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:

Exemption	*Document withheld*	*Part of document withheld*	*Total documents wholly or partly withheld*
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.

	ANNEX A. CHRONOLOGY OF EVENTS	
Date	**HIV/AIDS (HIV formerly known as HTLVIII)**	**Hepatitis C (formerly Non-A Non-B hepatitis NANBH)**
1973		
March		DHSS Expert Group on the Treatment of Haemophilia recommends that the NHS should be self-sufficient in blood products as soon as possible
1974		
August		Non-A Non-B Hepatitis (NANBH) first predicted in scientific literature.
December		Minister of State (David Owen) earmarks central funds of £0.5m, half of which is recurring, to increase the output of plasma to 275,000 donations annually for the preparation of factor VIII and 100,000 donations for cryoprecipitate
1975		
March		Department sets targets for NHS Regions based on estimate from the Expert Group on the Treatment of Haemophilia that 275,000 donations of blood would be required to achieve self-sufficiency in factor VIII.
May		WHO resolution states that each country should be able to supply sufficient quantities of its own blood and blood products to meet clinical needs
August		Craske et al. links an outbreak of hepatitis (some NANBH) after intravenous injections of commercial factor VIII concentrate.
1977		
June		Factor VIII production target set in beginning of 1975 attained; however demand has increased
1980		
October		Craske states that NANBH is mild and often asymptomatic, but might cause chronic liver disease.
1982		
		Studies begin to indicate that NANBH is more serious than previously thought.
July 1982	3 cases of a rare pneumonia among patients with haemophilia reported in US. Possibility of an immune response to large quantities of human product is considered more likely than a new virus.	
September	13 Sept: 13th meeting of Haemophilia Centre Directors noted the 'remote possibility' that commercial factor VIII may be connected to 3 haemophiliacs acquiring AIDS in the US – agreed to report any cases in UK.	
December	Report of 4 additional haemophilia patients with opportunistic infections and immune deficiencies in US – all had received FVII concentrates. First case in US of AIDS involving multiple blood transfusions.	

Date	HIV/AIDS (HIV formerly known as HTLVIII)	Hepatitis C (formerly Non-A Non-B hepatitis NANBH)
1983		
		Studies confirm that commercial and BPL concentrates carry equal risk of transmitting hepatitis.
January	The Lancet (15 Jan) reports on AIDS-type symptoms among haemophiliacs in New York and possible risk from blood products of American origin. DHSS medical advice (18 Jan) is that 'the value to severe haemophiliacs of clotting factors 8 and 9 far outweigh the possible, and as yet unproven hazards' of transmission of AIDS.	
23 March	US Food and Drug Administration (FDA) introduces regulations designed to exclude high risk groups from blood donor pools.	
4 May	Haemophilia Society releases statement from Professor Bloom to counteract 'unduly alarmist reports on AIDS'.	
5 May	UK blood service issues statement on blood and AIDS – asking gay men not to present as donors until more information is available	
9 May	Dr Spence Galbraith CDSC writes to DHSS expressing concern at cases linking commercial Factor VIII with AIDS and recommending imports should cease pending further examination	
13 May	UK HCDs meet and say 'there is not sufficient evidence to restrict the use of imported Factor VIII' – situation should be kept under review. DHSS MO agrees and advises that it would be 'premature in relation to the evidence' to restrict supplies and that Dr. Galbraith's advice is 'unbalanced' as it does not take account of risks to patients from withdrawing major source of medical supplies	
17 May	Haemophilia Society writes to Minister urging no ban on imported Factor VIII pending further investigations.	
29 June	World Federation of Haemophilia said insufficient evidence to recommend change in treatment, which should continue with products available, following advice of physician.	
13 July	Committee on Safety of Medicines (Biological sub group) considers risk of AIDS and licensed blood products. Meeting attended by Dr Galbraith. Committee recommends continuing to use imported Factor VIII to treat severe haemophilia. Accepted by main Committee 21/22 July.	
September	1st donor leaflet issued: 'AIDS and how it concerns blood donors'	
2 December	US CDC reports, as of 30 November, a total of 21 cases of AIDS in patients with haemophilia in US and 7 outside the US. Evidence suggests an infectious cause.	

Date	HIV/AIDS (HIV formerly known as HTLVIII)	Hepatitis C (formerly Non-A Non-B hepatitis NANBH)
1984		
January	Reported case of AIDS in wife of a haemophiliac.	
23 April	Announcement of discovery of retrovirus in people with AIDS – called HTLV-III – by US Secretary of Health and Human Services. Both Robert Gallo (US) and Luc Montagnier (Pasteur Institute, France) claim to have made the discovery	
30 November	Note to DHSS Ministers – a number of regular donors have now developed AIDS – this reinforces current policy which is: (i) new leaflet to dissuade high risk donors; (ii) develop and pilot a screening test; (iii) consider use of heat treatment of Factor VIII.	
December	Commercial heat-treated FVIII becomes available in reasonable quantity.	
1985		
		Studies revealed almost 100% transmission of NANBH following administration with untreated large donor pool clotting factor concentrate Hay et al. reported that progressive liver disease in patients with haemophilia was an understated problem
January	First report of acquired immunodeficiency syndrome in the child of a haemophiliac. 23 January. All FVIII produced in Scotland is heat-treated.	
20 February	DH press notice announcing: (1) NHS is asked to set aside funds for screening blood for HIV in 1985/86 – tests are to be evaluated and will be introduced when possible; (2) Imported heat treated product available – aim to have all BPL product heat treated by April; (3) 2nd donor leaflet issued 'AIDS – important new advice for blood donors'	
March	First test for anti-HIV licensed by FDA in the US.	
March-October	Evaluation of tests by PHLS; systems put in place in NHS for introduction of testing.	
April	All FVIII produced at BPL heat-treated from April. 20 April, BMJ: 38% of haemophiliacs sampled in 1984 were anti-HTLV-III positive. Most seroconversions occurred in 1983 and 1984. Important to identify seronegative haemophiliacs and treat only with heat-treated products.	
May	United States and Australia introduce screening of blood donations for HIV.	

Date	HIV/AIDS (HIV formerly known as HTLVIII)	Hepatitis C (formerly Non-A Non-B hepatitis NANBH)
1985		
June	Netherlands introduces screening. DHSS Press Notice (27 June) pre-announcing that a test to screen all blood donations for AIDS will be introduced. Minister & CMO stress it is important for reliability and operational aspects to be tested before introduction.	
July	Austria introduces screening. 9 July: Memo to CMO – all Factor VIII now heat treated. All imported product cleared for use has been heat treated since Dec 84, Elstree product since April 85 and Scotland product since Dec 84. Possible some unused stocks of untreated BPL product were still used prior to July.	
August	France and Belgium introduce screening.	
September	Greece, Portugal and Sweden introduce screening. 3rd donor leaflet issued: 'AIDS – important information for blood donors' – donations will be tested	
October	UK, Ireland, Germany, New Zealand and Spain introduce screening.	
November	Canada, Iceland and Switzerland introduce screening	
December	Italy and Norway introduce screening.	
1986		
January	Denmark, Finland, Malta and Turkey introduce screening.	
18 January	Lancet: Tests for anti-HTLV-III Oct 1984-Sept 1985 showed no rise in prevalence in haemophiliacs since 1984 (unlike homosexuals and people self-injecting drugs). Suggests reflects change to heat-treated products. Preventive measures have stemmed the spread to this group.	
11 February	DH press notice 11 February 'First results of screening blood for AIDS' – the NBTS tested over 500,000 donations to end-December 1985, of which 13 donors were found to HTLV III antibody positive and their donations were withdrawn. Incidence of infection is much lower than that reported from the U.S.	
9 June	Letter from CSM to HRCDs - suppliers of all commercial factor VIII have confirmed that all donors are being tested for HIV	
1989		
		Identification of hepatitis C. Studies provide evidence that the heat-treated product BPL 8Y introduced in 1985 appears to have prevented transmission of hepatitis C as well as HIV.
June	Beginning of HIV litigation (970 claims) against NHS and Government.	

Date	HIV/AIDS (HIV formerly known as HTLVIII)	Hepatitis C (formerly Non-A Non-B hepatitis NANBH)
1990		
January	Date of trial set for January 1991 (later slips to March 1991)	
June	Judge urges parties to consider compromise	
September	Plaintiffs seek £80-90 million as settlement – rejected by defendants in October	
November	Plaintiffs suggest £42 million as settlement	
December	Government accepts proposal on condition it is a final settlement to all affected parties whether or not a party to these proceedings. Legal advice to plaintiffs is 'strongly' to accept the offered compromise. Case settled out of court.	
1991		
September		UK introduces second generation hepatitis C screening of blood donations
1992		
		A study on long-term mortality after transfusion-associated NANBH concluded that there was no increase in mortality from all causes after transfusion-associated NANBH after an average of 18 years follow-up, although there was a small but statistically significant increase in the number of deaths related to liver disease.
1995		
		Look-back exercise started in UK to trace as many people as possible who had contracted hepatitis C through blood transfusions. Carried out between 1995 and 1997 and covered all donors who tested positive for the hepatitis C virus from the date of introduction of testing in September 1991.
2000		
October		Hepatitis C litigation against the National Blood Authority began. Action was taken under the Consumer Protection Act 1988.
2001		
March		All 117 claimants won damages of approx. £0.25 million each. These applied to people infected from a blood transfusion after the CPA 1988 until screening introduced in September 1991. The judge rules that screening or surrogate tests could have been introduced sooner, although the basis of settlement was 'strict liability' under the CPA, not negligence.

ANNEX B

STEPS IN PLACE TO MITIGATE AGAINST THE RISK OF TRANSMISSION OF INFECTIONS VIA BLOOD AND BLOOD PRODUCTS

Since the mid 1980s the position on both the safety and supply of blood components (red cells, platelets, plasma) and the products (including clotting factors) derived from blood has changed significantly.

Regulation

Blood and blood products are regulated in the EU via directives 2001/83/EC and 2002/98/EC (UK Blood Safety and Quality Regulations 2005). The regulations set standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components. Blood products wholly or partly produced outside the EU are subject to this regulatory framework if they are to be issued in the EU.

Blood components	**Blood products**
NHS Blood and Transplant (formerly the National Blood Service and the Blood Transfusion Service) became a national organisation in 1991. Their donor selection, testing, processing, storage and distribution policies are in line with regulatory requirements. Blood donations are tested for HIV, Hepatitis B and C and syphilis, which are mandatory requirements for all UK Health Departments. There is no test available for variant CJD but there are a range of precautionary measures in place to reduce risk of transmission via blood. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) are looking actively at further options for risk reduction of all blood products, pending the availability of an effective vCJD screening test.	Blood products, as medicines, are extensively assessed for their efficacy and safety before market authorisation, in line with regulatory requirements. Manufacturers are inspected by MHRA and must comply with standards of good manufacturing practice. The revocation of crown immunity for BPL forced BPL to improve their manufacturing standards to those expected of commercial manufacturers. Plasma collected outside the EU to produce blood products for use in the UK must reach standards in its provenance, collection and screening equivalent to those as stipulated in the EU. Controls on plasma collection are rigorously enforced, with MHRA certifying all operational protocols before plasma can be sent to the UK (UK plasma is not used to produce plasma products, due to the increased vCJD risk.) Since 1985, all plasma derivatives are subjected to heat treatment, in

	order to inactivate viruses such as HIV and Hepatitis B and C. There have been no recorded transmissions of HIV in the UK through concentrate use since the introduction of inactivation. Donors supplying plasma collected for BPL in the US since 2001 are individually tested for HIV, HBV and HCV. No virus positive donations are used in fractionation. Subsequent plasma minipools are tested in the US for HIV, HAV, HBV, HCV and parvovirus P19. In-process testing for HIV, HBV and HCV is subsequently carried out at BPL in the UK. BPL's process goes beyond mandatory requirements. Recombinant clotting factors (mainly Factors VIII and IX) are now in use in the UK: the Government announced in February 2003 that recombinant factor VIII and factor IX treatment would be made available to all haemophiliacs when they are suitable. Recombinant products are genetically engineered forms of factor VIII and IX. Unlike plasma derived products they are not manufactured from donated blood, and are safer than those derived from blood. Not all plasma products issued in the UK are recombinant, as certain patients require treatments that are not available in recombinant form.