

MS(PH)

From: Rowena Jecock

Approved: Ailsa Wight

Date: 26 February 2009

Copies: As below

**LORD ARCHER'S REPORT ON CONTAMINATION OF NHS BLOOD AND
BLOOD PRODUCTS DURING THE 1970s AND 1980s**

1. The report of Lord Archer's independent inquiry, published on 23 February, is critical of the speed of response of the NHS and Government to the threats of contamination of blood and blood products with HIV and hepatitis C in the 1970s and 1980s. We do not accept all his criticisms, but official documents do show problems at various times in the development of UK capabilities for manufacture of blood products, and in 2001, a judgment was made under the Consumer Protection Act in favour of 114 claimants who had been infected with hepatitis C after receiving an infected blood transfusion. In his judgment, Lord Justice Burton commented that the UK could have introduced screening or surrogate tests for hepatitis C earlier than it did.
2. You have asked a number of questions in relation to the Archer report. We respond to each of these in this submission, in the order in which they were set out in the commissioning note. In some cases, we have not been able to provide a full answer in the time available.
3. We have provided a brief note in response to question 9 on measures in place to stop a similar event happening again. There have been significant changes and improvements to the safety and supply of blood over the past 20 years, but no measures can be completely secure. We can provide further advice on this in due course, if you wish.
4. You may want to note the following points in particular, which we suggest you may wish to discuss with SofS. A draft note, covering these points, is attached at question 10:
 - A statement could be drafted, expressing this Government's regret at the events that occurred and the consequences for those affected. Legal advice is that this can be done, given the length of time that has passed, and the fact that there has been litigation during that period.
 - A number of anomalies exist in the three schemes set up to provide financial relief for those infected and for their dependents and carers, for example in relation to the conditions under which widows of those infected with Hepatitis C become eligible for benefit. Lord Archer has recommended that these be addressed, and an intention to review perceived anomalies could be announced at an early stage, ahead of the Government's substantive response to the report.

5. We are consulting widely across the Department to collect the necessary information to enable a consideration of all the recommendations in Lord Archer's report. We can move quickly to set out the options when you have had an opportunity to discuss an initial response with the Secretary of State.

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1. The documents withheld from release

Background to FOI decisions in general

Decisions under the Freedom of Information Act are made by officials under the authority of the Permanent Secretary. These decisions are subject under FOI to internal review, if requested, and then, if the applicant is not satisfied, a referral to the Information Commissioner. Where these decisions concern papers of a previous administration, current Ministers do not see the papers, to comply with the Cabinet Office convention and to protect Ministers from any charge of partiality.

Documents withheld under FOI from those issued to Archer

35 documents were withheld, in whole or part, from the 4,500 or so issued to Lord Archer under exemptions in the FOI Act as follows:

<i>Exemption</i>	<i>Document withheld</i>	<i>Part of document withheld</i>	<i>Total documents wholly or partly withheld</i>
Section 38—Health and Safety	1	9	10
Section 40—Personal information	3	6	9
Section 42—Legal professional privilege	8	1	9
Section 43—Commercial interests	6	1	7
Total	18	17	35

This information was provided to Lord Archer in letters accompanying the documents that he received, and has been given in PQs. No request for a review has been received by Lord Archer or another party.

The latest PQ announced that we would look again at the 7 documents affecting commercial interests, in order to remove all doubt by seeing if there is some way they can be issued, e.g., by communicating with the companies. To go further, we could volunteer to carry out a review of all the documents and publish the results. However, it is very unlikely that many, if any, would qualify for release.

Officials are satisfied that none of the documents adds anything significant to what is already known from the several thousand documents already released. No documents have been withheld on policy grounds. In general terms, the grounds for withholding were:

Section 38 Health and Safety – these were all documents with details of animal testing for R&D purposes. There is a cross-Government

understanding that material of this kind is withheld to protect the organisations and individuals involved, unless this risk is overridden by some other consideration. We have not announced the reasons for this decision as to do so could itself involve some risk to those in this field.

Section 40 Personal – documents containing personal data, e.g., CVs and patient details.

Section 42 Legal professional privilege – the documents covered 15 years (1970-85), with a few from later years, and over this time legal advice was sought on a number of issues. Legal advice is exempt from disclosure without time limit under FOI. There is a strong MoJ line that departments should not release legal advice when it may be beneficial to do so, as this impacts on future legal advice, and on all other occasions when legal advice is withheld.

Section 43 Commercial interests – information provided in confidence or that may damage commercial interests. We previously released to Lord Archer a number of documents marked 'Commercial in confidence' after contacting the company. We have already committed to revisiting these 7 documents and will be looking to find some way to release the information into the public domain, to remove all doubt on this issue.

2. Chronology of contamination and related events

A chronology of key events is attached as Annex A

Key events are indicated in yellow.

A notable event is the introduction of heat-treatment for all Factor VIII used in the UK during 1985 (whether home-produced or imported). This was introduced to prevent transmission of HIV, but was, following the identification of hepatitis C in 1989, also shown to have prevented the transmission of hepatitis C.

3. Details of any payments made directly to patients who received contaminated blood and blood products

The Department does not make payments directly to patients on grounds on infection with HIV, but to the independent Macfarlane and Eileen Trusts. DH does not have details of payments to individual patients.

People infected with hepatitis C receive a lump sum payment through the Skipton Fund of £20,000 (Stage 1 payment). Those developing more advanced stages of the illness, such as cirrhosis or liver cancer, get a further £25,000 (Stage 2 payment).

Since their inception, the Department has given £46million to the MFT, £1.2m to the ET and £98m to the SF.

Further details are in Section 4.

4. Background on the setting up of all three trusts - MacFarlane, Eileen and Skipton - specifically:

- how each was set up?
- why each was set up?
- how the amounts of funding were decided?

Macfarlane Trust (MFT)

This was the first mechanism of payment for the relief of haemophiliacs infected with contaminated blood or blood products. The MFT is a DH-funded registered charity, established in March 1988, when the Government committed £10 million. In 1990 the Department of Health made an *ex gratia* payment of £20,000 to each surviving infected person or their bereaved families, and in 1991, payments were made in settlement of potential litigation.

Eligibility to financial aid requires medical evidence of infection and is restricted to:

- haemophilia patients who contracted HIV following treatment with NHS blood products prior to screening programme;
- families of deceased infected patients;
- partners infected by haemophilia patients infected by NHS blood products.

How was funding decided?

We have not been able to ascertain how the original payment of £10m was arrived at. In the 20 years since its inception, DH has given the Macfarlane Trust total funding of £46m.

Eileen Trust

The Eileen Trust, also a DH-funded registered charity, was established by the Government in 1993 to extend the payments already provided for HIV infected haemophiliacs (through the Macfarlane Trust) to non-haemophiliacs who acquired HIV in the course of receiving treatment by blood or tissue transfer or blood products. The scope of the scheme applies to the UK.

The Eileen Trust makes the following lump sum payments:

- Infant - £41,500
- Single adult - £43,500
- Married adult without dependant children -£52,000
- Infected person with dependent children - £80,500

To infected intimates of the above:

- Adult spouse/partner - £23,500
- Child who is married - £23,500
- Other child - £21,500

In addition, regular monthly payments range from £100 - £432 per month are paid by the Eileen Trust, according to circumstances. In addition, single grants are also paid by the Trust.

How was funding decided?

We are unable to ascertain how the level of funding was arrived at in the earlier periods. Since the Trust's inception, in 1993, the Trust has received a total of approximately £1.2m.

Skipton Fund

The decision to set up the Skipton Fund was made on 29 August 2003, when the Secretary of State for Health and Health Ministers of the Devolved Administrations simultaneously announced that a United Kingdom wide scheme would be set up to make *ex gratia* payments to persons who were treated in the United Kingdom under the NHS by way of the receipt of blood, tissue or a blood product and as a result of that treatment became infected with the hepatitis C virus.

Every person in the UK who was alive on the 29 August 2003 and whose Hepatitis C infection is found to be attributable to NHS treatment with blood or blood products before September 1991 (when screening of blood donations for Hepatitis C was introduced) would be eligible for the payments.

The decision to not to make payments to dependants in respect of those who died before 29 August 2003 was based on the date that Secretary of State made his decision.

People infected with Hepatitis C receive initial lump sum payments of £20,000*. (**Stage 1 payments**)

- those developing more advanced stages of the illness - such as cirrhosis or liver cancer - will get a further £25,000 (**Stage 2 payments**)*; and
- people who contracted Hepatitis C through someone infected with the disease will also qualify for payment

How was funding decided?

The level of the Stage 1 and 2 payments were based on proposals made by the Scottish Executive (e.g. an initial payment of £20k and a further payment of £25k if a person's disease advances to a medically defined trigger point, probably cirrhosis). This structure was decided after comparison with the level of payments made by the MFT and ET and the recommendations made by the Lord Ross expert group in Scotland. Details of funding, based on the number of Stage 1 and 2 payments that are paid each year are given below..

**Numbers of Stage 1 & 2 applications paid,
and DH funding since inception**

Period	Application numbers		Cost of applications paid			DH funding
	Stage 1	Stage 2	Stage 1	Stage 2	Total	
			£000s	£000s	£000s	£000s
Mar 04-Mar 05	3,034	294	£60,680	£7,350	£68,030	£70,147
Apr 05-Mar 06	433	188	£8,660	£4,700	£13,360	£14,000
Apr 06-Mar 07	245	101	£4,900	£2,525	£7,425	£7,000
Apr 07-Mar 08	204	101	£4,080	£2,525	£6,605	£6,400
Total	3,916	684	£78,320	£17,100	£95,420	£97,547

5. Government's view on holding a public inquiry

This and previous administrations have maintained that an official inquiry was unnecessary and not justified, given:

- the time that has elapsed
- previous litigations and settlements - funds have been established to make payments to those infected with HIV and hepatitis C
- we have issued a full review of all the papers to 1985, with relevant documents – the review found no evidence of any wrongdoing by government or the NHS
- we have issued all available relevant official documents 1970-1985 – there is no need for an inquiry to find and set out the evidence
- the lack of prospect of new lessons being learnt – the causes of contamination in the 1970s and 1980s are well known, and the necessary remedies have been in place for many years
- and the high cost of a public inquiry (e.g., Bristol Royal Infirmary, over £14 million; Royal Liverpool Children's (Alder Hey) inquiry, £3.5 million; Victoria Climbié inquiry, £3.8 million).

6. The request for an apology to those affected

MS(PH) has noted that these events are being described as a 'health disaster' and has asked for advice on whether the Government can acknowledge this and apologise to those affected for what has happened without an admission of legal liability.

Advice from the Department's solicitors is that the term 'health disaster' is too strong a term, as if the available blood products had not been employed, patients may have died even earlier than they did. They suggest the term "a tragedy for those affected" as these patients suffered appalling health consequences in circumstances no fault of their own.

As regards liability, these events occurred many years ago and there has been litigation. In any speech or Press Notice, mention should be made that proceedings were brought in relation to both HIV and hepatitis C, and that as a consequence arrangements were made to make payments to those affected, beginning 20 years ago.

The Government was not in office at the material time. There is a need to be cautious in relation to previous administrations, but this is no reason to stop an expression of sorrow at what has occurred.

A possible form of words is:

"Whilst we believe that successive Governments have acted in good faith, we acknowledge that the circumstances in which patients contracted serious infections through their NHS treatment with blood and blood products were a tragedy for those affected and for their families. We want to say how sorry we are that this has happened."

7. Options for immediate additional support to Trusts

MFT and ET trustees have recently submitted to officials a set of options for large-scale long-term funding for the Trusts, involving sums in excess of £100m. These have yet to be assessed in any detail.

As the number of registrants in these Trusts is declining, the argument for increased funding will need to take account of the reduced number of people receiving payment.

In 2006, Caroline Flint (then MS(PH)), reviewed the funding position for the Macfarlane and Eileen Trusts, following a request from the trustees for significantly increased funding (a combined increase of over £4million/year).

The trustees argued that when the Trusts were established, registrants were not expected to survive for long. Modern treatments had changed that prognosis, and registrants needs had changed with it. Additional funding was needed, for example, for housing and associated maintenance, childcare, assisted conception, respite/stress relief, mobility, etc.

MS(PH) and SofS were not convinced of the strength of the case made by the trustees, and consequently agreed a partial acceptance of the trustees' claim, via a combined annual increase in funding of £400,000 to be shared between the Trusts pro-rata. This represented an increase of around 11% to the Trusts' funding, bringing the funding for MFT to over £3.7million, and funding for ET to £177,000.

8. Plan for considering recommendations in more detail

We are consulting widely across the Department to bring together the information needed to consider a response to the recommendations set out in Lord Archer's report.

9. Measures in place to safeguard supply today

See Annex B attached

10. Draft note to Secretary of State

To: SofS

From: MS(PH)

LORD ARCHER'S REPORT "NHS SUPPLIED CONTAMINATED BLOOD AND BLOOD PRODUCTS": PROPOSAL FOR INITIAL RESPONSE

Lord Archer's independent inquiry report, published on 23 February, is critical of the speed of response of the NHS and Government to the threats of contamination of blood and blood products with HIV and hepatitis C in the 1970s and 1980s.

Lord Archer says:

'Without necessarily apportioning blame, the state needs to act responsibly in addressing the tragedy of patients being infected with potentially fatal diseases through NHS prescribed treatment.'

Bearing in mind that apology may imply acceptance of liability in law, I have sought advice on whether this Government could seek to offer the victims of this long-running tragedy a meaningful expression of regret that this happened.

I am advised that this is possible, and recommend that we do so in a timely way, ahead of issuing a substantive response to Lord Archer's recommendations. If you agree to this, we must be careful how we go about it, given that the salient events occurred during earlier administrations. [DN: Nevertheless, in my view, there is a moral obligation on this Government not only to acknowledge the appalling health outcomes which the affected individuals have had to suffer, but also to express our regret that this happened following NHS treatment.]

With regard to Lord Archer's conclusions and recommendations, they are wide-ranging in their scope, and require careful consideration before we respond substantively. In particular, there are significant financial implications arising from the recommendation that payments should be at least equivalent to those made in Ireland. Potentially this could amount to £hundreds of millions.

I recommend therefore that:

- We prepare a statement expressing the Government's regret in the strongest terms. Subject to your agreement, I will open discussions with former Ministers in previous administrations on this proposal.

- [DN: As an initial response, we carry out an early, rapid review of perceived anomalies in the current set of payments to those affected.]
- We reiterate that we will give careful consideration to Lord Archer's [other] recommendations, need time to do so, and will respond in due course.