Agenda Item 2 **HC/S2/06/09/06**
18 April 2006

SUBMISSION FROM ROBERT MACKIE

Re: Answers from Mr A Kerr msp Minister for Health to questions from Carolyn Leckie msp re: Contaminated Blood and Blood Products with HIV/AIDS and HCV

My wife and myself were in attendance at the Health Committee Meeting, Tuesday 31 January 2006 and wish to point out questions Mr Kerr has replied to which are incorrect, the fact that these questions are misleading or false makes us ask the question "What else has Mr Kerr given answers to that are either misleading or false?"

Carolyn Leckie (Central Scotland) (SSP): *To ask the Scottish Executive whether it has learned any lessons from the fact that NHS Scotland has not implemented the Council of Europe Recommendation No. R (83) 8 on the prevention of possible transmission of AIDS to patients receiving blood or blood products.*

(S2W-22857)

Mr Andy Kerr:

Council of Europe recommendation R (83) 8 makes a number of recommendations in relation to AIDS. The recommendations dealt with the use of coagulation factor products prepared from large plasma pools; informing patients and recipients of the risks of blood products; and providing blood donors with information. Policy in Scotland in relation to blood products fully reflected these principles and recommendations. The risks of large plasma pools were recognised and appropriate warnings were provided on products. Clear warnings were also provided to blood donors by Scottish National Blood Transfusion Service (SNBTS) in 1983, specifically in relation to AIDS.

An earlier Council of Europe Recommendation No. R (80) 5, concerning blood products for the treatment of haemophiliacs, was discussed with Scottish Haemophilia Directors and Directors of The Scottish National Blood Transfusion Service at a meeting organised by the Scottish Health Department in 1981, at which it was agreed that "policy and practice in Scotland were consistent with this document, subject to further consideration of the recommendation on the setting up of a haemophilia register". It is believed that policy and practice in Scotland were also consistent with the subsequent Recommendation No. R (83) 8 concerning AIDS.

The Council of Europe recommendation R (83) 8 is not worded as Mr Kerr states, it should be "*…**to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks;**…*" however, this recommendation was never carried out, as haemophiliacs were never warned of the risk of AIDS (although the matter of whether to inform haemophiliacs of the dangers of AIDS was discussed between SNBTS and Haemophilia Centre Directors in 1983) Mr Kerr is correct when stating that "*Clear warnings were also provided to blood donors…*" as this was included in the AIDS information leaflet supplied when donating blood. "*… The risks of large plasma pools were recognised and appropriate warnings were provided on products …"* AIDS warnings were never given on bottles or package inserts in 1983 or 1984, in fact this warning was never included in package inserts (or on bottles) until **Late 1985**. *"… It is believed that policy and practice in Scotland were also consistent with the subsequent Recommendation No R (83) 8 concerning AIDS …"* If this is correct, then why has Professor Ludlum, Haemophilia Consultant, Royal Infirmary of Edinburgh stated that "*The existence of the Council of Europe Recommendation (number 8), … was not known to me nor was it discussed at any of the meetings I attended.*" If this recommendation was carried out as Mr Kerr states, perhaps it could have prevented haemophiliacs from becoming infected with AIDS, and **would** have prevented 16 haemophiliacs under the care of Prof Ludlum from becoming infected with AIDS after March 1984.

Carolyn Leckie (Central Scotland) (SSP): *To ask the Scottish Executive what explanation it has for any delays by previous governments in implementing an agreed compensation scheme for people participating in clinical trials of blood products, such as factor VIII.*

(S2W-22858)

Mr Andy Kerr:

The involvement of patients in clinical trials took place around the introduction of the SNBTS heat-treated Factor VIII product in 1987. Papers already released include correspondence in relation to eligibility for compensation for patients taking part in clinical trials. Although there were concerns expressed by clinicians about compensation arrangements, these issues were resolved and did not delay the introduction of a heat-treated Factor VIII product which was safe in terms of the transmission of hepatitis C.

The answer states that "*The involvement of patients in clinical trials took place around the introduction of the SNBTS heat-treated Factor VIII product in 1987."* According to information released under FOI, clinical trials were conducted before 1987, and as far back as 1983 doctors were raising the subject of "*eligibility for compensation for haemophiliacs taking part in clinical trials*" also stated was "*these issues were resolved and did not delay the introduction of a heat-treated Factor VIII product which was safe in terms of*

the transmission of hepatitis C" The introduction of heat-treatment was not delayed, but the compensation agreement was not resolved until **after** Hepatitis safe Factor VIII was produced. The issue was in fact not resolved (for a further 5 years) until **after** haemophiliacs were being treated with Z8 (Heat-treated to 75°/80° for 72 hours) and according to correspondence between Prof Ludlum and SNBTS/PFC patients were being given Z8 for clinical trials when there was no clinical trials certificate, no clinical trials exemption certificate or compensation scheme for patients doing trials. This product was issued without any of the above when it was known that a patient had "**symptoms of a potentially lethal condition during an infusion to test a new PFC produc**t".

Carolyn Leckie (Central Scotland) (SSP): *To ask the Scottish Executive over what period crown immunity applied to premises owned by NHS boards and bodies and to which individual premises such immunity applied.*

(S2W-23030)

Mr Andy Kerr:

Crown immunity applied to all NHS bodies from the date of the creation of the NHS, 5 July 1948, until its removal by means of the NHS and Community Care Act 1990 which came into force on 1 April 1991. Immunity therefore applied to all NHS premises during this period. In 1986, however, the NHS (Amendment) Act 1986 removed Crown immunity from the NHS in respect of food hygiene and health and safety legislation.

Mr Kerr states that "*Crown Immunity applied to all NHS bodies from the date of the creation of the NHS 5 July 1948…*" however, according to correspondence between J Walker SHHD and Health Board Secretaries, 13 May 1975 "*In England and Wales the view is taken that in law the activities of health authorities attract Crown exemption so that the provisions of the Medicines Act are not binding on them. … arrangements are being made whereby health authorities will be brought within the licensing provisions of the Act in a manner analogous to that which applies to commercial pharmaceutical manufacture.* ***Precisely similar arrangements cannot be adopted in Scotland, where Health Boards are not entitled to Crown exemption by virtue of their status as occupiers of hospital premises. As the Act is regarded as binding on Health Boards they will therefore be required to apply for and hold licences…***"

A look back study on Hepatitis C was carried out on blood/blood product recipients in 1995 as Mr Kerr stated, however, FOI documents state that in 1990 "*blood found to be positive in the pilot study would not be used,* ***with no look back at recipients of previous donations from positive donors****. (The no look back refers only to the pilot study.)*" Look back was carried out from 1995 to 1997 and included donors and recipients from 1991, which means that the recipients of the above pilot study were not informed as no look back

was to be carried out on the recipients of the positive blood, however, the positive donors of the above study were counselled.

At the Health Committee Meeting 31 January 2006 Mr Kerr stated "*The NHS did not knowingly infect anyone, and I resent any suggestion that that might have been the case…" again Mr Kerr has given false information as again according to documents released under the FOI before implementing ALT plus anti-HBc screening, research was planned between SNBTS, CDSC, DHSS, BTS and others included the following - "… the experts wished to include much more laboratory testing, relevant to the question of infectivity of the donations and the meaning of the presence of anti-HBc. The extra tests would be applied only to donations containing anti-HBc, and could detect very small amounts of HB virus, reverse transcriptase and other constituents. … to administer the blood to recipients in the ordinary way, and at one (English) centre to follow them up; follow-up without alarming the recipients is a tricky task. The extra tests required so much blood that there might be no donation left to administer; yet the ultimate test of safety is the effect on the recipient…*" this document goes on to state "*… the increase (in financial cost) is not wholly unwelcome if it hardens the science, since CSO will not wish to fund soft science.*" This research was carried out in the UK from 1988, but according to correspondence similar research had already been carried out in Scotland. If it was acceptable in 1988 to deliberately infect patients, perhaps it was acceptable in 1984, and raises the question of the "unusual circumstances" in which 16 haemophiliacs became infected with AIDS in 1984.

Deleted from the Committee Meeting Minutes of 31 January 2006 under the heading of "repetitions and redundancies" Mr Kerr stated that "*It does not matter what the doctors did or didn't do – It does not matter what the PFC did or didn't do*". I find this statement unacceptable, as the reason for an inquiry is "To ensure that no wrongdoing has been done and to ensure that past mistakes will not be repeated." If it does not matter what occurred in the past, then lessons will never be learned from past mistakes.

At the same meeting Mr Kerr stated "*First, I do not think that you have ever heard me say that this problem was in the past.*" The health committee or anyone else may never have heard Mr Kerr say this, but what he did say to Mr Paul Wilson a reporter for the Press and Journal in July 2005 was "***THAT IT WAS IN THE DIM AND DISTANT PAST***".

If Mr Kerr has read all documentation relating to Contaminated Blood/Blood Products then he will know that the information he has supplied is either misleading or false, and therefore anything he says cannot be taken as truth and is grounds for an inquiry, if he has not read the information then he has not carried out his duties as Health Minister and the above information is to Mr Kerr new information, therefore does this not justify grounds for an inquiry?

All information mentioned above comes from official documentation and has been made available to the Health Committee, but if verification is required we would be pleased to provide any information or confirmation you require.

Yours sincerely
Mr & Mrs Robert Mackie