.

Treatment

15 50% of sufferers from hepatitis may progress to chronic hepatitis with varying degrees of ill health - it can cause liver damage and mortality. Perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years. In addition a small proportion will develop primary liver cancer after a further time. Certain patient groups may have a worse prognosis and a more rapid disease progression, eg. immunosuppressed patients, those co-infected with HIV and/or hepatitis B, and possibly haemophiliacs.

16 Until recently there has been no widely accepted treatment for hepatitis C. Interferon alpha is the only extensively studied agent shown to be effective but results are disappointing. In approximately 50% of patients with chronic hepatitis C treated with interferon alpha there is evidence of the virus being cleared from the body. While relapse rates are high some 20 to 25% of patients currently being treated have a sustained response. Advances in the treatment of viral disorders are expeceted in the next few years that may improve response rates.

17 There will be advantage if good practice guidance can be prepared and made widely available to ensure that those affected may be given appropriate treatment. Consideration also needs to be given to ensuring that those infected through NHS treatment get access to treatment.

18 Further information about treatment and access is set out at **Annex B**. Annexes B and C are likely to be of most interest to medical copy addressees.

Research

19 There are a number of areas of research which may need to be considered as part of a response package. This might be directed to the understanding of hepatitis C and its most effective treatment and management. A note is included in **Annex B**.

Support for self-help initiatives

20 The Haemophilia Society has already submitted a bid for S64 support of a research programme they are setting up to identify the best way to help society members who are infected with HCV. The Department has already made a payment in 1994/95 to allow the project to get started but has not yet confirmed that they will provide funds for the full three years. This will be put forward as a high priority case within the next few weeks and Ministers will be invited to give approval, if necessary in advance of the normal cycle.

21 This is only one example of ways in which the Department can help a self help group. Transfusion recipients have no similar organisation working for them.

IMPLICATIONS FOR OTHER GROUPS OF PEOPLE INFECTED WITH HCV

22 The above actions are proposed because of the duty of care that Ministers may have for those infected through NHS treatment. It must be acknowledged that once treatment is available for any group all others with the same condition, irrespective of the source of their infection will expect access to the same facilities. The largest such group is those who have become infected through drug use involving the sharing of needles.

23 **Annex C** provides a note on the numbers of people infected with hepatitis C from all sources. It explains that the number of people infected in the UK is not known but offers a general figure in the region of 100,000. The largest numbers will be in intravenous drug misusers some of whom may have only injected occassionally and several years ago. Any estimate must therefore be treated with caution; some have suggested it may be as high as 400,000. There are already pressures to test all drug misusers and to offer treatment wherever appropriate and any special programme for those infected by NHS treatment would add to the pressure. This would have significant but as yet unquantifiable effects on costs and resources. They would have to be contained within existing programme costs.

Cost Implications

24 It is very difficult to get any estimate of the cost of the action proposed. The look-back exercise will have little direct cash cost for the Transfusion Service in identifying those at risk. The cost of the follow up counselling and treatment would have to come out of present programme costs and no separate provision has been made for this. Assuming all 6000 people infected as a result of NHS treatment were to receive interferon treatment then the cost of the drugs could be as high as £12m

25 In practice it is likely to be very much less than this. Some patients are already receiving treatment. Others would be unsuitable for it and as yet there is no evidence to show that its use on those who are asymptomatic is beneficial.

26 The cost of extending the same treatment to all those who are suffering from hepatitis C from whatever source cannot be even "guestimated at this stage". Such cost would need to include increased numbers of consultants.

CONCLUSION

27 The Department cannot dispute that a number of people have been infected through NHS treatment but deny negligence. The case does not have the same exceptional circumstances as did the HIV infection where those affected were all expected to die very shortly and were subjected to significant social problems including ostracism. Ministers have therefore made clear that they have no plans to introduce a payments scheme. There are practical steps that can be undertaken to assist those affected and those at risk.

28 In particular both the Departments lawyers and the MSBT advise that there is a duty of care towards those who may be at risk. Ministers have been advised by the MSBT that procedures should be put in place to identify those patients at risk and that this should be done on a UK wide basis. Subject to Ministers' agreement an ad hoc Working Party would be set up to put together guidance on counselling and treatment options.

29 In addition to the identification of patients at risk steps should be taken to ensure that treatment is made available and that consideration is given to any additional research which might be required to improve the treatment and management of those affected. The Department should also give sympathetic consideration to appropriate requests for support from any self help groups which might be able to provide cost effective assistence to their members.

ACTION PROPOSED

30 Since it is known that Lord Fraser is writing to PS(H) and colleagues informing them that the SNBTS will be going ahead with look-back immediately it may be best for PS(H) to wait for that letter and then to press for a UK wide approach. Although it may be necessary to accept that the Scots will make a start on their part of the exercise immediately, it may be possible to use this as some form of pilot for the wider task.

31 If Ministers accept MSBT's advice, then PS/(H) may wish to instruct Dr Metters, the Committee's Chairman, to set up without delay the ad hoc Working Party the Committee proposed. Officials will discuss with MSBT any other action which needs to be taken, including research.

32 Ministers will be in a stronger position to respond to any future calls for action and questions about the Government's response once such decisions have been taken.

Panorama Programme - Handling

33 Minister has already decided not to appear on the Panorama programme. A statement will be made instead in answer to the three questions posed. It may be appropriate to let it be known that the Health departments do intend to undertake a look-back exercise and that a Working Party has been convened to draw up suitable guidance so that it can be put in hand as soon as possible. Consideration is being given to what guidance needs to be given to GPs and other medical practitioners to deal with any enquiries from worried patients who may or may not have cause for concern.

SUBMISSION

34 Is PS(H) content? Does he wish to hold an urgent meeting with officials?

35 Copies of this submission have been sent for information to the Chief Medical Officers of the territorial Health Departments.

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HEPATITIS C - THE GOVERNMENT'S RESPONSE

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plus the CMOs from the territorial Health departments