RESTRICTED

To: SoS

From: Hugh Taylor

Date: 1st May 2007

Copy: MS(PH)
MS(Q)

BLOOD PRODUCTS – LORD FOWLER AND KENNETH CLARKE

Issue

1. Lord Fowler has written to me (Annex A), also on behalf of Kenneth Clarke, regarding the non-Governmental inquiry being conducted by Lord Archer. Given that their time in Government during the 1980s falls within the period being examined by Lord Archer, they expect to be approached by his inquiry in due course. In preparation for this, they have asked to have access to any relevant papers held by the Department.

Timing

2. An early response would be appreciated.

Recommendation

3. That you agree the draft letter at Annex B, which I intend to send to Lord Fowler, permitting him and Kenneth Clarke controlled access to papers from their time in office and attaching a chronology of events, as requested.

Background

4. Lord Fowler was SofS for Social Services between September 1981 and June 1987. Kenneth Clarke was Minister of State between March 1982 and September 1985 and then SoS for Health between July 1988 and November 1990. Lord Jenkin of Roding previously came in to the department (in June and September 2005) to view files relating to his own term of office.

5. Guidance received from Cabinet Office's Propriety and Ethics team advises that, as a basic rule, former Ministers are allowed reasonable access (at the Government's discretion) to papers from the period when they were in office. Reasonable access usually means sight of relevant papers in the department under controlled conditions appropriate to the sensitivity of the documents. Access to anything outside their time in office is treated in the same way as an FOI request.

6. In June 2006, Ministers commissioned a review to identify, catalogue and file all relevant documents related to haemophilia and plasma products held by the Department between 1970 and 1985 and to review those that relate to Non-A, Non-B hepatitis (NANBH). The report identifies 4,629 official documents that are available. 56 of these relate to NANBH, while the remaining papers cover a number of areas related to haemophilia and plasma products: HIV/AIDS; self-sufficiency; hepatitis and hepatitis B; and BPL/NHS re-organisation. These cover the period 1970 to 1990.

7. A submission went up last week to MS(PH) and MS(Q) recommending that the report together with the 56 papers relating to NANBH be released and that the remaining papers also be released in line with FOIA. MS(PH) has now approved this approach

8. The papers referred to above are in 102 files, 85 of which relate to the term of office of Lord Fowler and Kenneth Clarke.

9. DH has already released two sets of documents on this subject, in line with the Freedom of Information Act (FOIA), during the course of this review. The first set contained the referenced documents referred to in the published report 'Self-Sufficiency in Blood Products in England and Wales'. The second comprised photocopies of documents returned to the Department in May 2006 by the firm of solicitors who had represented claimants during the 1989 HIV litigation. These documents were released in August 2006 and November 2006 respectively.

Hugh Taylor
Permanent Secretary

ANNEX B

Rt Hon Lord Fowler
House of Lords
London
SW1A 0PW

1st May 2007

Dear

Thank you for your letter of the 19th April requesting to view papers that might be relevant to the non-governmental public inquiry into the blood supply in the 1970's and early 1980's.

We would be pleased to provide such access to files we currently hold at the Department's offices at Wellington House related to blood products. These range from 1981 to 1990; 14 of the files relate to your term of office and 71 to both your and Kenneth Clarke's term.

I attach, as requested, a chronology of events covering the period 1970 to 2006.

It would be helpful if you could contact Linda Page to discuss mutually convenient arrangements to view these files. Linda can be contacted at linda.page@ GRO-C , or by telephone on GRO-C

Hugh Taylor
Permanent Secretary

Chronology of Events

Date	Event
Early 1970s	Use of factor concentrates becomes more widespread.
November 1971	Screening for hepatitis B becomes available.
Early 1973	It becomes apparent that the production of actor VIII in the UK is insufficient to meet the stated needs of clinicians.
March 1973	DHSS Expert Group on the Treatment of Haemophilia recommends that the NHS should be self-sufficient in blood products as soon as possible.
August 1974	Non-A Non-B Hepatitis (NANBH) first predicted by Prince et al
December 1974	Minister of State (David Owen) earmarks central funds of £0.5m, half of which is recurring, to increase the output of plasma from Regional Transfusion Centres to 275,000 donations annually for the preparation of factor VIII and 100,000 donations for cryoprecipitate.
Beginning of 1975	Expert Group on the Treatment of Haemophilia estimated that 275,000 donations of blood would be required to achieve self-sufficiency in factor VIII.
March 1975	Department gave Regions provisional targets of increased production of plasma and invited estimates of the additional expenditure that would be incurred.
May 1975	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 1975	Mannucci et al. reports 45% of patients with NANBH had raised ALT levels; Craske et al. links an outbreak of hepatitis (some NANBH) after intravenous injections of commercial factor VIII concentrate.
April 1976	DH issues a press release re-affirming the aim of the UK to become self-sufficient in the supply of plasma products by mid 1977.
June 1977	Factor VIII production target set in beginning of 1975 attained; however demand has increased.
December 1977	Working Group on trends in the demand for blood products confirms estimate of 1000 iu per 1000 population pa and recommends complete transfer from the use of cryoprecipitate to fractionated freeze dried concentrate.
July 1979	Medicines Inspectorate inspection report published on plasma fractionation facilities at BPL recommending a set of actions that should take place immediately and others that should be implemented in the long term.
Early 1980	Plasma products begin to be heat-treated; yield is very low and not shown subsequently to inactivate NANBH.
August 1980	Short-term upgrading of facilities at BPL agreed at cost of 1.3m. Expected to double production capacity from 15m iu pa to 30m iu pa.
October 1980	Craske states that NANBH is mild and often asymptomatic,

	but might cause chronic liver disease not associated with overt disease.
November 1980	£21m allocated to the building of a new fractionation facility on existing site at Elstree.
April 1981	Regions started to receive BPL products relative to amount of plasma supplied i.e. pro rata distribution.
Mid 1981	Advisory committee to NBTS estimated that demand for factor VIII would increase to 100m iu pa by mid-1980s; regional targets for plasma set.
1982	Central Blood Laboratory established as a Special Health Authority.
1982/1983	Studies published that indicate that NANBH is more serious than previously thought.
1983	Studies such as that by Fletcher et al. (1983) confirm that commercial and BPL concentrates contain equal risk of transmitting hepatitis.
1983	Rizza and Spooner (1983) paper shows cerebral haemorrhage most common cause of death for patients with haemophilia; only 2% of patients die as a result of chronic hepatitis infection.
1983	Studies confirm that commercial and BPL concentrates carry equal risk of transmitting hepatitis.
1983	US patients with haemophilia contracted AIDS strengthening concerns over the safety of imported plasma.
March 1983	FDA introduces new regulations for the collection of plasma excluding donors from high-risk groups. The use of pre-March 1983 stocks was not banned owing to concerns that this would lead to a crisis in supply.
May 1983	Construction started at BPL.
May 1983	Haemophilia Society appeal not to ban imported blood products and urge patients not to stop treatment in response to concerns over potential risks.
May 1984	Trial issues of Heat-Treated factor VIII - HT1 (60° C for 24 hours).
December 1984	Haemophilia Centre Directors' meeting at BPL. Heated product preferred for all new patients, subject to availability; otherwise preferentially for treatment of HIV-antibody negative patients. BPL confirmed all factor VIII would be heated by April 1985. Heating would carry a 15-20% yield penalty.
1985	Studies revealed almost 100% transmission of NANBH following administration with untreated large donor pool clotting factor concentrate.
1985	Hay et al. reported that progressive liver disease in patients with haemophilia was an understated problem.
February 1985	First issues of heat-treated factor VIII - HT2 (70°C for 24 hours}.
February 1985	Trial issues of heat-treated factor VIII - HT3 (80°C for 72 hours).

July 1985	Trials of a new, high purity product, Factor 8Y, conducted in selected patients.
September 1985	BPL start general issue of its new Factor 8Y heat-treated factor VIII.
October 1985	All blood donations collected by the National Blood Transfusion Service screened for HTLVIII (HIV) since 14th October 1985.
Mid 1986	Re-development project costs for BPL escalate to around £52m; however project remains fully funded owing to Government's commitment to self-sufficiency.
1986	Research identifies the need for retrospective NANBH studies, recognising that the initial disease might be quite mild but progression to symptoms associated with severe disease may be very protracted.
September 1988	UK was not self-sufficient in plasma products due to errors in estimating both the amount of plasma stockpiled and the net yield for factor VIII production at BPL and could not expect to be so for a couple of years.
1989	Identification of hepatitis C.
April 1989	System of cross-charging in place to encourage RTCs to produce maximal amounts of plasma.
1989	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.
September 1991	Second generation hepatitis C virus screening assays become widely used in the screening of donor blood in the UK.
1992	A retrospective study questioned whether hepatitis C virus infection was a disease in waiting and confirmed that the acute infection was perceived in the 1970s as mild and that in 1980 analysis emphasised its relatively benign short-term prognosis.
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.
1993	Domestically sourced blood products account for 75% of the UK factor VIII market. There were concerns, however, at this time, that absolute self-sufficiency was not without its own risks.
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 and a subsequent search for recipients of each donation to offer counselling and treatment where appropriate.

October 2000	Hepatitis C litigation against the National Blood Authority began. Action was taken under the Consumer Protection Act. All 117 claimants won damages. (Note the Government was not party to this litigation).
October 2000	Identified that files relating to the Advisory Committee on the Virological Safety of Blood between May 1989 and February 1992 were missing. Independent audit identified that they were destroyed in error.
	Demands for a public inquiry in response to loss of documents. Lord Owen stated that as Minister for Health he had allocated finance in 1975 to increase the production of factor VIII to attain self-sufficiency and that the DH did not fulfill this policy.
January 2005	Subsequent to the identification of missing ACVSB files, a request for papers that were subject to a PII claim during the HIV litigation were requested and found to be missing.
February 2006	The report 'Self-Sufficiency in Blood Products in England and Wales A Chronology between 1973 and 1991 published.
May 2006	Documents relating to the HIV litigation returned to the DH by claimants' solicitors, independent Counsel appointed to review documents.
August 2006	Release, in line with FOIA, unpublished documents referenced in the report 'Self-Sufficiency in England and Wales A Chronology 1973 and 1991.
November 2006	Release, in line with FOIA, of documents returned to the DH by a firm of solicitors.

Note: This chronology only summarises the key points as far as we have identified them.