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Briefing for meeting between SofS and MS(PH) and Lord Archer on 11 March 2009

1. SofS and MS(PH) are meeting with Lord Archer on Wednesday 11 March to discuss the report of Lord Archer's independent inquiry into the circumstances surrounding the supply to patients of contaminated NHS blood and blood products, and the consequences for affected patients, particularly the haemophilia community. The report suggests further steps to address the needs of patients and bereaved families.

2. As requested, this briefing includes:
- a brief summary of the report's findings **(Annex A)**
- the report's conclusion and recommendations. Officials' initial reaction to the recommendations is included. **(Annex B)**
- details of the current ex-gratia payment schemes for those infected with HIV and hepatitis C **(Annex C),** and the potential cost implications (as far as we can presently assess) of Lord Archer's recommendations regarding a review of the financial relief available to those infected **(Annex D),** and two other areas where there could be further pressure for Government funding **(Annex E).**

3. In addition, I attach a brief chronological narrative of the main events pertinent to the supply of contaminated blood products during the 1970s to the mid 1980s when much safer blood products became available **(Annex F).**

Parliamentary Interest/Activity

4. Baroness Thornton answered a topical question in the House of Lords on 5 March on when the Government would respond to the Archer report. The answer given was:

'We take this issue very seriously. We will respond when we have given Lord Archer's report the consideration it deserves.

Whilst successive Governments acted in good faith, the serious infections inadvertently contracted by these patients as a result of their treatment have had tragic consequences. I am deeply sorry that this happened.

These events were the subject of long concluded legal proceedings: the Government has established three schemes to provide financial assistance to those affected.'

5. Lords Morris and Corbett have tabled an amendment to the Health Bill, to establish a statutory committee to advise Government on the management of haemophilia, in line with Lord Archer's recommendation.

6. An EDM was laid on 3 March. There are currently 37 signatures against the EDM.
That this House welcomes the publication of the Archer Report on the use of contaminated blood and blood products in NHS treatments and hopes that the victims of the use of such products will receive swift and appropriate recompense; and calls on the Government to make a full and speedy response to the report's findings and to make a commitment to implement its recommendations as soon as possible.

7. A public inquiry, chaired by Lord Penrose, has been convened by the Scottish Executive to examine these matters in Scotland. It may take two years. Officials have given an undertaking to co-operate as far as we are able to do so, for example in relation to documentation.

Government Position

8. The position of this and previous Governments is that this is a tragedy and there is every sympathy for those infected. However, it is important to remember the following points:

- the treatment given to haemophiliacs was the best available at the time and action was taken in good faith;
- such treatments markedly increase the life expectancy (formerly 25 years) and quality of life of haemophilia patients;
- as soon as technologies (heat treatment and testing) were available to improve safety, they were introduced;
- evidence in relation to hepatitis C emerged over time, and the very severe long term consequences of infection were only fully recognised by the scientific community during the late 1980s;
- legal proceedings in relation to HIV were settled out of court, on the advice of the litigants' counsel, without the Government being found liable;
- special payments were set up for people infected with HIV, who waived their right to take further action against the Government;
- although litigants won damages against the blood service in 2001 for the supply of whole blood that was contaminated with hepatitis C, this was under the Consumer Protection Act 1988, under which companies have 'strict liability' for the supply of defective products. It did not imply negligence;
- the present Government resisted calls for further funding until Scotland decided to make hepatitis C payments in 2003, when England followed suit.

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ANNEX A

SUMMARY OF THE REPORT'S FINDINGS

The Inquiry Report - background

Lord Archer published the report of his non governmental independent inquiry on NHS supplied contaminated blood and blood products on 23 February 2009. He wrote to SofS immediately prepublication enclosing a copy of the report.

The Haemophilia Society, of which Lord Morris is president, has over many years raised the issue of contamination of blood products, and the impact on haemophiliacs who have received these products. Lord Morris asked Lord Archer to conduct his inquiry, which was announced in February 2007.

Overview

Over 4,600 patients became infected with hepatitis C, and 1,200 with HIV, as a result of use of contaminated blood and blood products during the 1970s and 1980s, before tests on blood donations for these viruses were available and before the introduction of heat treatment of blood products (which destroys viruses) in 1985. Some patients were co-infected with HIV and hepatitis C

Importantly, the report does not identify any new information and Lord Archer does not find the Government to have been at fault, and does not apportion blame. However, the report states:

'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.'

The report also expresses dismay

'.....at the time taken by Government and scientific agencies to become fully alive to the dangers of hepatitis C and HIV infections, and also by the lethargic progress towards self-sufficiency in blood products in England and Wales.'

Key findings

1. There is a strong sense that the Government has never apologised for what happened, that little has been done to deal with the hurt of those affected and that their plight has never been properly recognised. Successive Governments, as the report makes clear, have declined to establish an inquiry, which might have helped to identify problems earlier.

2. This, coupled with difficulties in identifying documents, some of which were inadvertently destroyed in the early 1990s, has meant that there was a suspicion

of an 'exercise in suppressing evidence of negligence or misconduct', but, importantly, the report goes on to state

'...we have discovered no evidence of malicious destruction of relevant records.'

3. As demand for blood products increased during the 1970s, due to the success of the Factor VIII treatment for haemophiliacs, there was increased sourcing of commercial product from paid US donors. Procurement of such product at the time was a local decision, and although the report suggests that

'it is difficult to avoid the conclusion that commercial interests took precedence over public health concerns,'

there was no financial advantage to the NHS in the purchase of US products, which were expensive and necessary to meet growing numbers of patients who were being successfully treated.

4. The report also finds that there was little involvement of patients in decisions about their care, though it acknowledges that matters have improved considerably in this respect, particularly in relation to research activities, since then.

Whilst the report identifies sourcing and supply of treatment as a key concern for haemophilia patients, it also recognises that the availability, over recent years, of treatment with non human derived synthetic product is a 'significant move forward'.

Other Key Points from the Report

The report explicitly avoids apportioning blame and recognises that these are historical events. There is a suggestion that a secure supply of safer products could have been provided earlier by a faster drive towards self-sufficiency. However, it is debatable how much contamination could have been avoided, given that domestic products could not have been safeguarded against risk of HIV and hepatitis C any sooner than they were.

Overall, since the 1970s and 1980s, there is a tighter regulatory framework in place and the establishment of NHSBT has brought the safety and supply of blood products under closer control.

ANNEX B

REPORT'S CONCLUSIONS AND RECOMMENDATIONS

Summary of Conclusions

- A full public inquiry should have been held much earlier.
- Early achievement of UK self-sufficiency in blood products would have significantly reduced the scale of transmission of infection to patients.
- Doctors must involve their patients when making difficult clinical decisions.
- Commercial priorities should never again override the interests of public health.

Summary of Recommendations

- Establishment of a statutory committee to advise Government on the management of haemophilia in the UK
- Free prescription drugs and free access to other NHS and support services
- Secured funding by Government for the Haemophilia Society (a third sector organisation)
- Review of the current ex-gratia payments system, including bringing payments in line with those in Ireland (very much higher than in the UK), and incorporating them within the DWP benefits system
- Enabling haemophilia patients to have access to insurance, possibly by establishing a separate scheme.
- Establishing a 'look back' exercise to identify any remaining patients who may have been infected, and may not be aware of this.

Detailed Recommendations and Initial Response

Several of these recommendations are based on measures that have been implemented ion the Republic of Ireland (notably, establishment of a statutory haemophilia committee, establishing an insurance scheme for affected patients, and a generous compensation scheme, which we understand averages around £750,000/patient affected).

The situation in the UK is different to that in Ireland, where it was acknowledged that action to reduce the risk could have been taken earlier. The Irish Blood Service issued an apology acknowledging 'failures' in the past and their payment regime reflects this admission of mistakes.

1) Proposal to establish a statutory committee to advise Government on the management of haemophilia:

From the haemophilia patients' perspective, this would give them assurance that an independent body was providing dedicated advice on best management of their condition.

- However, we would not recommend acceptance of this recommendation.
  - It must be considered in the light of wider policy on patient consultation. We do not see the rationale for establishing on a statutory basis.
  - Other patient groups with long-term or hereditary conditions may seek a similar body.
  - Establishing and supporting a committee would have long-term resource implications for DH.

- This recommendation is the subject of an amendment by Lord Morris and Lord Corbett to the Health Bill in the House of Lords, for committee later this week.

2) Free prescription drugs:

- This will need to be considered in the context of Professor Ian Gilmore's review, looking at long term conditions.

3) Secured funding for the Haemophilia Society:

- We would not recommend acceptance of this recommendation.
  - This runs counter to policy on third sector organisations.

4) Review of ex-gratia payments system (see page 6 for more detail):

- The issue of financial relief for those affected and their families is a major theme of Lord Archer's report. The report states that haemophilia patients, especially those infected with hepatitis C or HIV find it extremely difficult to secure health insurance, life assurance or a mortgage. Also, many people died leaving dependents. Many others, who are living longer than originally anticipated, are unable to work and provide adequately for themselves and their families.

- The report identifies between the MacFarlane Trust Fund, established in 1988 to support haemophiliacs with HIV, and the Skipton Fund, established in 2004 to support those infected with hepatitis C. The report considers that discretionary payments, as the MacFarlane Trust provides, are not appropriate to the circumstances of many patients, and that those infected should be 'entitled to look to the Government for redress' and the solution

'should take the form of a standard payment or payments adequate for the purpose.'

5) Access to insurance:

- We will discuss this with the Association of British Insurers..

6) Lookback exercise:

- There has already been one lookback exercise in the 1990s to identify patients who may have been infected. If it were decided to carry out a further search, we would propose asking the UK Haemophilia Centre Doctors' Organisation to manage it.

ANNEX C

EX-GRATIA PAYMENT SCHEMES

The Department does not make payments directly to patients, but to the independent Trusts/Fund. The Department does not have details of payments to individual patients. Since their inception, the Department has given £46million to the Macfarlane Trust, £1.2m to the Eileen Trust and £95m to the Skipton Fund.

The Macfarlane Trust (MFT)

The Macfarlane Trust (MFT) is funded by DH at about £3.8m p/a and supports about 560 people, comprising some 360 primary registrants, 40 partners and 162 widows and dependent children (as at 31 March 2008).

The MFT, which is a registered charity, was created in March 1988, when the Government committed £10 million to MFT for the relief of those infected with HIV from contaminated blood. In 1990 the Department of Health made an *ex- gratia* payment of £20,000 for each surviving infected person or their bereaved families, following this in 1991 by payments 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.

The Trust is run by a board of independent trustees.

How was funding decided?

The Department has not been able to ascertain how the original payment of £10m was arrived at. Since inception in 1988 to 31 March 2008, the Department has given the MFT funding of £46m.

The Eileen Trust

The Eileen Trust (ET) is funded by DH at about £175k p/a. It has 22 beneficiaries (as of 31 March 2008).

The ET, a 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 ET makes the following one off lump sum payments:

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

Infected intimates of the above - Adult spouse/partner - £23,500, Child who is married - £23,500, and Other child - £21,500

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

How was funding decided?

The Department is 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 approximately £1.2m.

The Skipton Fund

The Skipton Fund (SF) currently pays out around £6m annually, but this is demand led rather than an annual payment to a discretionary trust.

The SF was set up in January 2004, when the Secretary of State (John Reid) announced the setting up of an *ex-gratia* payment scheme for patients infected with hepatitis C though National Health Service contaminated blood and blood products.

On that date, 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 will be eligible for the payments.

The scheme means that:

- people infected with hepatitis C will 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

- the scheme does not extend to cover widows or dependents of patients infected hepatitis C through blood or blood products before the scheme was set up in 2004.

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

ANNEX D

POTENTIAL COST IMPLICATIONS THAT MAY ARISE FROM A REVIEW OF FUNDING FOR THE EX-GRATIA PAYMENT SCHEMES

Background

There are three schemes that make ex-gratia payments to patients who acquired hepatitis C and/or HIV as a result of NHS treatment. Briefly, these are:

- The Macfarlane Trust (MFT) - initial lump sum plus **discretionary** payments to haemophilia patients infected with HIV (and dependents).
- The Eileen Trust (ET) - initial lump sum plus **discretionary** payments to non-haemophilia patients infected with HIV (and dependents).
- The Skipton Fund (SF) - **non-discretionary**, two stage lump sum payments to any patient infected with hepatitis C still living after the scheme was announced in August 2003, and payment to the estate of those who died after the scheme was set up.

Detailed information on the individual schemes is provided in Annex C.

There could be both one-off and recurrent funding implications, dependent upon the options chosen for review. None of these options are mutually exclusive, and should not necessarily be considered in isolation.

1. Options with one-off funding implications

We could rectify anomalies, particularly in relation to the SF.

1a) SF: extending the scheme to make payments to the estate (widows or dependents) of patients who died of hepatitis C before the scheme was set up.

We do not have a reliable figure for the numbers of people who died from hepatitis C infections as a result of NHS treatment with blood or blood products in that time. According to the Archer report, some 4670 cases of treatment-acquired hepatitis C infection have occurred. Using a working estimate of 1250 patients who may have died before 2004, each of whom left a dependent, payments to their estates could cost up to:

1250 x £20000 = £25m (stage one payment) plus, where indicated,
1250 x £25000 = £31m (stage two payments) = £56m.

Estimated one-off cost of a payment to estates (widows or dependents): in the order of £56m

The cost of this option could be considered with any decisions concerning changes to the base levels of payment under the SF (see option 3).

1b) 'Buying out' the MFT and the ET

The MFT and ET would like a final settlement which would enable them to give claimants a single one-off final payment and wind up the scheme.

The payments would need to be approximately equivalent to the periodic and discretionary payments they could expect to receive in future years if the Trusts remained in place as currently. Independent and unverified actuarial advice provided by the MacFarlane trustees suggests that this would probably cost in excess of £100m for the MFT beneficiaries. Similar calculations have not been done for the ET, but as it is about 6% of the size of the MFT an estimated increase in the order of £6m would appear realistic.

Estimated one-off cost: over £100m

There is, however, no guarantee that this would prevent any future claim from patients in financial need.

2. Option with recurrent funding implications

2) Increasing the recurrent funding for the MFT and the ET

This would allow an increase in the recurrent discretionary payments by the two HIV trusts (MFT and the ET).

Doubling the recurrent funding for MFT and ET, which make discretionary payments to applicants subject to funding available, would raise the overall funding from £3.7m to around £7.6m pa for the MFT, and £350K for the ET. However it should be noted that Lord Archer recommended moving away from discretionary payments and giving lump sum and periodic payments instead, so he may not be satisfied with this option. It should also be noted here that we have been encouraging the MFT and the ET towards merging, as the ET has 22 registrants (as of 31 March 2008), which is not a viable figure for an independent entity making this level of payments.

Estimated additional cost of doubling the current funding: £4m pa

3. Options with both one-off and recurrent funding implications

Increasing the value of the first stage and/or the second stage payments made to hepatitis C patients, through the SF would have both one-off and recurrent funding implications, as there are still new registrants coming forward.

Using the examples shown below of doubling the value of both payments, the combined **one-off cost would be around £100m, and the combined additional recurrent cost would be around £5m.**

3a) Increasing the value of stage one payments (on diagnosis with hepatitis C) to SF registrants.

A first stage payment of £20k is made to those diagnosed with hepatitis C via contaminated blood. Based on the current level of around 115 new stage one payments pa, doubling this would cost £2.3m pa. If in addition the 4013 stage one payments already made up to the end of January 2009 were topped up, there would be a one off cost of £80.3m.

Estimated additional cost of doubling stage one payments: £2.3m pa
Estimated one-off cost of backdating existing stage one payments: £80.3m

3b) Increasing the value of second stage payments (on diagnosis of cirrhosis or cancer) to SF registrants

A second stage payment of £25k is made to those who go on to develop severe liver disease. This could be doubled to £50k. Based on the current level of around 100 stage two payments pa, this would cost £2.5m. If in addition the 750 stage two payments already made were also doubled, there would be a one off cost of £19m.

Estimated additional cost of doubling stage two payments: £2.5m
Estimated one-off cost of backdating existing stage two payments: £19m

Neither of these estimates takes account of a possible reduction for those bereaved spouses, partners or dependents who have already been paid some monies by the MFT or ET because of their bereavement. We do not have these figures and would need to consider our approach to this potentially contentious issue.

Furthermore, these estimates would need to be considered alongside option 1 above (remedying existing SF anomalies in relation to the estates of patients who died before the scheme was set up).

ANNEX E

POTENTIAL FOR 'KNOCK-ON' IMPLICATIONS OF A REVIEW OF PAYMENT SCHEMES

The Thalidomide Trust

There has been some recent comparison between these bodies and the Thalidomide Trust. The aim of the Thalidomide Trust is to provide relief and assistance for those people born, in the United Kingdom, damaged as a result of their mothers having taken the drug Thalidomide (as manufactured by Distillers Biochemicals Limited) during their pregnancy. They currently are supporting 462 individuals, each in the main between 44 and 50 years of age who, for the most part, have two or four limbs missing. The Thalidomide Trust has been lobbying Government to introduce a state compensation scheme for victims of the Thalidomide disaster.

1. A private compensation settlement was agreed with Distillers (now part of Diageo plc). Diageo plc has agreed to continue making payments until 2037.

2. The Thalidomide Trust claim that the private settlement is not adequate and more money is required as their independence and quality of life is at risk, because they are experiencing deterioration in their physical condition as they get older.

3. In support of its claim, the Thalidomide Trust have compared the Government's treatment of Thalidomide victims with the financial support that is provided for people infected with variant CJD and those infected with HIV and Hepatitis C as a result of contaminated blood and blood products.

4. The Trust's campaign is supported by Lord Ashley of Stoke. Lord Ashley played a leading role in the Thalidomide campaign which led to increased compensation for victims from Distillers and improvements in drug safety. Lord Ashley has a oral question on a State compensation scheme for victims of thalidomide on 10th March.

Not gravely problematic
More topical
live policy
factual but topical

The vCJD Trust

Some comparison has been made with the vCJD Trust. This is a partly discretionary trust which has been settled by the DH with £67.5m. A small number of the beneficiaries are currently making a claim for Judicial Review of the DH handling of proposals for revision of the Trust Deed.

Summary of the Scheme

The Scheme provides for payments to be made in respect of up to 250 cases of vCJD up to a maximum of £67.5 million. If numbers exceed 250 cases, the scheme will be reviewed. Payments will be made under four headings, outlined below:

i) The experience of vCJD for the patient.

The sum of £70,000 will be paid in all cases, together with a further £5,000 in those cases where vCJD was diagnosed before the publication of the Phillips Report.

ii) The experience of vCJD for the patient's immediate family and/or carers

Each family would receive a minimum of £5,000 plus a further £5,000 where members of the family have cared for the victim during his/her final illness, to be split between the carers and immediate family. In the case of those diagnosed before publication of the Phillips Report, a further £5,000 would be payable. Where a member of the patient's immediate family has suffered psychiatric injury as a result of the patient having suffered vCJD, a further payment of £5,000 will be made. The Trustees have a discretion to award further sums in cases where the psychiatric condition gives rise to particular hardship.

iii) Costs incurred by the patient and family as a direct result of the patient's suffering from vCJD.

Payments will be made to cover funeral expenses and capital expenditure reasonably incurred. Where care was provided either commercially or gratuitously before the implementation of the Care Package announced in Parliament in October 2000, a sum will be payable in respect of that care. Where the patient and/or their carers have suffered loss of earnings and this has caused particular hardship, the Trustees will have discretion to make a further payment out of the Discretionary Fund.

iv) Future Losses caused to the patient's dependents as a result of his/her death from vCJD.

This category broadly reflects the common law approach but with the following important variations:

a) Subject to a residuary discretion on the part of the Trustees, there will be no payment in respect of anticipated higher earning capacity in the future;

b) However, a minimum earning capacity of a net £7,500 per annum will be attributed to all victims, even those not working or earning less than that amount at the time of the onset of their illness. This is to reflect their future earnings potential;

c) Compensation in respect of pension loss will not be payable except to those aged 45 or over, for whom a discounted sum in respect of pension loss will be payable;

d) All figures are reduced by an overriding discount of 10%.

For the first 250 cases only, an additional sum of £50,000 will be paid to each victim or family to take account of the legal and other difficulties the first families have had and the pressure they have had to bear.

ANNEX F

SHORT CHRONOLOGY OF EVENTS IN RELATION TO 1) SELF SUFFICIENCY IN BLOOD PRODUCTS AND 2) SAFETY OF BLOOD PRODUCTS

1) Self-Sufficiency in Blood Products

In line with WHO and Council of Europe recommendations, during the 1970s and most of the 1980s, the UK Government pursued the goal of self-sufficiency in plasma products – mostly due to the aim of reducing reliance on expensive imported concentrate.

At the same time, development of a new formulation in the early 1970s to enable Factor VIII, a blood-clotting product, to be stored in a fridge at home and self-administered by patients with haemophilia for bleeding prophylaxis, led to changes in the dosage regimens. Increased frequency of treatment, and the use of blood clotting agents and other plasma products has helped to increase the life expectancy for patients with haemophilia beyond the average of 25 years to almost that of the general male population. These factors resulted in increasing demand for Factor VIII from the mid 1970s.

Due to increasing demand, it remained necessary to continue to import blood products. These were derived from paid donor panels in the US, but, at this time, groups representing patients with haemophilia felt that there were dangers in absolute self-sufficiency. The main reasons for their concerns were that the risk of relying on a sole domestic supplier could lead to a shortfall which may endanger lives of patients, and that the lack of competition could stifle innovations (many of which were from the commercial sector).

Following investment in development of blood processing facilities and blood service infrastructure, by 1977 the Government was able to achieve its 1975-set target in production of blood clotting factor, manufactured by Blood Products Limited (BPL, now known as Bio Products Limited, which was formed in 1954 to develop and manufacture products derived from human blood for NHS England and Wales). However, demand had increased beyond those targets.

An adverse report on the then BPL by the Medicines Inspectorate in 1979, and the realisation that the existing laboratory did not have capacity to provide enough product for self-sufficiency, led to redevelopment of BPL from late 1980 until 1987. However, underestimation of the amount of product needed and lower than predicted production yield meant that BPL would be unlikely to supply more than 70% of the total requirement. The important safety measure of heat treatment, introduced in 1985, also meant that greater amounts of plasma were required per unit.

By 1993, BPL produced around 75% of the total requirement for Factor VIII for England and Wales, meaning that there was still a demand for commercially produced Factor VIII.

2) Safety of Blood and Blood Products

About 4600 patients became infected with hepatitis C and over 1000 with HIV as a result of treatment with blood and blood products in the 1970s and early 1980s. At least 3000 of these were patients with haemophilia who became infected through blood products.

Following the development of tests for hepatitis A and B in the early 1970s, it emerged that other types of viral hepatitis could be transmitted by blood, and these were termed Non A Non B hepatitis (NANBH).

The prevailing medical opinion in the 1970s and early 1980s was that NANBH was mild and often asymptomatic, and patients with haemophilia in conjunction with their doctors were required to balance the improvements in quality of life against risk of treatment. A 1981 BMJ editorial (anonymous; 1981;283:1-2) stated that early death from liver disease might be viewed as a price that might have to be paid by patients with haemophilia for the improved quality of life afforded by clotting-factor concentrates.

Even in 1983 when it became apparent that NANBH was associated with long-term chronic consequences, and that there was some evidence of potential transmission of AIDS via blood donations, the consensus among medical professionals was that the benefits of treating patients with haemophilia with blood products outweigh the risks.

In March 1983, the US Food and Drugs Administration (FDA) introduced regulations designed to exclude high-risk groups from donating blood.

In May 1983, the UK Haemophilia Society urged the Government not to put a ban on imported plasma products from the US, over concerns that a shortage in blood products would put lives of patients with haemophilia at risk. In the same year, the World Federation of Haemophilia said there was insufficient evidence to recommend change in treatment, which should continue with products available.

Studies conducted in 1983 confirmed that commercial and BPL blood products carry equal risk of transmitting hepatitis. Before 1989, potential blood donors could only be screened for NANBH using surrogate tests, considered unreliable in the UK. In addition, the test developed in 1989 for NANBH was associated with a large number of false- positive and negative results, and was not approved for use in the UK until second-generation tests became available in 1991.

The identification of the HIV virus (at that time called HTLV III) as the cause of AIDS took place in April 1984, and as soon as a suitable test was available in 1985, screening of donations was introduced.

In 1985, the UK Blood Products Laboratory (BPL) developed a new high purity heat-treated blood coagulation product, Factor VIII Y, which was believed to prevent onward transmission of NANBH and HIV. Studies since

then show that after the introduction of Factor VIII Y there has been no increase in hepatitis C and HIV among patients with haemophilia.

Reliable tests for HIV and hepatitis C were developed in 1985 and 1991 respectively, and since then all blood donations used in the UK, irrespective of their country of origin have been screened for both HIV and hepatitis C.