INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF MR DUNCAN MACNIVEN

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 22 March 2022

I, Mr Duncan Macniven, will say as follows: -

Section 1: Introduction

1. ***Please set out your name, address, date of birth and professional qualifications.***

   1.1 My name is GRO-C. My address is GRO-C I was born on GRO-C 1950. I am a graduate (MA Aberdeen 1972; MLitt Aberdeen 1978), with honorary degrees (LLD) from Robert Gordon University (2008) and University of Aberdeen (2012). I was awarded the CBE in 2012.

2. ***Please set out your employment history with dates if possible, including the various roles and responsibilities that you have held throughout your career.***

   2.1 I joined the Scottish Office as a graduate trainee in 1973 and worked on a variety of subjects (none relevant to the topic of the Inquiry) until 1986. I was then promoted to Assistant Secretary in the Scottish Home and Health Department (SHHD), to head the Division whose responsibilities included the

Scottish Office's interest in the blood transfusion service (as well as many other matters). My answer to question 9 gives more details.

2.2 After leaving that post in 1990, I worked for a year on the preparation of the Scottish elements of legislation which became the National Health Service and Community Care Act 1991. After the passage of the legislation, I worked until 1995 for Historic Scotland (for most of the period as Deputy Director in charge of the historic properties in state care such as Edinburgh Castle). From 1995 to 1998 I was head of the Scottish Office's Police Division (responsible for the Secretary of State for Scotland's interest in the police service). I was promoted to Director in 1998, as head of the Police, Fire and Emergencies Group. From 1999 to 2003, I was an executive Forestry Commissioner, responsible for back-office functions (finance, human relations and information technology).

2.3 From 2003 until my retirement in 2011, I was Registrar General for Scotland, responsible for collecting information about people (mainly through the registration of vital events and through the census) and making that information available, with appropriate security, to the public, to a wide range of statistical customers and to family historians.

3. ***Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership.***

3.1 None.

4. ***In addition to the Penrose Inquiry, please confirm whether you have provided evidence or have been involved in any other inquiries, investigations, criminal or civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products. Please provide details of your involvement.***

4.1 I have not.

Section 2: Previous statements and evidence

5. ***What materials were made available to you when you gave evidence to the Penrose Inquiry?***

5.1 I was provided with scanned copies of papers from the files kept by my Division on the topics on which I gave written and oral evidence (viral inactivation; surrogate testing for NANB hepatitis; and indemnity for subjects of clinical trials of Factor VIII). These gave a complete history of our work on the subject, bringing together internal SHHD minuting and correspondence with the CSA, SNBTS and other relevant external bodies.

6. ***Did anyone else assist you in preparing your evidence? If so, who, and what assistance did they provide?***

6.1 A lawyer working for the Scottish Government was allocated to advise me (and others in a similar position). I cannot recall her giving significant assistance.

7. ***The Inquiry understands that you provided the following written statements and oral evidence to the Penrose Inquiry:***

a. ***9 September 2011 statement regarding viral inactivation 1985-1987 [PRSE0001934].***

b. ***16 September 2011 statement regarding compensation and indemnity arrangements for Z8 [PRSE0002830].***

c. ***12 October 2011 statement regarding surrogate testing for Non-A Non-B ("NANB") hepatitis [PRSE0002324].***

d. ***3 November 2011 oral evidence [PRSE0006061 pp.150-168].***

e. ***17 November 2011 oral evidence [PRSE0006065 pp.132-188].***

f. ***14 December 2011 oral evidence [PRSE0006078 pp.1-36].***

Please confirm whether these statements and the oral evidence you gave are, to the best of your knowledge and belief, true and accurate. If there are any matters within your evidence to the Penrose Inquiry that you do not consider to be true and accurate, please explain what they are and how the

inaccuracy occurred. Please also identify any evidence you gave to the Penrose Inquiry which is not listed here.

7.1 Yes, I confirm that these statements and the oral evidence that I gave are, to the best of my knowledge and belief, true and accurate. To the best of my knowledge and belief, you have identified all the evidence.

Section 3: Structure and organisation of the Scottish Home and Health Department and Scottish Office

General

8. ***Please describe, in broad terms, your role, functions and responsibilities as Assistant Secretary at the SHHD.***

8.1 From 1986 to 1989, I headed the Division of the Department which discharged the Secretary of State for Scotland's responsibilities for the following subjects (in addition to blood transfusion services): health service land and property; health service building procedures and standards; procedures for the procurement of goods and services; emergency planning; oversight of the Common Services Agency; the ambulance service; and services for physically disabled people. I had over 40 staff. My role, broadly speaking, was to provide leadership, purpose and direction to my staff, to contribute to policy-making and advice to ministers, to liaise with relevant external parties and to resolve difficult issues.

9. ***To the best of your ability, please outline the organisational structure of the Scottish Office during your time as Assistant Secretary, insofar as relevant to the Inquiry's Terms of Reference. If you are aware of any differences relative to the period before you joined the SHHD, please describe them. When providing your answer, please:***

   a. ***describe how ministerial responsibilities were allocated, in particular with respect to health matters, including who determined those responsibilities;***

b. ***outline how, if at all, those ministerial responsibilities changed over time; and;***

c. ***explain (insofar as you have not done so already) the different roles played by the Secretary of State, the Minister of State, and Parliamentary Under-Secretaries of State, in respect of health matters (and in particular matters relating to blood and blood products).***

Insofar as it is relevant to do so, please comment on the role and responsibilities of the SHHD, and the Common Services Agency ("CSA"). Further questions on these bodies are contained below, but please feel free to structure your answers as you see fit.

9.1 The organisational structure of the Scottish Office, and in particular SHHD, compiled by the Penrose Inquiry is among the documents which you supplied to me (PRSE0000358), I was consulted when it was being drawn up and it seems to me accurate. I expand on it below. So far as I recall, the organisation did not alter during the period 1986-89.

9.2 The Scottish Office was organised in a number of functional departments, of which the relevant one was SHHD, responsible for home affairs and the health service. Each department was headed by what is now called a Director General but which was then called a Secretary, who reported to the Permanent Secretary. Each was divided into "groups" of divisions, headed by an Under Secretary (in today's parlance, a Director) – in my case, Group IV, one of two Groups responsible for the health service (the other being Group V). My Division was called IVD and was one of four Divisions in the Group. In parallel, there were medical, nursing, pharmaceutical and scientific experts, with their own hierarchies. That sounds ponderous. It was not. We operated very effectively in small teams brought together informally to work on specific topics. In the case of blood transfusion services, I worked very closely indeed with our medical staff and where necessary with experts in pharmacy, finance, public relations and the law.

9.3 On my other responsibilities, I worked with different teams – architects, quantity surveyors, doctors and nurses in the case of building procedures for example. There was a collegiate approach to that teamworking and it was a good environment to get things done. The main problem was the volume and diversity of business.

9.4 Each department reported to one or more junior ministers – the Minister for Health was the one relevant to my Division – and through the junior minister to the Secretary of State for Scotland. The responsibilities of the junior ministers were, I assume although I do not know for certain, allocated by the Secretary of State and I do not recall them changing in the period. The Ministers of State were more senior than the Parliamentary Under-Secretaries of State but, as far as I understood, they all reported to the Secretary of State: there was no hierarchy in terms of subject responsibilities. Thus, at any given time there would be two ministers responsible for health matters – the junior minister (who might be a Minister of State or a Parliamentary Under-Secretary) and the Secretary of State.

9.5 The Common Services Agency (CSA) was not part of the Scottish Office. It was a statutory body, part of the health service, akin in governance to the 15 territorial health boards. It was essentially a holding company providing a wide variety of services to the territorial health boards or directly to the public – including blood transfusion, through the Scottish National Blood Transfusion Service (SNBTS), and also (for example) the ambulance service, legal services, building services and health education. The CSA was formally responsible to the Secretary of State for Scotland, who appointed its Management Committee. It had a close relationship with SHHD and in particular with my Division, which was responsible for appointments to, and general oversight of, the CSA as well as having a specific responsibility for the oversight of the SNBTS (and the Scottish Ambulance Service). Indeed, its Management Committee included two appointees from SHHD – the Group IV Under Secretary (who was my boss) and the Deputy Chief Medical Officer.

10. Who had ministerial responsibility for blood and blood products during your time as Assistant Secretary?

10.1 The Ministers of Health with whom I recall having contact were successively John MacKay MP, Lord Simon Glenarthur and Michael Forsyth MP. I do not recall having direct contact with the Secretary of State about blood transfusion services during the period, although (in line with standard practice) the submissions which I made to the Minister for Health were copied to the Secretary of State's office.

11. To the best of your ability, please describe in broad terms the roles and functions of the SHHD, constitutionally and in practice, during your time as Assistant Secretary. In doing so, please explain which ministers and parliamentary under-secretaries had oversight of, or influence over, SHHD activities.

11.1 In constitutional terms, the SHHD exercised the powers of the Secretary of State on his behalf. In practice, most decisions were taken by the officials of the Department without reference to the small number of ministers, with only the most difficult or politically-contentious matters being decided personally by ministers.

12. Please describe, in broad terms, your experience of how the decision-making process within the SHHD worked, including how, typically, decisions were requested of and taken by the Secretary of State and ministers; the procedures within the SHHD for providing advice to the Secretary of State and ministers; and the flow of information within the SHHD as between civil servants and the Secretary of State or ministers.

12.1 These difficult or politically-contentious issues were normally the subject of written submissions from the responsible officials to ministers. The formal procedure was for officials to write submissions to the relevant junior minister. These submissions were always copied to the Secretary of State's office, to keep him in touch and allow him to intervene if he wished. Occasional matters were routed through the junior minister to the Secretary of State – for instance if the matter involved the Secretary of State's personal responsibilities (for

appointments, for example) or had been initiated by the Secretary of State. The written submission would normally be replied to in writing but occasionally would be the subject of a meeting or phone call between officials and ministers. Ministers were based in London for 4 days in the week during the Parliamentary session, so meetings were not frequent. But the 400 mile separation was not otherwise an impediment, because the Scottish Office had a secure communications network linking all its significant offices, which was used to communicate instantaneously in writing with ministers, as one would now send an attachment to an email.

12.2 I had much contact with ministers. It was normal practice for me to give advice directly to ministers on matters for which I was responsible. It was unusual for submissions to ministers on operational matters of that kind to be referred up the departmental hierarchy I have described in answer to question 9, although my bosses' doors were open if I needed guidance.

13. ***Please describe how SHHD officials brought information and issues to the attention of ministers. In particular, please explain:***

    a. ***Which criteria determined whether a matter was of sufficient importance to be brought to the attention of ministers.***
    b. ***Who would make those decisions?***
    c. ***How effective the process was, in your experience, in ensuring that relevant ministers were suitably informed of the key issues with which SHHD was concerned during your time as Assistant Secretary.***

13.1 I recall no set criteria. It was a matter of judgement whether at any given time it was necessary to refer a matter to ministers. That judgement would be exercised by the responsible official at or above Assistant Secretary – in consultation if necessary with more senior officials. I can think of few cases, and none relevant to this Inquiry, where ministers complained that a particular matter should have been referred to them for decision. Nor can I recall any instance where a minister complained that it had been unnecessary to refer a matter to him.

14. ***To the best of your ability, please identify (by name and position) the ministers and senior civil servants within the SHHD with whom you principally dealt, or from whom you received advice, in relation to the following issues: blood and blood products, the licensing and regulation of pharmaceutical companies and products, risks of infection from blood or blood products, the response to such risks, and compensation or other financial support to people with haemophilia or other bleeding disorders who had been infected with HIV. You may be assisted by PRSE0000358, a document prepared during the Penrose Inquiry and referred to during your oral evidence [PRSE0006065 pp.133-135].***

14.1 At ministerial level, my contact on these matters was always with the Minister for Health. At official level, I worked as part of a team drawn from the various professional disciplines within the SHHD in the way I have described in answer to question 9. Besides my own staff and my boss (the Group IV Under-Secretary – successively Hugh Morison and Hamish Hamill) these consisted of two members of the Chief Medical Officer's staff (Archie McIntyre and John Forrester), the Chief Pharmacist (Graham Calder) plus, if financial issues were involved, a member of the Finance Group in the Scottish Office (I particularly recall Hamish Robertson and Norman Kernohan). On all these matters, we depended heavily on advice from the experts in the Scottish National Blood Transfusion Service (SNBTS), principally its Medical Director (John Cash).

15. ***Please describe the respective roles of ministers and SHHD officials in:***

a. ***setting up advisory groups;***

b. ***determining their terms of reference; and***

c. ***imposing any conditions on their functioning.***

15.1 I do not recall there being general criteria. Each proposed group was considered individually.

Funding

16. ***Please describe the process by which the SHHD budget was decided upon and approved during your time as Assistant Secretary. In doing so, please describe (i) the function of the Public Expenditure Survey and the Treasury in this process, (ii) the role (if any) of the Department of Health and Social Security ("DHSS"), (iii) the roles (if any) of the SHHD and the CSA, (iv) your involvement and ministers' involvement in this process.***[1]

16.1 In my recollection, the budget was set by means of a 3-year forward look (the Public Expenditure Survey) followed, with regard to the year immediately ahead, by the Supply Estimates which were approved by Parliament. The details varied from spending area to spending area. But in the case of the SNBTS, the process involved a request from my Division to the CSA for bids covering all its functions, including the SNBTS. These bids were scrutinised by the team mentioned in my reply to question 14 above, and amalgamated into a bid covering the whole of SHHD, which was in turn incorporated in a Scottish Office-wide bid approved by ministers which was the subject of discussions with the Treasury, with the final decision being taken collectively by the Cabinet. I do not recall DHSS having any part in the process, though we probably compared notes informally, to ensure that the collective decision of ministers was taken on a comparable basis.

17. ***Please explain how Scottish blood services were funded during your time as Assistant Secretary. If there were changes in the funding arrangements over this period, please describe them.***

17.1 The SNBTS received a grant from the SHHD, as part of the CSA's budget. I think it retained any other income (for instance, from the supply of blood to private hospitals and research grants), with its grant from SHHD being set on the basis of such expected income. I recall no changes during the period of my involvement.

[1] It is noted that the Department was later split, with the Department of Health retaining control of health policy. For ease of reference, "DHSS" is used in this request to cover both the Department of Health and Social Security and the Department of Health.

18. ***Please describe the process by which government funding was granted for specific health matters not budgeted allowed for in the Scottish Office or SHHD budget during your time as Assistant Secretary. In doing so, please describe:***

    a. ***how an application was made for such funding;***
    b. ***who took such decisions;***
    c. ***the extent of your involvement, and ministers' involvement, in determining whether such funding would be applied for or granted;***
    d. ***the factors taken into account, and by whom, when determining whether such funding should be granted; and***
    e. ***whose responsibility it was to determine how such funding should be allocated and whether any conditions should be imposed on such funding.***

18.1 The general rule was that unexpected extra costs (or reduced costs) arising after the annual budgets were set, should not require the budget to be altered. If that could not be achieved, it was possible to seek a Supplementary Estimate, which needed Parliamentary approval. I do not recall the detail of that procedure, nor do I recall that it was ever necessary during my period of involvement with the SNBTS.

Role of CMO

19. ***What was your understanding, in broad terms, of the role of the Chief Medical Officer ("CMO") for Scotland during your time at the SHHD? Please comment, in particular, on the following areas:***

    a. ***The extent to which the CMO was responsible for informing ministers about risks to public health.***
    b. ***The extent to which the CMO was responsible for shaping policy and informing ministers of policy options.***
    c. ***The extent to which the CMO was responsible for issuing guidance, advice or instruction to clinicians and health bodies as to the risks of infection from blood or blood products.***

d. ***The extent to which the CMO was responsible for issuing guidance or advice to patients, and in particular patients reliant on blood transfusions or blood products.***

19.1 The precise formal role of the CMO will be ascertainable from published sources: I am not familiar with the detail. It seemed to me that he was responsible for all medical and public health advice to Ministers. I do not recall whether he issued advice to clinicians and health bodies on the risk of infection from blood and blood products: I would not have been involved in the formulation of such advice. I do not recall him issuing advice to patients: it seems to me that that would be a matter for their clinicians, or the SNBTS.

20. Please describe the relationship that you had with the CMOs with whom you worked while Assistant Secretary. Please describe any relevant differences in approach between the CMOs with whom you worked.

20.1 I did not have a close working relationship with the CMO. My relationships as regards the SNBTS were with his deputy (Graham Scott) and particularly with Archie McIntyre and John Forrester. There were no differences during the relevant period, although the CMO changed (Ken Calman replacing Iain Macdonald, in 1988 or 1989).

21. Please describe how SHHD officials brought information and issues to the attention of the CMO. In particular, please explain:

a. ***Which criteria determined whether a matter was of sufficient importance to be brought to the attention of the CMO.***
b. ***Who would make those decisions?***
c. ***How effective the process was, in your experience, in ensuring that the CMO was suitably informed of the key issues with which the SHHD was concerned during your time as Assistant Secretary.***

21.1 It would be the medical staff in SHHD who would have brought information and issues to the CMO's attention and I do not recall exactly how that was done. The process seemed effective, however: the CMOs seemed well-informed judging from my contact with them at the time, and from Iain Macdonald's evidence to Lord Penrose's inquiry.

22. ***What contact, if any, would SHHD officials have with the CMOs for England for England, Wales and Northern Ireland? If there was any contact, please explain how, when and why it would be arranged.***

22.1 I understood that the UK CMOs met from time to time and they no doubt had other informal and formal contact – although I was not involved in their meetings and have no knowledge of what they discussed. The other medical staff of SHHD may have had contact with the other UK CMOs (and certainly had contact with their staff), but I had none.

23. ***To the best of your knowledge and recollection, how significant a role did the CMO for Scotland play in forming policies on blood and blood products (and any other matters relevant to the Inquiry's Terms of Reference) during your time as Assistant Secretary?***

23.1 Since the CMO was Ministers' principal medical adviser, and since the supply of blood and blood products was an important part of the health service, I imagine that the CMO would have played an important part. That is supported by Iain Macdonald's evidence to Lord Penrose's Inquiry. I do not however recall the detail.

Section 4: Relationships with the UK government and devolved administrations

24. ***Please describe, in broad terms, the relationship between the SHHD and the DHSS in respect of health policy in Scotland during your time as Assistant Secretary, with particular reference to policy related to blood, blood products and haemophilia. You may be assisted by considering the following:***

a. ***How much oversight, if any, did the DHSS retain over health policy decisions made in respect of Scotland? Please provide any relevant examples?***
b. ***To what extent did the Scottish Office and/or the SHHD interact with and influence the DHSS on matters relating to blood and blood products?***

c. ***To what extent did the Scottish Office and/or the SHHD attempt to align its policies and activities with those of the DHSS on such matters?***

d. ***How would disputes between the DHSS and the Scottish Office/SHHD be resolved?***

24.1 Responsibility for the health service in Scotland was entirely devolved to the Secretary of State and through him to the SHHD. The DHSS had no oversight role. As a matter of good administration, SHHD and DHSS will have kept each other in touch with developments in one country which might affect the other, and I mention specific examples below. I do not recall any significant disputes between the two departments. If they existed, they would have been resolved by senior-level discussions, or in the end by contact between the relevant ministers.

25. Please describe, in broad terms, your interactions as Assistant Secretary with the DHSS in relation to health policy. Please also identify by name and position the ministers and civil servants with whom you liaised in the DHSS. Please address, in particular, any such involvement in decisions relating to: blood and blood products, the licensing and regulation of pharmaceutical companies and products, risk of infection from blood or blood products, the response to such risks, and compensation or financial support for people infected as a result of treatment with blood or blood products.

25.1 On each aspect of health policy for which I had responsibility, I will have taken care to establish and maintain communication with opposite numbers in DHSS. In the case of blood transfusion, I recall Malcolm Harris, with whom (the documents which you have provided show) I had correspondence to ensure we took a compatible attitude to the use of unscreened plasma stocks (see my answer to question 67 below). I would have had no contact on the licensing and regulation of pharmaceutical companies, which were not among my responsibilities.

26. Please describe, in broad terms, your interactions as Assistant Secretary with the Welsh Office and Northern Ireland Office in relation to health. Please also identify by name and position the ministers and civil servants with whom you liaised in each government. Please address, in particular, such interactions in relation to decision-making about: blood and blood products, the licensing and regulation of pharmaceutical companies and products, risk of infection from blood or blood products, the response to such risks, and compensation or financial support for people infected as a result of treatment with blood or blood products.

26.1 I recall no such contact. As regards Northern Ireland, the documents which you have provided show that I had contact on one matter (see my answer to question 76) with a Mr Scott of the Department of Health and Social Services, although I do not now recall that or any other contact with the Department.

27. As Assistant Secretary, to what extent were you involved in, or did you influence, the development of UK policy and the alignment or divergence of UK and Scottish policies on the following issues: blood and blood products, the licensing and regulation of pharmaceutical companies and products, risk of infection from blood or blood products, the response to such risks, and compensation or financial support for people infected as a result of treatment with blood or blood products.

27.1 On matters for which I was responsible, I do not recall a "UK policy". It was for each health department to develop its own policies. As I have said, we kept in touch on matters where a co-ordinated approach was desirable, including the use of untested plasma stocks (see my answer to question 67 below) – but that was not a "UK policy" in the normal sense of the term. I was not responsible for pharmaceutical licensing and regulation.

28. What was the impact of having different organisations and structures responsible for blood in Scotland and England? In particular, did this lead to differences in service delivery in the two countries? You may be assisted by the following documents, concerning an article published in the British Medical Journal by Professor Cash:

- ***4 September 1987 minute from Hugh Morison [SCGV0000052_115].***
- ***7 September 1987 minute from Dr MacDonald [SCGV0000052_114].***
- ***Your 10 September 1987 minute, enclosing a draft of the article [SCGV0000052_016].***
- ***Professor Cash, "The blood transfusion service and the National Health Service", 12 September 1987, British Medical Journal [PRSE0000598].***

28.1 Differences in service delivery in the various UK countries were an inevitable consequence of the separate responsibilities of the 4 health departments, because each department could (and did) take different decisions on policies and funding priorities. This applied to the blood transfusion services as well as the rest of the NHS. John Cash's BMJ article highlighted the consequences which he believed flowed from organisational and policy differences between Scotland and England – including the different policies adopted by the separate Royal Colleges as well as by the government departments.

29. In your evidence to the Penrose Inquiry, you referred to Dr Forrester's description of the DHSS and SHHD as "Punch and Judy" [PRSE0001934 pp.2-3 and PRSE0003962]. What did you understand Dr Forrester's comment to mean? Did you agree with it? Also enclosed is the 10 June 1987 DHSS minute referred to in Dr Forrester's note [BPLL0007211].

29.1 I do not think that John Forrester was referring to DHSS and SHHD coming to blows: the two departments had, in my experience, cordial if not close relationships. Rather, in my opinion, John Forrester was contrasting the antipathy between the senior figures in the blood transfusion services in Scotland and England (evident, for example, in John Cash's article in the BMJ in September 1987) with the good working relationships between the working-level staff of the two services. I did not have first-hand experience of these relationships but it seemed to me that John Forrester's account was consistent with what I had seen at second hand. It is supported by the report of the Penrose Inquiry (see my answer to question 47 below).

Section 5: Relationships between the SHHD and others

30. In your evidence to the Penrose Inquiry, you wrote that blood transfusion in Scotland was "run by the NHS Common Services Agency" [PRSE0001934]. Please explain what you meant by this statement. Please also describe the working relationship between the SHHD and CSA, and describe any interactions you had with the CSA in relation to: blood and blood products, the licensing and regulation of pharmaceutical companies and products, risk of infection from blood or blood products, the response to such risks, and compensation or financial support for people infected as a result of treatment with blood or blood products. As well as documents referred to elsewhere in this letter, you may be assisted by your 22 March 1988 and 21 June 1989 letters to Mr Donald at the CSA [SBTS0000625_111 and PRSE0002337].

30.1 My statement that blood transfusion in Scotland was "run by the NHS Common Services Agency" was intended to explain that, in my period of involvement, the SNBTS was one of the component parts of the CSA (see my response to question 9 above). I had innumerable interactions with the CSA on blood and blood products and allied matters over the 3 years of my involvement – but not on the licensing and regulation of pharmaceutical companies and products, which were not among my responsibilities. I do not recall the details of these interactions, but the scope and flavour are illustrated by the notes of the periodic meetings I had with the CSA and the SNBTS, which you have provided (SCGV0000687_079, SCG0000V178_011, PRSE0004722, PRSE0002769, PRSE0001655, SBTS000687_079).

Relationship between the SHHD and the SNBTS

31. Please describe the working relationship between the SHHD and the SNBTS. In particular, please address the following:

a. the lines of communication between the SHHD and SNBTS, including how information was shared between the organisations;

b. ***the principles and policy objectives which underpinned the relationship between the SHHD and SNBTS;***
c. ***the internal structure at the SHHD for managing the relationship with the SNBTS, including the role of the SHHD official(s) present at any SNBTS meetings;***
d. ***any areas of overlapping responsibility between the SHHD and the SNBTS, and how these were navigated;***
e. ***how information received by the SHHD from the SNBTS was communicated to ministers, including the standard information ministers would be briefed on when first taking office;***
f. ***how ministers were kept up to date with developments in the SNBTS.***

31.1 The SHHD - both my Division and the CMO's staff - had a close relationship with the SNBTS, reflecting the importance to the health service of its work. That relationship was mediated mostly through John Cash, the SNBTS's Medical Director, with whom I had frequent contact both orally and in writing. Our joint aim was to ensure that the health service in Scotland was sufficiently supplied with safe and efficacious blood and blood products. My boss, and the Deputy CMO, were members of the CSA's governing body and attended its formal meetings (at which SNBTS matters were discussed) and of its Blood Transfusion Service Committee. A member of the CMO's staff attended the quarterly meetings of the SNBTS directors, chaired by John Cash. Besides these formal links, I and my staff (and the Deputy CMO and his staff), had frequent contacts with the SNBTS (mostly with John Cash) - sometimes separately and sometimes jointly with the CSA's General Manager. Our responsibilities were less overlapping than hierarchical: the SNBTS was part of the CSA which, like the rest of the Scottish health service, reported through SHHD to ministers. On taking office, ministers were briefed on their responsibilities, including the formal structures and any current issues. I recall no system of regular factual reports to ministers but important new issues were reported to them in the way I have described in my answer to question 12 above, and they took key decisions on the resource allocation to the SNBTS as to the other parts of the health service in Scotland.

32. Were you aware of any difficulties in the working relationship between the SNBTS and SHHD during your time as Assistant Secretary, or have you become aware of any such difficulties subsequently? If so, please explain whether you consider that they had any material impact on the issues being considered by the Inquiry. You may wish to consider the enclosed August-October 1986 correspondence between the Professor Cash and the SHHD [PRSE0004596 and PRSE0002521], as well as documents from May and December 1988 [SCGV0000090_128 and SBTS0000187_032].

32.1 There was longstanding tension between the SNBTS and SHHD. These tensions pre-dated my involvement and I do not know their origins. While at the macro level there was a high degree of shared aims, and my colleagues and I were vicariously proud of the SNBTS's work and supportive of its endeavours, at the micro level there were contentious issues where agreement was hard to achieve. There were at times, on both sides, suspicion of the motives of the other: SHHD was concerned that the SNBTS sought resources which could be better spent on other aspects of patient care in the health service, while the SNBTS was at times irritated by what it saw as unwarranted obstruction of its ambitions. These tensions were not in general personal (though as PRSE0004596 shows, there was a poor relationship between John Cash and John Forrester) and I had a good working relationship with John Cash (and his boss Jim Donald, the CSA's General Manager). I saw it as part of my role to act as a conduit between John Cash and SHHD, to a greater degree than I would have done had professional relationships been better: it was helpful that these two lines of communication (medical and lay) existed. Part of the tension was caused by a lack of understanding of the constraints under which both parties worked and I generally tried to elucidate SHHD's constraints and understand the SNBTS's constraints. Despite these difficulties of relationship, my impression both at the time and looking back today is that the SNBTS was in general well-supported by SHHD in financial and other terms, reflecting the vital importance of the service it provided to the wider NHS in Scotland.

Relationship between the SHHD and PFC

33. Please describe the working relationship between the SHHD and PFC. In particular, please address the following:

- a. ***the lines of communication between the SHHD and PFC, including how information was shared between the organisations;***
- b. ***the principles and policy objectives which underpinned the relationship between the SHHD and PFC;***
- c. ***the internal structure at the SHHD for managing the relationship with PFC, including the role of the SHHD official(s) at any PFC meeting;***
- d. ***how information received from PFC was communicated to ministers, including the standard information ministers would be briefed on when first taking office;***
- e. ***how ministers were kept up to date with developments at PFC.***

33.1 The Protein Fractionation Centre was part of the SNBTS and did not have a separate formal relationship with SHHD. I recall occasional contact with its director, Bob Perry – but it is my recollection that PFC matters were normally the subject of contact between John Cash and SHHD rather than directly.

Relationship between the SHHD and haemophilia clinicians

34. Please describe the working relationship between the SHHD and haemophilia clinicians in Scotland, whether individually or collectively. In particular, please address the following:

- a. ***the lines of communication between the SHHD and clinicians, including how information was shared;***
- b. ***the principles and policy objectives which underpinned the relationship between the SHHD and clinicians;***
- c. ***the internal structure at the SHHD for managing the relationship with clinicians;***
- d. ***how the SHHD ensured clinicians were informed and kept up to date about the risk of infection from blood and blood products;***

e. ***how information received from clinicians was communicated to ministers, including the standard information ministers would be briefed on when first taking office;***

f. ***how ministers were kept up to date with developments from clinicians.***

34.1 The relations between SHHD and the haemophilia directors (who worked for the health boards, and had direct contact with patients) were the responsibility of the CMO's staff and, although I recall attending part of one meeting between them, I have insufficient knowledge to answer these questions.

35. Please answer the same question in relation to the UK Haemophilia Centre Directors' Organisation ("UKHCDO").

35.1 I do not recall such a body and cannot answer questions about it.

Relationships between the SHHD and commercial pharmaceutical organisations

36. Please describe the relationships between the SHHD and pharmaceutical companies involved in the manufacture, importation and/or supply of blood products. What role, if any, did you play in such relationships, and what structures were in place to manage and facilitate the relationship?

36.1 I played no role in these relationships which, if they existed, would have been the responsibility of SHHD's Chief Pharmacist.

Section 6: Licensing and regulation of blood and blood products

37. The Inquiry understands that, during the 1970s and 1980s, the UK licensing authority for medicines was formally comprised of the Secretaries of State for Health, Agriculture and Scotland. During your time there, what role did the SHHD play in relation to the licensing and regulation of blood and blood products?

37.1 The SHHD role in medicines licensing was the responsibility of the Chief Pharmacist and I had only a peripheral involvement. It seems to me that the

answer to the question appears in his letter of 16 November 1987 to Jim Donald (PRSE0003017).

38. ***Insofar as you are able to do so, please explain how PFC blood products were licensed or, if not licensed, what regulatory oversight was in place to ensure the safety of these products. As well as the documents listed below in relation to compensation/indemnity arrangements for Z8, you may be assisted by the following:***

- ***Your note of a 26 October 1987 meeting [PRSE0004722].***
- ***Note of a 13 November 1987 meeting [PRSE0001713].***
- ***16 November 1987 letter from Graham Calder [PRSE0003017].***
- ***25 November 1987 letter from Professor Cash [SBTS0000473_284].***
- ***Note of an 8 January 1988 meeting [PRSE0001655].***
- ***Your 18 July 1988 letter to the CSA [SCGV0000126_073].***
- ***20 July 1988 letter from Professor Cash [PRSE0000462].***
- ***Chapter 12 of the Penrose Inquiry Preliminary Report, "Licensing" [PRSE0007003 internal pp.532-537].***

38.1 This is a complicated matter in which I was only slightly involved: the SHHD responsibility lay with the Chief Pharmacist. I do not recall anything which adds to the information given in the documents listed above. It seems to me that the note of the 26 October 1987 meeting, which was one of a series of joint SHHD/CSA/SNBTS meetings intended to make progress on various topics affecting the SNBTS, gives a good summary of the position.

39. ***In relation to product licences, the note of the 13 November 1987 meeting records you as having said that "there was a theoretical risk that a licence for a safe, efficacious BTS product might be refused unless a change was made which was outwith the ability of the Crown to achieve" [PRSE0001713]. To the best of your ability, please explain what you meant by this comment.***

39.1 I am at a loss to know what I meant. So, evidently, was the reader who wrote "?? Example" in the margin.

Section 7: Knowledge of and response to risk/safety of blood and blood products

40. What decision-making structures and processes were in place (and with what oversight) during your time at the SHHD:

a. ***for ensuring that the SHHD was kept informed of developing knowledge (internationally and/or domestically) about the risks arising from blood and blood products and the various national and international responses to such risks?***

b. ***for briefing ministers about the risks from blood and blood products, including any risks posed by the purchase of commercially supplied blood products?***

c. ***for ensuring that ministers and the CMO for Scotland were kept informed of changes in the understanding of relative risk?***

40.1 So far as I can recollect, SHHD was kept informed on that important topic principally through the SNBTS, because its staff (particularly John Cash) had the necessary international and UK links. To some extent, the staff of the CMO were also able to do so, but they were less expert and less specialised. The normal process for briefing ministers, which I have already described in response to question 12, would have applied to the subject, while the CMO would have been kept in touch by his own staff.

41. What kinds of decisions, relating either to the risks arising from blood and blood products or the response to such risks, would be taken personally by (a) ministers or (b) the CMO for Scotland? Please provide any relevant examples.

41.1 There was as far as I remember no set categorisation of decisions of the kind implied by the question.

42. When you joined the SHHD, what was your knowledge and understanding and (to the best of your knowledge) that of the SHHD:

a. ***of the risks of infection associated with blood and blood products;***

b. ***of the risks of the transmission of hepatitis from blood and blood products;***

c. ***of the nature and severity of the different types of blood borne viral hepatitis;***

d. ***of the relative risks of infection from the use of commercially supplied blood products and the use of domestically sourced blood and blood products?***

42.1 My memory, after more than 35 years, may not be perfect. But my recollection is that, in mid-1986, the risk of transmitting HIV through blood or blood products had been eliminated by heat treating; that there was still a worry that other infections (particularly what was then known as non-A non-B hepatitis, hepatitis C having not then been identified) might be capable of transmission; that non-A non-B hepatitis, while a matter of great concern like other forms of hepatitis, was a much less serious condition than HIV; and that SNBTS blood and blood products were likely to be less risky than those from other sources, because of the excellent pool of voluntary donors and because of the care taken in fractionation. That recollection may not be entirely correct: it should be verified from contemporary sources.

43. How, if at all, did your knowledge and understanding of these issues develop or change during your time at the SHHD? Who or what were the sources of your knowledge and understanding of these issues during this time?

43.1 The quality of blood and blood products was a matter of great concern and energetic international research, with which SNBTS (and to a lesser extent SHHD's medical staff) kept in touch. They will have been the source of my knowledge of the subject, although I do not recall the detail.

44. What was your and the SHHD's understanding of NANB hepatitis and the potential harm it posed to those infected by it? As well as the documents referred to below in relation to surrogate testing for NANB hepatitis, you may wish to consider the enclosed 30 August 1988 minute from Dr Forrester [PRSE0003962].

44.1 My understanding at the time was that, although the nature of NANB hepatitis was not fully known, it was (like other forms of hepatitis) a serious illness – though not as malign as HIV. John Forrester's minute (PRSE0003962) makes only a passing reference to the subject: it should not in my view be taken as the sum of his (or the Department's) knowledge. Chapter 16 of the report of the Penrose Inquiry analyses what was known about NANB hepatitis in the relevant period and (because the scope for infection through blood products was a live and important matter) a digest of that information is likely to have been provided by the SNBTS to SHHD, and in particular to the medical staff of the Department, although I cannot recall the details.

45. Please explain what if any steps were taken (and when and by whom) to ensure that the serious nature of NANB hepatitis was known to, and understood by:

- **a.** ***ministers;***
- **b.** ***the CMO for Scotland;***
- **c.** ***clinicians;***
- **d.** ***NHS bodies;***
- **e.** ***patients who were or might be treated with blood or blood products;***
- **f.** ***the public.***

45.1 I do not have the recollection and knowledge necessary to answer this question authoritatively and have no knowledge whatsoever about the information flow to clinicians, other staff in NHS bodies, patients or the public. The CMO would in my opinion have been kept informed by his professional staff, but I have no evidence of that. I would have been involved in communicating with ministers and I recollect no such communication. Any such communication would in my opinion have been in the context of a decision on action which should be taken to reflect the growing understanding of NANB hepatitis, rather than a change in the understanding per se.

Section 8: Heat-treatment/viral inactivation

Development of heat-treated products and links between PFC and BPL

46. Please describe your role in the development of virally inactivated PFC concentrates in Scotland. In doing so, please address what you knew, and when, about the effectiveness of PFC's inactivation methods against HTLV-III/HIV and NANB hepatitis. As well as the documents referred to below in relation to compensation/indemnity arrangements for Z8 and surrogate testing for NANB hepatitis, you may wish to consider the enclosed minutes of the 5 March 1986 meeting of SNBTS and haemophilia directors [PRSE0001081], as well as a report prepared by Dr Perry for that meeting [PRSE0003457].[2]

46.1 I had no direct role in the development of virally-inactivated concentrates: that was the responsibility of the SNBTS. I would have drawn my knowledge of the matter from the SNBTS, both directly and through my medical colleagues. SHHD was, before and during my involvement, entirely supportive of the SNBTS's work on viral inactivation, which is exemplified by Bob Perry's comment in PRSE0003457 that "This programme of work [viral inactivation of Factor VIII] has been afforded the highest priority over the past twelve months."

47. In his evidence to the Penrose Inquiry, Professor Cash stated that there were no formal links between the Bio Products Laboratory ("BPL") and PFC, and that such links "did not enjoy the support of Ministers" [PRSE0000651 p.7]. He suggested that a formal relationship was "in the public interest" (p.7) and "may have made a significant difference" to research and development, particularly in respect of heat-treated products (p.5).

Do you agree with Professor Cash's assessment that a formal relationship between BPL and PFC was desirable, but lacked support from ministers? Please explain your response.

[2] The meeting took place shortly before you joined the SHHD but was attended by Dr McIntyre and Mr Morison.

a. ***If that is your view, why did ministers not support such a relationship?***
b. ***In your view, did a lack of ministerial support have a material effect on the relationship between BPL and PFC? What was the impact on research and development, particularly in respect of heat treated products?***
c. ***Please provide any further comment that you consider to be relevant on the degree of co-operation between BPL and PFC (be it on a formal or informal basis) and how that affected research and development (i) in respect of heat-treated products, and (ii) more generally.***

You may be assisted by the following documents, referred to in your evidence to the Penrose Inquiry [PRSE0001934]: 12 March 1986 NBTS committee minutes [PRSE0000128]; 11 December 1986 letter from Dr Gunson to Professor Cash [DHSC0001732]; 9 April 1987 response from Professor Cash to Dr Gunson [DHSC0001731]; Dr Forrester's note of the 17 June 1987 NBTS advisory committee meeting [PRSE0002034].

47.1 As I made clear in my evidence to the Penrose Inquiry, I agree with John Cash that formal links between BPL and PFC would have been desirable – although they would have been no substitute for the good working-level links to which John Cash also refers in PRSE0000651. I have no evidence that ministers were opposed to formal links, nor can I see any reason why they would be. In my period of involvement, I do not recollect any opposition from Scottish ministers, who were in principle supportive of formal liaison in 1989 at least, as PRSE0000967 shows. At official level, SHHD would have welcomed formal arrangements on research, as PRSE0002034 demonstrates. DHSC0001731 and BPLL0007211 suggest that, in 1987 at least, it was SNBTS which opposed formal machinery, for reasons summarised in BPLL0007211.

47.2 I have no view on whether the problems of relationship between BPL and PFC delayed developments. The conclusion of the Penrose Inquiry (paragraph 24.245 of its report) was that "There was ample circumstantial evidence illustrating the extent of cooperation, if seldom collaboration,

between responsible officers of the two organisations in the exchange of data and of their experimental and development findings……this openness was not a characteristic of relationships between senior management of the organisations, but there was no evidence to suggest that there were consequential difficulties among scientists."

Compensation/indemnity arrangements for Z8

48. ***Please describe your involvement in the SHHD's consideration of compensation/indemnity arrangements for the clinical evaluation and use of Z8, a heat-treated PFC concentrate. In doing so, please outline the roles of the SHHD, CSA, DHSS and Treasury (and any other relevant bodies). As well as your evidence to the Penrose Inquiry on this issue [PRSE0002830 and PRSE0006061 pp.150-168], you may be assisted by the following documents:***

- ***5 December 1986 letter from Dr Boulton to Professor Cash (copied to Dr Forrester) [PRSE0003951].***
- ***11 December 1986 letter from Dr Ludlam to Professor Cash [PRSE0000696].***
- ***29 December 1986 minute from Drs McIntyre and Forrester [PRSE0003720].***
- ***5 January 1987 letter from Dr Ludlam to Professor Cash [PRSE0003282].***
- ***7 January 1987 minutes to you from Dr Forrester [PRSE0002267 and SCGV0000217_087].***
- ***9 January 1987 letter from Dr Ludlam to Professor Cash [PRSE0002134].***
- ***9 January 1987 minute to you from Graham Calder [SCGV0000217_080].***
- ***13 January 1987 letter from Professor Cash to Dr Ludlam [PRSE0003297].***
- ***14 January 1987 letter from Mr Kernohan to the Miss Everest-Phillips [PRSE0003888].***
- ***5 February 1987 letter from the Treasury to the DHSS [PRSE0002950].***
- ***5 February 1987 letter from Professor Cash to the CSA [PRSE0003850].***
- ***6 February 1987 letter from Mr Murray to Professor Cash [PRSE0000760].***

- ***Minutes of the 9 February 1987 meeting of SNBTS and haemophilia directors [PRSE0002769].***
- ***Your 10 February 1987 minute [SCGV0000217_064].***
- ***11 February 1987 response from Mr Calder [SCGV0000217_062].***
- ***Extract from papers for a 25 February 1987 meeting [PRSE0004718].***
- ***26 February 1987 note from Dr Forrester to Mr Murray [PRSE0004360].***
- ***12 March 1987 letter from Dr Ludlam to Dr Forrester [PRSE0000948].***
- ***25 March 1987 minute from Dr Forrester to you and others [PRSE0001132].***
- ***Note of a 31 March 1987 meeting [SBTS0000484_002].***
- ***4 June 1987 minute to you from Mr Murray [SCGV0000217_034].***
- ***Minutes of the 10 June 1987 SNBTS directors' meeting [PRSE0000633].***
- ***10 June 1987 letter from Mr Murray to the CSA [PRSE0000037].***
- ***11 June 1987 letter from Dr Ludlam to Dr Forrester [PRSE0003563].***
- ***Your 23 June 1987 letter to Professor Cash [SCGV0000217_028].***
- ***25 June 1987 letter from Professor Cash to Dr Ludlam [PRSE0000866].***
- ***30 June 1987 letter from Dr Ludlam to Professor Cash [LOTH0000010_038].***
- ***6 July 1987 letter from Dr Ludlam to the MDU [LOTH0000010_047].***
- ***6 July 1987 letter from Dr Ludlam to Dr Leonard and Dr Leonard's response [PRSE0004430].***
- ***8 July 1987 letter from Professor Cash to you [PRSE0002256].***
- ***17 July 1987 minute from Dr Forrester [SCGV0000217_015].***
- ***24 July 1987 letter from Dr Forrester to Dr Ludlam [PRSE0003573].***
- ***9 November 1987 letter from you to Professor Cash [LOTH0000010_040].***
- ***19 November 1987 letter from Dr Ludlam to Professor Cash [LOTH0000010_043].***
- ***Your 21 June 1988 letter to Professor Cash [SBTS0000414_130].***
- ***Your 3 November 1988 letter to Mr Donald [SBTS0000666_068].***

48.1 I have nothing to add to my written and oral evidence to the Penrose Inquiry (PRSE0002830 and PRSE0006061). The report of the Penrose Inquiry

(volume 3, paragraphs 24.160 – 24.165 and 24.209 – 24.225) gives an authoritative account of all the evidence, concluding that the compensation issue briefly delayed clinical trials, though not the supply of the new product to patients.

49. So far as you understand it, why had the question of compensation/indemnity arrangements for clinical trials of PFC products not been resolved by late 1986? In your view, what, if any, responsibility did the SHHD bear for the lack of resolution by this point? Are there other bodies whom you think bear responsibility?

49.1 To the best of my recollection, the question had not been resolved because, under pressure of other tasks, my Division had put it to one side until it became critical. Once Chris Ludlam had made clear that he would not start clinical trials unless compensation was available, we focussed on his immediate concern (compensation for patients on whom the new product would be trialled non-therapeutically) and resolved it quickly, separating it from the wider and more open-ended question of a scheme covering all clinical trials of all possible future SNBTS products.

49.2 I do not think that other bodies had a significant responsibility for the delay. My colleagues had for some time hoped that the CSA (bringing together the expertise of the SNBTS and the Central Legal Office, which was also part of the CSA) would have devised a compensation scheme. The task was however too complex for the CSA and I do not recall that any progress had been made by December 1986, when the matter became critical.

50. Please explain why the issue took several more months to resolve during the course of 1987, both with respect to: i) putting in place compensation/indemnity arrangements for the first phase of the Z8 trial; ii) extending the arrangements to cover therapeutic treatment pending the grant of a product licence. Do you consider that the SHHD, or any other body, bore any responsibility for the time it took to resolve this issue? Either way, please provide reasons for your answer.

50.1 My recollection is that, having resolved Chris Ludlam's immediate concerns, allowing the clinical trial to proceed, we turned to the wider question of a compensation scheme for other clinical trials including therapeutic treatment. That was a less urgent matter, because the absence of a scheme was not holding up developments, and it was more problematic because it gave rise to a greater potential liability for the taxpayer. We were however able to establish the wider scheme, covering the whole period of clinical trials (of Factor VIII) by November 1987 (LOTH0000010_043). Again, SHHD was responsible for the time taken to set up the scheme.

Availability of 8Y

51. As far as you can from your recollection and the documents provided or made available to you, please describe what you knew, and when, about the development and effectiveness of virally inactivated concentrates in England and Wales (in particular, the BPL product 8Y).

51.1 I do not recall anything about this. I would have gleaned such knowledge from the SNBTS, either directly or through my medical colleagues. There is an excellent account of the matter in Chapter 24 of the report of the Penrose Inquiry, which suggests (paragraph 24.31) that the SNBTS may have gained that knowledge in September 1986, albeit cautionary and unconfirmed. I would have heard of that later – perhaps not immediately.

52. What role, if any, did you or SHHD colleagues have in disseminating knowledge in Scotland about the effectiveness of 8Y in inactivating HTLV-III/HIV and NANB hepatitis? If you did not have such a role, do you know who (if anyone) did?

52.1 I do not recall being involved in that subject. It would I think have been a matter for the expert staff of SNBTS, who had direct lines of communication with the relevant clinicians.

53. So far as you can recall, did you or SHHD colleagues take any steps to obtain supplies of 8Y to be used in Scotland during: i) the period in which Z8 was being developed; ii) the period following the development of Z8, before it

was available for clinical trials and general use? If not, do you consider that the SHHD should have taken such steps, in particular with respect to previously untreated patients? You may wish to consider paragraphs 22.41-22.74 and 24.19-24.34 of the Penrose Inquiry Final Report [PRSE0007002 internal pp.907-915 and internal pp.1017-1020], as well as the minutes and accompanying report of a meeting between SNBTS and haemophilia directors on 5 March 1986 [PRSE0001081 and PRSE0003457].[3]

53.1 It was not the role of SHHD to obtain supplies of 8Y or any other blood product. That was the role of individual clinicians, informed by their contacts with colleagues including the SNBTS. There was as far as I can remember no bar to their prescribing blood products from any source, including commercial pharmaceutical firms and, as paragraphs 22.54 – 22.69 of the report of the Penrose Inquiry shows, Chris Ludlam obtained a supply of 8Y for his patients in mid-1986 (although the product was unproven and supplies at the BPL were slender).

Section 9: Donor selection/screening

NANB surrogate testing

54. Please describe your role in decisions concerning the potential introduction of surrogate testing for NANB hepatitis for blood donors in Scotland. The evidence you gave to the Penrose Inquiry on this issue is enclosed to assist you [PRSE0002324, PRSE0006065 pp.132-188 and PRSE0006078 pp.1-36], in addition to the following documents:

- ***SNBTS 1986 public expenditure survey programme narrative [PRSE0001473].***
- ***Dr Forrester's 12 June 1986 note [PRSE0000857].***
- ***Dr Forrester's 30 June 1986 minute to Dr McIntyre [PRSE0000017].***
- ***Alexander Murray's 21 October 1986 minute to Dr Scott [PRSE0004313].***
- ***Mr Murray's 12 November 1986 minute to you [SCGV0000135_049].***

[3] It is noted that the 5 March 1986 meeting took place shortly before you joined the SHHD, but that it was chaired and attended by SHHD officials. So far as you can, please address what, if any steps, you/the SHHD took in response to the developments described at the meeting.

- ***Dr Forrester's 26 January 1987 note [PRSE0001376].***
- ***Minutes of the 3 March 1987 meeting of SNBTS directors [PRSE0004163].***
- ***Dr McIntyre's 6 April 1987 minute [PRSE0000618].***
- ***Dr Scott's 7 April 1987 minute to Dr McIntyre [PRSE0002916].***
- ***Your 9 April 1987 minute to Dr McIntyre [PRSE0000784].***
- ***1 May 1987 note to you from Dr Forrester, enclosing an article from the Lancet [SCGV0000163_171].***
- ***14 May 1987 minute from Dr Forrester [PRSE0001191].***
- ***14 May 1987 minute from Dr Scott [PRSE0002731].***
- ***18 May 1987 minute from Dr Forrester [PRSE0001663].***
- ***Dr Mcintyre's 21 July 1987 minute to you with 23 July annotation [PRSE0004562].***
- ***22 July 1987 minute from Mr Calder [SCGV0000217_009], commenting on 6 July 1987 letter from Dr Ludlam [LOTH0000010_028].***
- ***Dr Forrester's 20 August 1987 minute with 2 September annotation [PRSE0000607].***
- ***Dr Forrester's 1 October 1987 minute to you [PRSE0004545].***
- ***Your 2 October 1987 minute [PRSE0003515].***
- ***7 October 1987 minute to you from Dr Forrester [PRSE0003307].***
- ***17 December 1987 minute from Dr Forrester [PRSE0001159].***
- ***SNBTS 1987 public expenditure survey [PRSE0003941].***
- ***Alexander Murray's C2 statement to the Penrose Inquiry [PRSE0000662], which the Inquiry understands was provided to you during your evidence to Lord Penrose.***
- ***George Tucker's C4 statement to the Penrose Inquiry [PRSE0002387], which the Inquiry understands was provided to you during your evidence to Lord Penrose.***

54.1 The role of the SHHD, of which I was a senior staff member, was to consider, in the light of emerging evidence including the advice of the SNBTS, whether the surrogate testing of Scottish blood donations should be introduced. My recollection is that our consistent and unanimous conclusion, throughout the

period to which these documents relate, was that there were insufficient scientific or medical grounds for its introduction.

55. In June 1986, Dr Forrester addressed the introduction of NANB hepatitis in a minute summarising a recent meeting of SNBTS directors [PRSE0000017], as well in a note [PRSE0000857]. You suggested to the Penrose Inquiry that you would not have seen these documents when they were prepared, as they were not addressed to you, but that you would have subsequently when reviewing the file.

- **a.** ***So far as you can recall, did you have any concerns about the extent to which the documents relied on information in a PhD thesis, completed in 1985, by Dr Dow? If so, did you request any additional information? If not, please explain why not.***
- **b.** ***In particular, did you have any concerns about Dr Forrester's suggestions that NANB hepatitis was "not as a rule serious" [PRSE0000857] and "heterogeneous and generally mild (except in pregnant women)" [PRSE0000017].***
- **c.** ***Similarly, did you seek any additional information in relation of the conclusion summarised in Dr Forrester's documents (namely, that the cost of introducing surrogate testing in Scotland would be extremely high and the benefit minimal)?***

55.1 The question implies that Dr Dow's thesis, and John Forrester's short summary of the nature of NANB hepatitis, was the only source of information available to SHHD on the subject. That is incorrect. In reality, as chapter 27 of the report of the Penrose Inquiry illustrates, we had access (through the SNBTS and the DHSS) to an increasing amount of information on the seriousness of NANB hepatitis; the extent to which it might be transmitted by blood transfusion (although there was a lack of UK data on that subject, which SHHD and DHSS sought to remedy by a research project involving English and Scottish blood transfusion centres, as PRSE0000618 shows); the effectiveness of surrogate testing in reducing the risk to patients; and the other consequences of introducing testing (including the loss of blood donations and the effect on blood donors).

56. The SNBTS 1986 funding bid included a figure for NANB hepatitis surrogate screening in 1987/1988 [PRSE0001473]. Dr Scott, Deputy CMO, sought clarification on the SNBTS's request in a 16 October 1986 minute to Dr Forrester and Mr Murray, highlighting the need to involve the DHSS [PRSE0004812].

- **a.** ***To the best of your knowledge and understanding, why would the "CMO DHSS"[4] have been "worried" that, if Scotland introduced the screening, England and Wales would "have to follow suit"?***
- **b.** ***Did you agree with Dr Scott that there would need to be "consultation with DHSS" before the SHHD agreed to fund the screening? If so, what would such consultation involve?***
- **c.** ***So far as you can recall, were you involved in discussions around this time with Dr Scott, the CMO for Scotland (Dr Iain Macdonald) and/or the DHSS about introducing surrogate screening? If so, please describe, so far as you can, the content and effect of such discussions on your view as to whether screening should be introduced.***

56.1 We had so far as I can recall no reason to think that the problem of blood-borne NANB hepatitis, or the effectiveness of surrogate testing, in Scotland was any different from that in the rest of the UK. It seemed sensible therefore for the Health Departments to take the same decision on the introduction of testing. That may have been the reason (I have no direct knowledge) for the English CMO's worry, and for Graham Scott's concern that we should consult the DHSS before acting. We did indeed keep in touch with the DHSS (consultation would have involved an exchange of correspondence at official level, probably augmented by telephone conversations, although I have no recollection of the detail). It is clear from the Penrose Inquiry report that the SNBTS kept in touch with its comparator in England.

56.2 I recall many discussions, and exchanges of correspondence, with my medical colleagues on the subject. While we will have reviewed the matter repeatedly over the period, we always came to the same unanimous conclusion – that there was an insufficiently strong case for introducing testing.

[4] I.e. the CMO for England.

I do not recall any personal contact with the DHSS on this subject but I would certainly have known that they (and their experts in the NBTS) were also unconvinced that surrogate testing should be introduced. That will have reinforced our conclusion.

57. In a 21 October 1986 minute, Mr Murray informed Dr Scott that the SNBTS's funding request for screening had not been included in the SHHD's bid [PRSE0004313].

- **a. *So far as you can, please describe your involvement in the decision not to bid for funding for surrogate screening in 1987/88, as well as the rationale behind it.***
- **b. *To the best of your recollection, did you or others in the SHHD seek further information from the SNBTS, Professor Cash or any other source before making this decision?***

57.1 In answer to (a), I do not recall the details but I would certainly have been involved in the decision, which would have involved also my boss (Hugh Morison) and the Deputy Chief Medical Officer (Graham Scott), who were the SHHD representatives on the CSA's Blood Transfusion Committee.

57.2 In answer to (b), we almost certainly sought further information about the proposal from the SNBTS – because the few lines of text in the funding request were an insufficient basis for a decision – but I do not recall the details.

58. In a 26 January 1987 memo, "Material for PMO Report", Dr Forrester described NANB hepatitis as a "residual rag-bag when Hepatitis B and Hepatitis A are excluded" and as "relatively benign" [PRSE0001376].

- **a. *What was the "PMO Report" and what was the purpose of this memo? So far as you can recall, did you see the memo at the time or subsequently?***
- **b. *If so, what did you understand Dr Forrester to mean when describing NANB hepatitis as "relatively benign"? Did you accept Dr Forrester's description or seek any additional evidence?***

c. ***Did anyone challenge Dr Forrester's characterisation of NANB hepatitis as "relatively benign"?***

58.1 In answer to (a), "PMO" was the abbreviation for Principal Medical Officer. Archie McIntyre, John Forrester's boss, was the PMO concerned with blood and blood products. I do not know, however, what the "PMO Report" was. The brevity and shorthand style of John Forrester's contribution suggest that it may have been a periodic report by each PMO to the CMO, briefing the latter on current issues.

58.2 In answer to (b), I do not recall seeing the memo at the time, but I saw it in the course of Lord Penrose's inquiry. I do not know what John Forrester meant by the term – a matter on which he was questioned orally by the Penrose Inquiry.

58.3 In answer to (c), I do not recall.

59. At a 3 March 1987 meeting attended by Dr Forrester, SNBTS directors agreed to recommend to the SHHD "that surrogate testing for NANB should be implemented with effect from 1 April 1988 as a national development requiring strictly new funding" [PRSE0004163]. So far as you can recall, were you aware of and did you understand the reasons for the SNBTS's recommendation? If so, please explain your understanding of the SNBTS's reasoning at the time. Did you seek any further explanation of the SNBTS position by contacting Professor Cash or others?

59.1 I well recall the recommendation. It came as a surprise, because we knew that the SNBTS directors shared our reservations about the scientific basis of surrogate testing. Their reasoning needed to be elucidated. I cannot now remember how we did so, although it would have been most natural for us to have asked John Cash. The papers listed above, and the report of the Penrose Inquiry (paragraphs 27.160 – 27.185), show that the directors did not have clear evidence of the value of surrogate testing but thought it likely that they would be forced to follow other counties in so introducing it, to avoid claims

that their product was less safe. I would no doubt have gleaned that at the time, either directly from John Cash or via John Forrester.

60. In a 6 April 1987 minute, Dr McIntyre summarised the background to this issue and the SNBTS position, and proposed that Scotland should take part in research proposed by the UK Transfusion Associated Hepatitis Working Party before "embarking on such an expensive programme" [PRSE0000618]. In a manuscript note, Mr Morison set out his initial reaction and asked for your advice.

- **a. *Did you agree with Dr McIntyre's summary of the reasons why the SHHD had declined the SNBTS's 1986 request for funding for screening?***
- **b. *Was Dr McIntyre's description of the SNBTS's reasons for proposing the screening the same as your understanding?***

60.1 In answer to (a), I agree with Archie McIntyre's summary, except that it puts particular stress on the previous CSO-funded study, whereas my recollection is that there was other evidence of low incidence of transfusion-related transmission of NANB hepatitis in Scotland. The relevance of the study to his minute may have been that it was CSO funded, and his minute was proposing further CSO-funded work.

60.2 My understanding of the SNBTS's motivation (b) is given in my answer to question 59. Archie McIntyre's minute expresses much the same understanding, more briefly.

61. You and Dr Scott responded to Dr McIntyre in minutes dated 7 and 9 April 1987 [PRSE0002916 and PRSE0000784].

- **a. *What did you understand Dr Scott to mean by: "We must do whatever we can to prevent the BTS going ahead with a full scale introduction of this testing – or at least trying to blackmail us into the provision of funds"?***
- **b. *Which sources of finance for the Edinburgh research proposal was Dr Scott referring to?***

c. ***Please explain why, as recorded in your minute, you and Mr Morison entirely agreed with Dr Scott's comments. In doing, please expand on your comment that it was "important that the decision on whether or not to screen all blood for Non-A and Non-B Hepatitis, which will not be cheap and may not be certain, should be taken on the basis of the sort of UK research" Dr McIntyre had suggested.***

d. ***What was your understanding of the anticipated length of time for UK research into screening to be carried out? So far as you can recall, what were the sources for your understanding?***

61.1 I do not recall in detail.

61.2 On (a), Graham Scott was expressing the scepticism we all shared, about the value of surrogate testing and was reflecting also our view that UK-wide action was necessary.

61.3 On (b), the normal source of funding for the research at the Edinburgh Blood Transfusion Centre would be SHHD's Chief Scientist Office, which held the department's research budget, and it is clear that Graham Scott had that source in mind.

61.4 On (c), Hugh Morison and I agreed with Graham Scott because he was restating briefly the views which we all shared. My comment reflected the widely-held maxim that policy should be based on evidence, which was incomplete in this case and would be greatly improved by the proposed research – particularly because it had been advocated by the relevant expert UK working party.

61.5 On (d), I do not recall knowing what timescale was proposed.

62. ***In his 14 May 1987 note, which was copied to you, Dr Forrester wrote that "we are under pressure to spend some 800k annually on screening all blood donations in an indirect way, in the hope of some reduction in transmission of this group of diseases" [PRSE0001191]. Please explain what you***

understood Dr Forrester to mean by this comment, and whether you shared his view.

62.1 I do not recall my contemporary reaction, but it seems to me that John Forrester was correctly summarising the position at the time, to remind his boss of the context. I seem to have been puzzled about a different part of his note, which he clarified.

63. ***On 13 June 1987, the Lancet published letters arguing against the introduction of NANB surrogate testing without further research, including one co-authored by Dr Dow [PRSE0002104]. On 4 July 1987, it published a letter from Professor Cash and others, which proposed that surrogate testing be introduced without further research [PRSE0001444]. These letters were referred to in a 21 July 1987 minute from Dr McIntyre to you [PRSE0004562].***

    a. ***As far as you can recall, did you read the letters themselves at the time? Were you aware of either or both of them before they were published?***
    b. ***If you did read the letters, what was your response to Professor Cash's suggestion that research into surrogate testing would take 3-4 years, and that the time for it had passed?***
    c. ***What was your response to the other reasons advanced in Professor Cash's letter? In particular, what was your view of the suggestion that surrogate testing was necessary as a result of new product liability legislation? You may be assisted by the enclosed 13 February 1987 minute from Graham Calder [PRSE0002005], as well as your 23 February 1988 letter [SCGV0000227_082].***
    d. ***How likely or realistic was the possibility, outlined in Dr McIntyre's minute, that the SNBTS would seek to introduce surrogate testing without additional funding and without the SHHD's approval?***
    e. ***Dr McIntyre described the DHSS's "concern and dismay at the letter by Professor Cash and colleagues", which had been interpreted as SHHD policy. At this stage, how influential was the DHSS in the SHHD decision not to accept the case for screening without further research?***

f. ***Is the manuscript note on Dr McIntyre's minute yours? If so, what does it say?***

63.1 On (a), I read the Lancet articles at the time. On (b), I do not recall having any reaction.

63.2 On (c), I do not think (although I cannot now recall the details) that our view on surrogate testing would have been affected by the introduction of product liability under the Consumer Protection Act 1987. The essence of product liability, as paragraph 4 of my letter of 23 February 1988 makes clear, is that a litigant who had allegedly suffered damage from a blood product would no longer have to prove negligence on the part of the SNBTS, as well as proving that the damage occurred and that the product was defective. But that was a lower test than we already expected the SNBTS to meet. We were reasonably confident that they would not be negligent. What mattered was whether the product was defective. On that, surrogate testing was, SHHD and SNBTS agreed, by no means a conclusive safeguard. The SNBTS advocacy of testing was not because it would make the product safer, but rather that it would give more assurance to clinicians and others, at a time when some commercial producers were undertaking testing.

63.3 On (d), we had been surprised by the SNBTS Directors' advocacy of surrogate testing, so could not have guaranteed that they would not act unilaterally, perhaps at one Centre. At the time, I would almost certainly have thought that unlikely to happen in the short term (the SNBTS proposal was not to start testing until 1 April 1988) or in the longer-term (it was patently a costly step and the SNBTS had understandably made clear that it could not go ahead without special funding). But it was theoretically possible.

63.4 On (e), I cannot recall. The English Blood Transfusion Service Directors' hostility to the introduction of surrogate testing will have played a part in our assessment that we should not introduce it but I do not remember the DHSS's view being influential.

63.5 On (f), the manuscript note is Hugh Morison's and it says: "Mr Macniven: Advice please. My initial reaction is (a) it would not make sense to screen all blood for non-A non-B. The benefits appear out of all proportion to the risks. (b) we should therefore participate in the Research (c) CSO should be encouraged to fund it."

64. The Inquiry understands that the question of whether and when to introduce NANB surrogate screening in Scotland was never put to SHHD or Scottish Office ministers.

- **a.** ***So far as you are aware, is that correct?***
- **b.** ***If so, what consideration, if any, had you or SHHD colleagues given to involving a ministerial decision-maker by mid-1987? For example, was there such consideration after the 3 March 1987 SNBTS meeting, or following Professor Cash's letter in the 4 July 1987 Lancet?***
- **c.** ***If a decision was taken not to involve ministers, please explain the basis for it. In doing so, please explain whether any steps were taken to inform ministers of the issue (rather than seek a decision). If no such steps were taken, please explain why not.***

64.1 In response to (a), as far as I am aware that is correct.

64.2 In response to (b), I cannot recall.

64.3 In response to (c), it was a matter of judgement whether and when to put a decision to ministers, who had wide responsibilities and had many decisions to take. We would not have put a matter to ministers simply for information: that would have been tantamount to asking them to take a decision on the matter. We would have put to ministers any decision to introduce surrogate testing, because of its expenditure implications – particularly if it were not planned to introduce it in the rest of the UK. Although I do not remember a conscious decision, we would (it seems to me from a reading of the documents you have provided) have concluded that the arguments against its introduction

were sufficiently decisive that it was unnecessary to refer the question to ministers.

65. On 2 October 1987, you responded to a minute from Dr Forrester concerning surrogate testing [PRSE0004545 and PRSE0003515]. You wrote that you were "very anxious indeed" for the SHHD's decision on "whether or not to put resources into NANB testing" to be "properly informed by research evidence", and that the "worst of all possible worlds" would be that "research cannot get off the ground".

a. ***At this stage, what was the timescale in which you envisaged that research would or could be completed in order to inform a decision on surrogate screening?***

b. ***Did you consider that "increasingly irresistible pressure to spend the money in any case" would be avoided by research being started, even if it was expected to take 3-4 years (as suggested by Professor Cash)?***

65.1 I do not recall being concerned about the timescale. I was concerned to obtain the information necessary to take a proper decision.

66. If it had reached the conclusion that surrogate testing should be introduced in Scotland, could the SHHD have done this without the DHSS's agreement? In your view, would such a step have been taken?

66.1 As the circumstances were similar in all parts of the UK, my recollection is that we and the DHSS were of one mind: that the health departments should co-ordinate any introduction of testing (as was in fact done when direct testing, for hepatitis C which had by then been identified, was started in 1991). So, while theoretically surrogate testing could have started in Scotland without DHSS agreement, the question is hypothetical.

Use of unscreened material

67. Please describe your involvement in decision-making around the PFC's use of plasma stocks which had not been screened for HIV. In doing so, please

confirm whether the Inquiry is correct to understand that this issue related to plasma intended for purposes other than the manufacture of factor concentrates. You may wish to consider the following enclosed documents:

- ***21 April 1987 letter to you from Professor Cash, with enclosure [SCGV0000215_114 and SCGV0000215_115].***
- ***27 April 1987 minute from Dr Forrester [SCGV0000215_058].***
- ***Your 1 May 1987 letter to Professor Cash [SCGV0000215_056].***
- ***6 August 1987 minute from Dr Forrester [SCGV0000215_045].***
- ***Your 25 August 1987 minute [SCGV0000215_035].***
- ***27 August minute from Dr Forrester [SCGV0000215_034].***
- ***Your 11 September 1987 letter to Dr Perry [SCGV0000215_032].***
- ***Note of a 19 October 1987 meeting [BPLL0010087].***
- ***Your 25 November 1987 minute [SCGV0000216_145].***
- ***4 December 1987 minute from Felicity MacFarlane [SCGV0000216_140].***
- ***Your 8 December 1987 minute [SCGV0000216_131].***
- ***11 December 1987 minute from Dr Forrester [SCGV0000216_130].***
- ***Your 25 February 1988 draft submission [SCGV0000216_100].***[5]
- ***Your 13 May 1988 letter [SCGV0000216_044].***
- ***10 June 1988 letter to you [SCGV0000216_040].***
- ***Your 29 November 1988 minute and draft submission [SCGV0000216_162 and SCGV0000216_163].***
- ***7 December 1988 minute from Mr Lugton [SCGV0000216_011].***
- ***8 December 1988 minute from Dr McIntyre [SCGV0000216_010].***
- ***1 May 1989 letter from Professor Cash commenting on an article in the Observer [SCGV0000216_008 and SCGV0000216_009].***
- ***3 May 1989 minute from Dr McIntyre [SCGV0000216_005].***
- ***23 August 1989 letter from Mr Panton to Dr Perry [SBTS0000629_162].***

67.1 I only dimly recall this matter and am reliant on the documents provided to answer the questions about it. It is clear from these documents that, although

[5] A marked-up copy of this draft, with what appear to be proposed amendments, is available at SCGV0000216_002.

the plasma was originally collected (before the introduction of HIV antibody screening in October 1985) for the production of blood products generally, the question which SHHD was addressing in the period 1987-89 was whether it might be used for much more limited purposes. These purposes did not include the manufacture of Factor VIII, Factor IX and IVIG (see for example John Cash's letter of 21 April 1987). The documents you have provided show that the DHSS faced a similar (but less pressing) question and that we co-ordinated our decision on what should be done with the stocks.

68. To the best of your recollection, how was this issue ultimately resolved?

68.1 I do not recall, but Rab Panton's letter of 23 August 1989 (SBTS0000629_162) gives the answer: some of the plasma was cleared for research use while the rest was disposed of.

69. A manuscript annotation on Dr McIntyre's 8 December 1988 minute appears to read: "This is very helpful and narrows the range of issues which need to go up to Minister. (I don't think we should neglect to tell him the story entirely)" [SCGV0000216_010]. Who do you believe is most likely to have been the author of this annotation?

69.1 The author was Hamish Hamill, my boss at the time.

70. So far as you can recall, were ministers ever involved in decision-making on this issue? Did you believe that they should be? Either way, please describe the reasoning behind your view and whether it changed over time. Please also explain whether your position differed from that of other SHHD officials.

70.1 I cannot recall whether ministers were asked to take a decision. The papers show that we were preparing to do so: I drafted submissions to them in November 1987 and November 1988. We may well have done so in the summer of 1989, before Rab Panton wrote his letter of 23 August. If we did not do so, we would have concluded that the final solution was unlikely to be controversial, whereas some of the solutions we had earlier considered (such as those advocated by the expert group which met on 19 October 1987) involved the use of material which could not be tested for HIV infectivity and

might have called into question the safety of the final product. It is clear from his manuscript note on Archie McIntyre's minute of 8 December 1988 that Hamish Hamill then considered that ministers should be involved (as we were at that stage preparing to arrange) whereas Archie McIntyre was questioning whether that was necessary.

Section 10: Self-sufficiency

71. What was your understanding, during your time as Assistant Secretary, of the aim of achieving "self-sufficiency" in blood products in Scotland? Did you understand it to continue to be a policy objective of the SHHD during your time there? If so, what were its principal features, and what was your involvement in trying to achieve it? Was it achieved during your time at the SHHD?

71.1 My recollection is that SHHD was proud of the fact that Scotland was, at the time I joined SHHD, one of the few countries in the world which were self-sufficient in blood and blood products. That accorded with a World Health Organisation recommendation and, coupled with the care which the SNBTS took to ensure the safety of its inputs and outputs, was likely to be in the best interests of patients. I do not recall in detail what I did to help achieve that aim, but it is clear from the documents listed in question 73 that SHHD took very seriously the prospect that self-sufficiency might be lost.

72. Did you understand others to have a different definition of self-sufficiency, or a different view on whether it was a policy objective during your time at the SHHD?

72.1 No. My clear recollection is that everyone in SHHD regarded it as an important objective and can recall no definitional differences. I see from the documents you have provided that John Cash was uncertain whether or not it was an objective: I am at a loss to know why.

73. *Did Scotland cease to be self-sufficient at any point while you were Assistant Secretary? If so, please describe your understanding of the reasons for this development. You may wish to consider the following documents:*

- *Your 2 June 1988 minute, enclosing a 1 June 1988 letter from Mr Donald [SCGV0000110_131].*
- *6 June 1988 minute from Dr Forrester [SCGV0000110_157].*
- *Your 9 June 1988 minute [SCGV0000126_086].*
- *William Reid's 14 June 1988 letter to the CSA [PRSE0000711].*
- *Your 14 June 1988 minute [SCGV0000126_085].*
- *Note of a 15 June 1988 meeting [SBTS0000178_011].*
- *30 June 1988 letter from JT Donald to general managers [SCGV0000110_117].*
- *1 July 1988 minute to you from Dr McIntyre [SCGV0000110_114].*
- *4 July 1988 minute from Dr Macdonald [SCGV0000110_113].*
- *6 July 1988 letter from the Haemophilia Society to Malcolm Rifkind, with enclosure [PRSE0003441 and PRSE0003849].*
- *Your 12 July 1988 minute and enclosed draft response to the Haemophilia Society [SCGV0000110_148 and SCGV0000110_152].*
- *Your 14 July 1988 minute [SCGV0000110_096].*
- *Your 15 July 1988 letter to Mr Donald [SCGV0000110_093].*
- *19 July 1988 response to the Haemophilia Society from Dr Macdonald [HSOC0015345].*
- *20 July 1988 letter from Professor Cash to Mr Donald [SCGV0000110_086].*
- *20 July 1988 minute from Jane Rougvie [SCGV0000110_085 p.2].*
- *Your 22 July 1988 minute to Ms Rougvie [SCGV0000110_084].*
- *24 August 1988 letter from Mr Donald to Mr Hamill [PRSE0003250].*
- *26 August 1988 minute from Dr Forrester, with enclosure [SCGV0000110_026 and SCGV0000110_027].*
- *30 August 1988 minute to you from Dr Forrester [SCGV0000110_023].*
- *Note of 30 November 1988 meeting [SBTS0000687_079].*

- ***Paragraphs 10.197-10.276 of the Penrose Inquiry Preliminary Report [PRSE0007003 internal pp.383-401].***

73.1 The documents show (although I do not myself recall the details) that, although Scotland remained self-sufficient in blood and many blood products, rising demand for other blood products (notably Factor VIII) coupled with production difficulties at the PFC meant that we were probably no longer self-sufficient in these products from mid-1988. I note that there was difficulty at the time both in forecasting demand from clinicians for blood products and in discovering the scale of their prescribing of products bought from commercial sources (as they were free to do). So the magnitude of the loss of self-sufficiency was uncertain.

74. What, in your opinion, were the principal reasons why the UK as a whole did not become self-sufficient in blood products? Please interpret "self-sufficiency" in this question to mean the production of sufficient blood products to allow all NHS patients to elect to use an NHS blood product on request, including for prophylactic use.

74.1 My knowledge is restricted to Scotland. I was never involved in the balance between supply and demand for blood and blood products in the rest of the UK.

75. Please describe your involvement in arrangements for PFC to process plasma for Northern Ireland. In doing so, please address, so far as you can, the reasons for the arrangements and whether, in your view, they operated successfully. As well as the documents set out in the next question, you may be assisted by the following from 1986:

- ***19 May 1986 minute to you from Alexander Murray, with enclosure [SCGV0000104_020 and SCGV0000104_021].***
- ***2 May 1986 minute to you from Mr Murray [SCGV0000104_031].***
- ***Your 21 May 1986 minute to Mr Robertson [SCGV0000104_019].***
- ***2 June 1986 response from Mr Robertson [SCGV0000104_017].***
- ***Your 5 June 1986 letter to Professor Cash [SCGV0000104_016].***

75.1 The health service in Northern Ireland did not have an equivalent of the PFC so there were arrangements for Northern Irish plasma to be fractionated at the PFC and for the products to be returned to Northern Ireland, The DHSS(NI) paid the gross cost of the processing. To the best of my recollection, these arrangements worked well. On my arrival in SHHD, I was alerted to alarm in the SNBTS at an increase in the plasma coming from Northern Ireland – for the processing of which John Cash did not think the SNBTS was adequately remunerated. (He did not consider that the processing capacity of the PFC was under strain as a result.) A meeting with John Cash, and my letter of 5 June 1986 to him, were sufficient to explain that the financial arrangements were in fact fair (and apparently left the SNBTS slightly better-off).

76. Please describe your involvement in proposed changes to the arrangements with Northern Ireland in 1988, including their relationship with Scotland's apparent loss of self-sufficiency. In doing so, please explain, so far as you can, whether the arrangements changed and the reasons for any changes. You may be assisted by the following documents:

- ***Your 4 October 1988 letter to Dr McQuiston [SCGV0000105_021].***
- ***Your 28 November 1988 letter to Dr McQuiston [SCGV0000105_020].***
- ***14 December 1988 letter to you from J Scott [SCGV0000105_019].***
- ***Your 15 December 1988 letter to Mr Scott [SCGV0000105_018].***

76.1 Although I do not recall the matter, the documents you have provided show that, as a consequence of the inability of the SNBTS to meet clinical demand for Factor VIII in mid-1988, we reviewed the agreement with Northern Ireland, which prompted the correspondence listed above. We checked that the DHSS(NI) wished to continue the arrangement, sought a contribution to the capital cost of building work at the PFC (if that work turned out to be necessary) and cleared with the DHSS(NI) the arrangements agreed by the Haemophilia Directors (including Dr Mayne from Northern Ireland) to continue to administer the PFC product to Northern Irish patients who already received it, with other patients receiving commercial products. The DHSS(NI) confirmed that the

arrangements should continue and I do not remember there being a problem in doing so.

Section 11: Compensation and other financial support

77. ***Insofar as you are able to do so from your recollection and the documents provided or available to you, please provide a chronological account of your involvement in decisions and actions taken by the SHHD in relation to compensation or other financial support for individuals infected with HIV through blood transfusions and blood products. You may wish to consider the following documents:***

- ***16 February 1987 minute to you and David Stevenson from CM Lugton [SCGV0000229_229].***
- ***Mr Stevenson's response [SCGV0000229_227].***
- ***18 February 1987 minute from Alexander Murray [SCGV0000229_228].***
- ***28 July 1987 letter from Dr Forrester [LOTH0000010_033].***
- ***7 October 1987 memo to you from CM Lugton, with enclosure [SCGV0000229_194 and SCGV0000007_051].***
- ***27 October 1987 minute to you from Hugh Morison [SCGV0000268_033].***
- ***3 November 1987 minute from Mr Lugton [SCGV0000229_180].***
- ***6 November 1987 minute from Mr Lugton with enclosure [SCGVx0000229_166 and SCGV0000229_177].***
- ***11 November 1987 minute from Mr Lugton [SCGV0000229_171].***
- ***13 November 1987 minute from Mr Lugton, with enclosure [SCGV0000229_165 and SCGVx0000229_156].***
- ***Note of 18 April 1988 meeting [SBTS0000687_089].***
- ***Your 15 February 1989 minute [SCGV0000229_052].***
- ***25 April 1989 letter from Clive Winter to Mr Hamill [SCGV0000229_048].***

77.1 I do not recall anything about this topic, and the papers listed above are of little help. The SHHD Division concerned with HIV/AIDS took the lead on the question of special financial help for patients infected with HIV from blood products, and I was only peripherally involved. The documents which you have

provided show that the question of litigation by infected patients against SHHD and the SNBTS was the responsibility of my Division but I do not remember anything about it, perhaps because the litigation was at an early stage.

Section 12: Other issues

78. ***Please outline your involvement in responding to reports of declining blood donations in Scotland in the late 1980s. In doing so, please address, to the best of your ability and knowledge: i) your understanding of the reasons for the decline; ii) whether, in your view, the decline was linked to other issues being considered by the Inquiry (for example, steps taken to exclude high risk donors). You may be assisted by the following documents:***

- ***29 October 1987 letter from Professor Cash to Jim Donald [SCGV0000269_156].***
- ***Your 2 December 1987 minute [SCGV0000269_155].***
- ***7 December 1987 response on behalf of Mr Forsyth to your minute [SCGV0000269_154].***
- ***Your 23 December 1987 minute [SCGV0000269_148].***
- ***Your 28 January 1988 minute [SCGV0000269_137].***
- ***Your 29 August 1988 minute [SCGV0000269_109].***

78.1 The decline in blood donations was of great concern to SHHD officials and the Health Minister – as well as, of course, to the SNBTS. The papers listed above (I do not recall the matter in detail) show that the SNBTS, with our support, took energetic action including a publicity campaign, better communication with donors, and changes in the rules applying to donors (for example, raising the maximum age and reducing the minimum interval between donations). The SNBTS also commissioned a study on donor motivation, which concluded that donors were deterred by a combination of relatively minor factors, perhaps combined with an ill-defined concern about AIDS. The exclusion of high-risk donors seemed to have played a part, exacerbated perhaps by people wrongly self-excluding. Shortage of blood (and plasma) does not, however, seem to have been a factor in the inability of

the SNBTS to meet clinical demand for Factor VIII from mid-1988 – which suggests that the SNBTS's action to encourage donation was successful.

79. ***Please outline your involvement in the creation of the Advisory Committee on Virological Safety of Blood. You may be assisted by the following documents:***
    - ***Your 11 November 1988 letter to the DHSS [PRSE0002344].***
    - ***9 January 1989 letter from Dr McIntyre to the DHSS [PRSE0001884].***
    - ***Your 6 February 1989 minute [PRSE0001975].***
    - ***8 February 1989 letter from Mr Forsyth [PRSE0000967].***

79.1 I have no recollection of the setting-up of the Committee but the documents show that I was involved in official-level consideration by the health departments and in briefing the Scottish Health Minister to agree to the proposed Committee and its remit.

80. ***Other than as set out previously in your answers, are there other aspects of the Scottish Office's policies relating to infections through blood and blood products that you consider could or should have been handled differently during your time as Assistant Secretary? If so, please explain what these were, how you think the matters could or should have been handled, and why they were not so handled.***

80.1 At this distance, over 30 years after I ceased to be involved in the matter, I can recall no examples.

81. Please provide any further comment that you may wish to provide on matters that you believe may be of relevant to the Infected Blood Inquiry. To assist, we have provided a list of issues (attached).

81.1 I have no other comments.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 8 June 2022