Trustees' News and Information 5

27 October 2000

- **SCOTTISH HCV INQUIRY**

Herewith the summary report of the Susan Deacon inquiry in Scotland plus the Society's press release in response and copy of our letter to Scottish MSPs.

- **CJD COMPENSATION SCHEME**

This week we have also been involved in media activity around the announcement of a compensation scheme for CJD families. I took part in an interview on BBC You and Yours programme (25.10.00) and the attached release was distributed to press and media on Monday 23.10.00.

- **TRUSTEE'S INDUCTION SESSION**

Please note a session is being organised on **Thursday 16th November** for newer trustees who have not had an induction. George Levvy and Alex Susman-Shaw are taking part but if there is any other trustee who feels in need of induction do contact Sue Rocks.

- **TRAVEL COSTS AND ARRANGEMENTS**

We have recently had some instances of claims for reimbursement for travel costs from trustees attending Society meetings which have caused concern. These have included air fares to London booked by trustee members themselves and the costs claimed have been significantly higher than we would have expected to pay through the office. Would trustees please bear in mind that the office has access to a variety of discounts, particularly through using Lawson International, which enable us to save the charity's valuable resources. For this reason we would ask you **always** to make your air travel arrangements through the office and to do this **at least two weeks** ahead of the proposed travel dates. Thank you for your co-operation.

- **N.I.C.E. APPRAISAL INTERFERON/RIBAVIRIN**

The appraisal report is due out on 31 October; it will be posted on the NICE web site that morning (www.nice.org.uk). Also, trustees will be interested to know that George Levvy has been appointed as a new member of NICE's appraisal committee.

Karin Pappenheim
Chief Executive

Attachments:

1. **Scottish Inquiry report**
2. **Scottish Executive press release**
3. **Society's press release**
4. **Letter to Susan Deacon**
5. **CJD statement**

SCOTTISH EXECUTIVE

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News Release

24 October 2000

BLOOD PRODUCTS AND HEPATITIS C
- FACTFINDING EXERCISE PUBLISHED -

Health Minister Susan Deacon has concluded that Scotland's national blood authority was not negligent in its efforts to remove the risk of contracting Hepatitis C from blood products in the 1980s.

The announcement follows an exhaustive fact-finding exercise into the heat treatment of blood products in the mid 1980s, the report on which has been published today.

The Minister asked officials to undertake this exercise last year after concerns had been raised that haemophiliacs who contracted the Hepatitis C virus through blood products in Scotland need not have been exposed to such a risk.

The report concludes that the Scottish National Blood Transfusion Service (SNBTS) worked actively during the 1980s to find a way of eliminating the Hepatitis C virus. This virus, much better understood today, had begun to pose a threat in infecting vital blood products - such as Factor VIII - the potentially life saving product used by haemophiliacs.

The report confirms that the SNBTS did not develop successful heat treatment until after the Bio Products Laboratory (BPL), their counterparts in England had done so. The report concludes, however, that the technical processes involved were complex, and that the method used by BPL was not actually proven to eliminate the virus until after SNBTS had also managed to develop a comparable method.

Ms Deacon said:

“The cases of people contracting Hepatitis C in the 1980s are a real human tragedy. I have listened carefully to the points raised with me and have given the matter very careful consideration.

"Having studied all the facts, I have concluded that there is no evidence that the relevant authorities did anything other than their best for patients. As a result I do not believe that the NHS should pay compensation for non-negligent harm to those haemophiliacs who contracted Hepatitis C during the period covered by the report.

“When I announced this exercise I stressed that we would – as a new Executive – take a fresh look at the evidence. And we have done this.

“But we have seen no new evidence and nothing to demonstrate that compensation is owed. I fully understand that there will be disappointment at the outcome. However, our decision is one based on the facts as they stand before us now – some 20 years on. Medical treatment is always complex and often involves a balance of risks, not least the necessity of using blood products to protect the lives of haemophiliacs.

"I do not, for one moment, want to underestimate the suffering which has occurred in these cases. But the sad fact is that the evidence shows that nothing further could have been done to avoid this unforeseen outcome given the level of scientific knowledge at that time.

“Last month's publication of the Scottish Needs Assessment Programme (SNAP) report on Hepatitis C, sponsored by the Scottish Executive, shows how important it is to ensure that we improve our understanding of the prevention and treatment of Hepatitis C. It must now be Scotland's priority to ensure that treatment and care are put in place for all of those people infected."

Commenting on the results of the factfinding exercise, Professor Mike Greaves, Professor of Haematology at Aberdeen University said,

"The development of factor VIII concentrates represented a major advance in the management of the life-threatening bleeding disorder haemophilia A. Use of concentrates in treatment has had an overwhelmingly beneficial effect on the crippling long-term consequences of recurrent bleeding and has saved lives. An important and sometimes tragic side effect of this treatment has been the transmission of the virus responsible for Hepatitis C.

"The Scottish Executive has produced a carefully researched and detailed report on the events relating to the introduction of heat treatment of factor VIII concentrate for use in haemophilia in the 1980s. The information provided to patients with haemophilia about the risks of contracting hepatitis from blood products at that time has also been investigated. It is clear that the technical challenge of producing virus-free factor concentrates was substantial.

"It is clear that the need for the rapid development of safer products was recognised by SNBTS and that timely and concerted efforts were made to this end.

"The report from the Scottish Executive represents a thorough and balanced assessment of the complex clinical and scientific problems surrounding the issue of the development of the safe and effective factor VIII concentrates which are essential for the treatment of haemophilia A."

NOTE TO NEWS EDITORS

1. The remit of the exercise was to examine evidence about the introduction of heat treatment in Scotland for factor VIII in the mid 1980s, to assess whether Scottish haemophilia patients were exposed to the risks of the hepatitis C virus longer than they should have been, given the state of knowledge at the time and to examine evidence about the information given to haemophilia patients in the 1980s about the risks of contracting hepatitis C virus from blood products.

2. CHRONOLOGY

Late 1983 – SNBTS prepare batch of pasteurised Factor VIII for clinical evaluation

January 1984 - First patient in clinical evaluation for SNBTS pasteurised Factor VIII suffers adverse reaction, and trial is abandoned.

1984 - The Plasma Fractionation Laboratory (PFL) in Oxford (a pilot plant laboratory for Bio Products Laboratory in Elstree) managed to dry heat a Factor VIII product to 80°C for 72 hours. It was expected that this would give greater protection against HIV. There was no indication whether this temperature would have an effect on the agent responsible for Non A Non B hepatitis (NANBH) – not at that time recognised as hepatitis C. The Scottish National Blood Transfusion Service (SNBTS) decided to keep trying to develop pasteurisation.

December 1984 - SNBTS were able to heat treat a year's supply of Factor VIII at sufficient temperatures to render it HIV-safe.

September 1985 - BPL heat treating all of its Factor VIII at 80°C for 72 hours. This accounted for 25% of the requirement in England and Wales.

August 1986 - SNBTS produced the first trial batches of their new Factor VIII product heat treated to 80°C for 72 hours.

September 1986 - A BPL/PFL preliminary report was published which indicated that heat treatment of Factor VIII at 80°C for 72 hours might prevent the transmission of NANBH.

March 1987 - The clinical trial of the SNBTS Factor VIII product (heat treated at 80°C for 72 hours) was completed.

April 1987 - SNBTS Factor VIII product (heat treated at 80°C for 72 hours) was available for clinical use.

October 1988 - The full results of a study were published in the *Lancet* showing that heat treatment of Factor VIII at 80°C for 72 hours was effective against NANBH.

1989 - Hepatitis C virus finally isolated and identified.

1993 - Results published confirming the clinical safety of both SNBTS and BPL products as regards HCV transmission.

3. This report has been sent to the Scottish Parliament's Health and Community Care Committee and to the Haemophilia Society.

4. Copies of the report are available on the Scottish executive web-site at www.scotland.gov.uk

Contact: Kate Cunningham: GRO-C
News Release:
Internet: www.scotland.gov.uk

25 October 2000

STATEMENT IN RESPONSE TO SUSAN DEACON REPORT

Responding to today's publication of the Scottish Executive report on Hepatitis C infection through NHS contaminated blood products, Karin Pappenheim, chief executive of the Haemophilia Society, commented:

"This report is a very thin, incomplete piece of work which does not represent the full inquiry we were seeking. The report fails almost entirely to address the impact of the contaminated blood products tragedy on the haemophilia community in Scotland – not only the medical, but the emotional and social consequences of the virus which have devastated lives. Significantly there is no commitment to action either in the form of financial recompense or even so much as a promise to ensure that all those infected with hepatitis C receive proper care and support.

"This is a wholly inadequate response to what has been described as one of the greatest treatment disasters in the history of modern medicine and to the effect this has had on the Scottish haemophilia community. We have waited more than a year for this document and it still has not addressed the central concerns of people with haemophilia and hepatitis C in Scotland.

"It flatly contradicts the evidence put forward by the Society and our members that patients were not clearly informed of the risks and that many were informed of their diagnoses late or by accident.

"The report does not offer any hope to those people suffering the consequences of this tragedy.

"Reading this today people in the haemophilia community must feel a strong sense of injustice because so many issues of vital concern to them have not been touched upon. The report does not indicate there will be any financial help in the future as they cope with the physical and emotional effects of this tragedy.

"This report is not enough and the Haemophilia Society will continue to push for a full public inquiry to ensure all the issues are dealt with."

-ends-

For more information contact Mark Weaving or Sean Haran on GRO-C

50th ANNIVERSARY
1950 2000

Caring for people with bleeding disorders

THE
HAEMOPHILIA
SOCIETY

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Susan Deacon MSP
Minister for Health and Community Care
Scottish parliament
EDINBURGH
EH99 1SP

27 October 2000

Dear Susan Deacon

Scottish Executive report on haemophilia and hepatitis C

I write to express the Haemophilia Society's extreme disappointment and concern at the recently published report by the Scottish Executive on the infection of people with haemophilia with hepatitis C. Representatives of the Society would like to meet urgently with you to discuss our concerns and I hope we can arrange a date at the earliest opportunity.

Briefly, our view is that the report is a very thin, incomplete piece of work which does not represent the full inquiry we were seeking. The report fails almost entirely to address the impact of the contaminated blood products tragedy on the haemophilia community in Scotland – not only the medical, but the emotional and social consequences of the virus which have devastated lives.

Significantly there is no commitment to action either in the form of financial recompense or even so much as a promise from yourself as Health Minister to ensure that all those infected with hepatitis C receive proper care and support. In producing the report the Scottish Executive has apparently not even taken the basic step of making sure that every person with haemophilia who may have contracted HCV has been traced; and no assurance is given in the document that all have been properly tested and advised. No accurate figure is given for the number of HCV infected people with haemophilia in Scotland.

From comments in your press statement it appears that on the basis of this report you have ruled out the possibility of providing financial assistance for people with haemophilia who were infected with hepatitis C.

Yet this issue is not even properly considered within the content of the report. A precedent has already been set in 1987 when the Conservative Government of the time accepted a moral responsibility and agreed to provide an ex gratia financial assistance scheme for people with haemophilia infected with HIV through contaminated blood products. Only this week it has been announced that an ex gratia financial assistance scheme is to be set up by Government for victims of new variant CJD. Again this step has apparently been taken on moral grounds – how then can Ministers such as yourself justify not taking a similarly compassionate approach for this very small group of people with haemophilia who have suffered hepatitis C infection?

This report in the view of the patient community is a wholly inadequate response to what has been described as one of the greatest treatment disasters in the history of modern medicine. It pays scant regard to the effect this has had on the Scottish haemophilia community. We have waited more than a year for this document which still has not addressed the central concerns of people with haemophilia and hepatitis C in Scotland.

The Society is especially disturbed at the claims in the report that all patients were fully informed about the risks of hepatitis. This directly contradicts the evidence put forward by the Society and our members that patients were not clearly informed of the risks and that many were informed of their diagnoses late or by accident. We know from the accounts of our members that patients and their relatives were not routinely advised by doctors of the risks of hepatitis; many individuals did not even know that they had been tested for HCV by their doctors.

Most disturbingly, the report appears to have reached its conclusions about the information given to patients without even talking to patients themselves. Surely it is patients and their families who are best able to provide evidence on what, if any information, was provided about the risks of blood borne viruses in haemophilia treatment products?

Finally, the Society is concerned about the process adopted for the inquiry. When we first met with you and your officials in September 1999 you gave assurances that this would be an open and transparent process. Instead, the investigations carried out by the Scottish Executive have gone on behind closed doors. The Society at a very early stage in this investigation made the point that given the questions of possible negligence and liability there was a potential conflict of interest for the Scottish Executive in carrying out an internal inquiry. Therefore in December 1999 we recommended that the inquiry should be carried out by an independent task force made up of patients, clinicians and scientists. We have never had a response to this point nor to the critical matter of conflict of interest.

I look forward to meeting you very soon.

Yours sincerely

GRO-C

Karin Pappenheim
Chief Executive

23 October 2000

Chris Hodgson, Chairman of the Haemophilia Society, said:

"We welcome the decision to provide compensation to victims of variant CJD, as we believe it is entirely appropriate for the Government to provide financial recompense to those who have suffered as a result of the inadequacies of the NHS.

"However, if it is right to provide assistance for those with variant CJD it must also be right to provide it for people with haemophilia infected with hepatitis C through their NHS treatment. It is well known that many of these patients have now died.

"While we welcome the speed of response from the Government for vCJD, it has been far slower to respond to the plight of the haemophilia community infected with hepatitis C. More than 4,800 people with haemophilia have been infected with hepatitis C and of them around 1,200 were also infected with HIV – all through the use by the NHS of contaminated clotting factors.

"We hope that the Government's moves to provide help for people with other medical conditions signals a change of heart for those still living with the effects of this previous medical disaster and that it will reexamine the plight of people with haemophilia who are still waiting for financial recompense for their infection with hepatitis C."

ends