Closing submissions to the Infected Blood Inquiry

by the Scottish Government

Introduction

1. The Scottish Government is acutely aware of the suffering of those who were infected with HIV or hepatitis as a result of NHS treatment with blood or blood products. It is a matter of profound regret that anyone should have suffered in this way. It is important to acknowledge the courage of those who have given evidence to enable the Inquiry to understand the extent to which infection affected their lives and those of people close to them.

2. The Scottish Government apologises sincerely and without reservation to those infected or affected by NHS treatment with blood or blood products. It reiterates what the First Minister said on 26 March 2015 in a statement to the Scottish Parliament:

> 'As First Minister of Scotland, and on behalf of the Government of Scotland and the national health service, I take the opportunity to say a sincere and heartfelt sorry to everyone who has had to deal with the devastating impact of infected NHS blood and blood products.
>
> I cannot begin to understand the difficulties and many hardships that individuals and their families have had to contend with. It is important that we apologise to them openly and without reservation and I do so on behalf of the Government of Scotland and the NHS.
>
> I established the Penrose inquiry because I felt that it was vital that we understand the series of events that led to such a devastating impact on so many people. Now, as First Minister, I am determined that we do everything possible to give all of those who are affected the support that they deserve.
>
> The Cabinet Secretary for Health, Wellbeing and Sport will make a full statement this afternoon setting out the Government's response to the inquiry's findings. I am sure that I speak for everyone in the chamber and throughout Scotland when I say that we must do everything in our power to ensure that such terrible events never ever happen again.'[1]

3. The Scottish Government looks forward to the report and recommendations of this Inquiry. It will at that time make a full statement of its response to the Inquiry's findings and of the

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1 https://www.parliament.scot/chamber-and-committees/official-report/search-what-was-said-in-parliament/meeting-of-parliament-26-03-2015?meeting=9877&iob=90467

steps it will take to implement them.

Scope and structure of these submissions

4. At the outset it may be helpful to explain the scope and structure of these submissions.

5. First, the Scottish Government does not attempt to deal in these submissions with all the issues which the Infected Blood Inquiry is seeking to address. It does, however, set out its position on the main issues which confronted government when concerns about the safety of blood and blood products arose from the early 1980s onwards. These submissions also explain the present position in Scotland in relation to the issues the Inquiry is addressing, and they set out the government's views on recommendations which the Inquiry may consider making. They do so in particular where it would be for the Scottish Government to take forward recommendations and where the Scottish Government believes there are issues which the Inquiry may wish to consider in relation to making any such recommendations.

6. Second, in relation to events in the past, in these submissions the Scottish Government attempts to do no more than put forward a summary of the position as it appears from the evidence. The Inquiry is considering issues which go back to the 1980s. It is clear with the benefit of hindsight that some things that were done then could have been done differently. There have, as the Inquiry is well aware, been many advances in medical science and changes in clinical practice since that time. Given the passage of time, evidence from many of those directly involved has not been available to the Inquiry. There have since the 1980s been several changes of government as well as numerous changes in the personnel advising government. And the system of government itself changed in Scotland in 1999 as a result of devolution. Against this background, in these submissions the Scottish Government does not seek to comment on the appropriateness of actions taken in the past or seek to support or defend or indeed to criticise, decisions made by ministers in previous administrations or advice given by officials advising them.

7. Third, in relation to the present, the Inquiry has evidence about the current position in Scotland in relation to public health and in relation to administrative decision-making in general. In particular, it has heard evidence about the importance of the Civil Service Code, the Scottish Ministerial Code, and the National Performance Framework. It has heard evidence about measures taken to promote good decision-making based on evidence; to promote diversity and inclusion; to mitigate against 'groupthink'; and to learn lessons from

the past.[2] These are important issues, but the evidence is also clear and undisputed, and there is no need for these submissions to repeat it.

8. The structure of these submissions is as follows.

9. First, a brief review of some key issues in relation to blood and blood products: in particular, self-sufficiency in Scotland in relation to blood and blood products; when certain types of screening were introduced; and the consideration given to issues such as making *ex gratia* payments to those infected by NHS blood or blood products.

10. Second, submissions in the light of those issues on the general themes of decision-making and relations between government and other relevant bodies.

11. Third, an account of the provision, financial and other, which is currently made in Scotland for those infected or affected.

12. Fourth, submissions in relation to the Compensation Framework prepared for the Inquiry.

13. Fifth, submissions on aspects of the current position in Scotland, in order that the Inquiry has the background necessary for considering what recommendations it may wish to make.

I Key issues in relation to blood and blood products

Self-sufficiency

14. A striking feature of the position in Scotland throughout the period with which the Inquiry is concerned is that SNBTS sought to be self-sufficient in blood components and blood products for use in Scotland. For much of the period this goal was achieved, albeit from time to time there were pressures on supply in relation to blood products for patients with inherited bleeding disorders.

15. The details are set out in a presentation prepared for the Inquiry.[3] Among other things, it charts increasing demand for Factor VIII during the mid-1980s which, coupled with decreased yield owing to heat treatment, from time to time raised concerns about stock levels of some blood products.[4]

16. It is clear that SHHD was committed to the principle of self-sufficiency in the supply of blood and blood products. SHHD medical officers repeatedly emphasized that commitment and indicated that if possible, clinicians should use NHS blood products in preference to imported products. At a meeting of the SNBTS and Haemophilia Directors on 21 January 1983, Dr Bell of SHHD stressed that '…SNBTS had been set up to have the capability to

[2] On administrative decision-making generally, see witness statement of Lesley Fraser WITN7351001; oral evidence of 14 November 2022. On public health provision, see witness statement of Caroline Lamb WITN7458001.
[3] Presentation INQY0000343; Annex A INQY0000344.
[4] On issues of supply and demand, see esp §§ 257, 263, 288, 318, 341, 347-8 of presentation INQY0000343.

cope with all Scottish requirements … and that in terms of national policy the purchase of commercial products should be avoided so far as possible."[5] At a further meeting of the Directors on 2 February 1984 Dr Bell again emphasized that '… the aim of SNBTS and of national policy was for Scotland to be self-sufficient, and although the Department would not wish to intervene in what clinicians prescribed, it was not sensible to purchase imported material when suitable NHS product was available.'[6]

17. Developments in haemophilia treatment, notably the advent of home therapy and prophylactic therapy, meant that the amount of product required for self-sufficiency was constantly rising. Projection of demand was difficult, and the Protein Fractionation Centre ('PFC') faced a constant battle to maintain supplies in the period leading up to 1983.[7]

18. By 1983 Scotland had largely achieved self-sufficiency in the manufacture of blood products. Indeed, by early 1984, production may have been exceeding demand. SNBTS obtained sufficient blood, and PFC produced sufficient product to ensure that, under most normal circumstances, domestic product was available for use by clinicians to treat patients, including haemophilia patients. At the Joint Directors' meeting of 2 February 1984, Dr McDonald indicated that clinicians at the West of Scotland's adult haemophilia centre were totally satisfied with the NHS product and that there was no longer any need to purchase commercial product.[8]

19. In this period there were therefore only rare occasions on which it ought to have been necessary to prescribe imported products. Nonetheless, it was neither possible nor viewed at the time as appropriate for SHHD or the Scottish CMO to issue guidance banning or restricting the use of commercial blood products. Haemophilia clinicians were in a better position than government officials to decide whether it was appropriate to prescribe imported blood products for their patients. They were free to decide whether to do so.

20. Mr Macniven refers to SHHD being, at the time he joined it in 1986, proud that Scotland was one of the few countries self-sufficient in blood and blood products and explains that this accorded with the recommendations of the World Health Organization.[9] Although he appeared to have no very precise recollection of this, he acknowledged that self-sufficiency in Factor VIII may have been lost for a while in mid-1988.[10]

21. Even at times when Scotland was self-sufficient, it appears that some clinicians continued to

[5] PRSE0001736.
[6] PRSE0001556.
[7] See e.g. PRSE0003902.
[8] PRSE0001556.
[9] WITN7064001_0046 at § 71.
[10] WITN7064001_0048 at § 73.

prefer to use commercial products, which they regarded as more reliable in quality and potency than NHS product. SHHD officials monitored purchases of commercial products during 1983, and appear to have expressed concern about 'substantial purchases' in the West of Scotland region at a meeting of the SNBTS Directors in December 1983.[11]

22. Although SHHD's clearly expressed preference was that NHS product should be used where possible, the choice of product to be prescribed for a particular patient or patients was (and remains) a matter for the treating clinician. The principle of clinical freedom was (and remains) an important one. Provided that a product had been licensed for use in the UK (and in some circumstances, even where a licence had not yet been granted) clinicians were free to use what in their view was the most efficacious product. At the Joint Directors' meeting of 2 February 1984, Dr Bell clearly wished to emphasize that in his view, purchase and use of commercial products was neither sensible nor desirable. Nevertheless, as the minutes of that meeting show, he also plainly felt that he required to acknowledge the principle of clinical freedom. During 1983 and at least part of 1984, many haemophilia clinicians took the view that the benefits of continuing with treatment with factor concentrate outweighed the risks.[12]

23. The Committee for the Safety of Medicines, which was made up of experienced professionals, itself took the view in July 1983 that the balance between the risks and benefits of treatment with factor concentrate was so fine that a decision to continue treatment with imported concentrates was a matter of clinical judgment. The Committee's view was that there was no justification for banning commercial products, and that it was a matter for individual clinicians to assess.[13]

24. SHHD advice of September 1983 sought to emphasize that nearly all of the Factor VIII used to treat haemophilia in Scotland was produced from Scottish plasma, which at the time was genuinely believed to be a low risk plasma source.

25. Government in Scotland had indicated to haemophilia clinicians even before the AIDS crisis emerged that commercial products should be avoided if possible. Government relied heavily on advice from experts, and there appeared to be little agreement among experts at that time as to the gravity of the risk posed by blood products, particularly imported blood products, and as to the appropriate treatment for haemophiliacs.

26. *Scottish Government position.* Scotland was self-sufficient in blood products from around 1983, albeit at certain times such as in 1988 self-sufficiency was temporarily lost. The preferences of individual clinicians meant that commercial concentrates continued to be prescribed even

[11] PRSE0002899.
[12] PRSE0001556.
[13] PRSE0002336

during periods of self-sufficiency.

HIV screening

27. Screening was introduced throughout the UK on 14 October 1985.[14]

28. The policy to introduce HTLV-III (HIV) screening on 14 October 1985 was formulated after taking account of expert views about the reliability of initial screening tests and confirmatory tests; the various practical arrangements for counselling and alternative testing that needed first to be put in place; and an assessment of the desirability of adhering to a uniform starting date throughout the UK.

29. There was consensus that it was necessary to evaluate the various test kits that were on offer before adopting them in practice. There was also consensus that the tests ought to be introduced throughout the UK at the same time. Evaluation of the tests was sponsored by DHSS and carried out at centres in England. SNBTS had originally intended to carry out its own evaluation but this did not in fact take place.

30. Had SNBTS carried out its own evaluation and obtained satisfactory results with one or more of the test kits, it is possible that screening might have been introduced in Scotland before 14 October 1985. But this would have depended on numerous difficult issues first having been resolved: availability of tests to evaluate; satisfactory evaluation of the tests; an adequate confirmatory test; appropriate arrangements for donor counselling; and availability of alternative testing facilities. It would also have involved departing from the consensus view that tests should be introduced throughout the UK at the same time, which was a matter of significant public policy given the issue of alternative testing.

31. DHSS and SHHD officials kept in touch about the issue of HTLV-III screening. DHSS had on 11 January 1985 made a submission to the minister seeking approval in principle for introducing screening in the NBTS. The submission was copied to SHHD the following week, where the approach taken was to await the DHSS minister's response before making a submission to the minister in Scotland. Around the same time Professor Cash reiterated his concern that this was a matter that should be pursued at a UK level.[15]

32. A series of internal SHHD documents discusses the practical issues that needed to be resolved before the test could be introduced; reference is made to the fact that the decision to introduce the test, once taken in England, meant that there was no practical alternative but to follow suit in Scotland. SHHD was keen to have Professor Cash's advice on this matter.[16]

[14] On this topic generally, see Inquiry presentation INQY0000373 at §§ 336 ff.
[15] PRSE0004386.
[16] PRSE0002457, PRSE0001925, PRSE0003846, PRSE0001054, PRSE0003641.

33. On 21 March 1985 a submission was made to the ministers in Scotland, recommending a phased policy leading to routine screening of blood donors. The recommendation was accepted on 26 March 1985. The rationale for the recommendation of phasing was that numerous challenges had to be addressed before the test could safely be introduced. To summarize the main ones: kits were needed to test, and there were supply problems with them during 1985; there needed to be an adequate confirmatory test; appropriate arrangements would also need to be in place for donor counselling; and, crucially, there must be alternative testing facilities, in order to avoid the risk of some people wishing to donate so that they could obtain an HIV test, thus potentially encouraging individuals at higher risk of HIV infection to donate even though they were by that time being asked not to do so. Dr McClelland produced an exhaustive list of what needed to be in place for testing to begin in his own centre. He also observed in his witness statement on this issue for the Penrose Inquiry that his recollection is that 'we were quite pressured to meet the timescales [14 October 1985] once the two kits had been designated as approved for use'.[17]

34. *Scottish Government position*. DHSS took the lead on the question when testing should be introduced. As the Inquiry has seen in relation to other topics, the notion that there should be a UK-wide approach was not set in stone: where local circumstances in Scotland demanded a different approach, officials in SHHD would be prepared to advise the Minister to that effect. This, however, was not one of them.

35. The Scottish Government is not in a position either to defend or criticise the decision that was made at the time.[18]

Surrogate testing for NANB Hepatitis

36. The following paragraphs summarize the position with regard to surrogate testing for NANB hepatitis in general.

37. The scientific justification for introducing surrogate testing for NANB hepatitis in the 1980s was inconclusive. Research, ideally a full prospective study, was needed, but the time and cost for this were viewed as prohibitive. Responsibility for deciding whether surrogate testing should be introduced in Scotland lay with the Scottish minister responsible for health. In making such a decision he would have relied on the advice of officials, who would in turn have relied on expert scientific and clinical advice; SNBTS was an important source of such expert advice.

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[17] PRSE0003243, PRSE0003157 at page 17(witness statement).

[18] The issue was examined by the Penrose Inquiry; a summary of its conclusion is given in the Final Report at §§ 30.256-62.

38. SHHD medical officers kept abreast of the medical assessment of NANB hepatitis; they also kept abreast of medical views for and against surrogate testing, but these were sharply divided.

39. SHHD would have been willing to put in place funding for surrogate testing once persuaded by the medical evidence that this was an appropriate use of public funds.

40. In fact, the question was not put to ministers for decision.

41. The context was this: there was no specific test for NANB hepatitis. And there were drawbacks associated with making use of non-specific tests. It was generally acknowledged that the tests which were available had poor sensitivity and specificity, and that the lack of a confirmatory test meant that it would be difficult or impossible to distinguish between a true and a false positive result. That could have caused real problems in counselling donors and maintaining a sufficient blood supply.

42. These drawbacks meant that expert opinion was divided on the value of introducing such tests. The division of opinion is clearly seen in the contrasting letters sent by various transfusion directors to the *Lancet* in April and July 1987. In essence Professor Cash's view was that in 1987 SNBTS did not think surrogate testing should be introduced but thought it might have to be. A DHSS memo of 29 January 1988 makes it clear that the reasons for introducing testing were considered to relate to commerce, competition or politics rather than to scientific rigour.[19]

43. The position is usefully summarized in evidence given by Dr Macdonald to the Penrose Inquiry: 'If departmental medical staff had been persuaded, after consulting colleagues with relevant expertise, that surrogate testing for NANBH was a reliable procedure which would give few false results (positive or negative) and be free from adverse effects, they would have advised administrators accordingly and it would have been highly likely that funding would have been provided. In the event departmental medical staff were not sufficiently persuaded and advice reflected this.'[20]

44. Dr McClelland made much the same point in this way: 'I think the minister would inevitably be heavily dependent on the burden of the advice that he or she was given, and if there was very strong, clear, consistent, well-argued and rational advice coming from, say, the clinical and scientific community through the [SHHD] to the minister, I find it hard to believe that most ministers would not have acted according to it. And it's perfectly clear that the advice that was, as it were, coming from the relevant professional community was not clear and

[19] PRSE0000038.
[20] Penrose report § 27.297 quoting from Dr Macdonald's witness statement.

consistent.'[21]

45. Mr Macniven made the same point in his witness statement for this Inquiry: his recollection is that the consistent and unanimous conclusion within SHHD in the second half of the 1980s was that there were insufficient scientific or medical grounds for introducing such testing.[22]

46. In 1989 DHSS established ACVSB, a committee of experts to advise it on the virological safety of blood. There were two members from Scotland, as well as an observer from SHHD, Dr McIntyre. ACVSB contained the leading experts on the issues, and it was tasked with advising government and others. The committee advised against introducing testing.[23] That being so, there was no solid medical or scientific basis for SHHD or DHSS to introduce it.

47. *Scottish Government position.* With the benefit of hindsight, it is clear that surrogate testing could have led to some hepatitis C infection through blood transfusion being avoided from the late 1980s to the start of the 1990s. However, it is clear that officials and medical advisers in SHHD had genuine concerns that surrogate testing would not be sufficiently accurate and could lead to a significant proportion of false positive tests, and that they adopted their position in the context of a lack of full understanding at the time of the seriousness of the health impacts of NANB hepatitis.

Screening for Hepatitis C

48. The position changed with the identification of the hepatitis C virus. Screening for that virus began throughout the UK by 1 September 1991.

49. On the central question whether HCV testing should be introduced, a number of issues had to be resolved: first and foremost, the need for a confirmatory test; the need, if an American (Ortho) test was to be used, for the reassurance that it had obtained FDA approval; and pilot studies of the test in the UK. This was the position recorded in the minutes of ACVSB of November 1989.[24] An export licence for that test did not become available until the end of November 1989. The minutes of subsequent ACVSB meetings reveal differences of emphasis among the members of the committee on matters of timing and scientific rigour but a general understanding that the likelihood was that an HCV test would be introduced in the UK. The determining factor, according to Dr Perry, was the availability of a confirmatory test.

50. By 24 April 1990 Dr Perry and Dr Gunson were satisfied that there was sufficient data to warrant taking a decision in principle to introduce HCV testing, but the majority of ACVSB

[21] Report § 27.309 quoting from Dr McClelland's oral evidence.
[22] WITN7064001_0033 § 54.
[23] NHBT0000072_025 (minutes of 3 July 1989); PRSE0001071(minutes of 6 November 1989).
[24] PRSE0001071.

and the Department of Health preferred a more cautious approach.[25]

51. By 2 July 1990 ACVSB was willing to recommend to Ministers that HCV testing should be introduced, but that a pilot study using the Ortho and Abbott tests should first be carried out to decide which was the better test for the regional transfusion centres.

52. On 21 November 1990 ACVSB recommended the introduction of HCV testing as soon as practicable; individual centres would decide which test to use. While the minutes of the meeting do not mention a target date, Dr McIntyre's note of the meeting notes that as being 1 April 1991.[26]

53. In January 1991 the Department of Health approved the introduction of HCV testing on a date yet to be fixed, since some testing laboratories would require new equipment. 1 April 1991 was suggested as the target date for the earliest possible introduction, with regional transfusion centres to come into line thereafter. Mr Tucker of SHHD pointed out to a colleague in SHHD that to delay for the slowest could mean a long wait.

54. By February 1991 the date that was under consideration in the Department of Health was 1 July 1991.[27] By March 1991 it had emerged that 1 July was not practicable for NBTS; Dr Gunson was going to advise the Department of Health that the date should be delayed until an evaluation of the new screening tests had been completed. The delay caused concern in SHHD: Mr Panton noted 'This is worrying …'.[28]

55. The date for introduction of HCV testing was set by DHSS, once they were satisfied that the regional transfusion centres were able to carry it out; the evaluation of second-generation tests had been completed; and the advisory committee had signalled that they were happy with that.

56. When to introduce the test in Scotland was a matter for the Minister of State, whose decision was based directly on advice from SHHD and ultimately on the expert advice obtained from ACVSB. The Department of Health decision was crucial for Scotland too, because there was a consensus among ministers, their officials, and the medical and scientific community that it was appropriate for HCV testing to begin in Scotland at the same time as it began in England. That view was based on and strongly supported by leading figures in SNBTS, as well as by NBTS. It was also the clear view of ACVSB that the decision was a UK decision and should be implemented in a co-ordinated manner across the UK. Given the UK context, it is fair to say that the Department of Health took the lead in the process, with the advice of ACVSB.

[25] NHBT0000072_098.
[26] PRSE0001481; PRSE0000206.
[27] See Inquiry presentation INQY0000373 at §§ 545-547.
[28] PRSE0003692.

57. So far as the practicability of introducing testing is concerned, Dr Gillon indicated in response to a query from Professor Cash in November 1990 that the earliest date on which the Edinburgh centre would be able to start testing was 25 February 1991.[29]

58. Professor Cash in particular advocated the importance of holding a UK line. His correspondence with Dr Gunson in 1989 shows that they were working together on the introduction of screening and that this was precisely what Professor Cash wanted; as he wrote to Dr Gunson, 'We will not move unilaterally unless instructed to do so by SHHD, thus close collaboration seems certain'.[30] The same understanding appears from the minutes of the SNBTS directors' meeting in September 1989;[31] and in Professor Cash's letter to the directors of 27 November 1990, which emphasizes the importance to everyone of a UK simultaneous start date.[32] Many other instances in the evidence show this. One is a letter in January 1991 expressing a firm commitment to starting testing on the same day as NBTS colleagues.[33]

59. Did the delay in introducing HCV testing have an impact on the safety of the blood products produced by PFC? This Inquiry raised that question with Dr Perry, and his answer was that it did not. He explained that, following the introduction of severe heat treatment between 1985 and 1987, PFC products were already considered to be free of the risk of HCV infection. The introduction of testing for Hepatitis C therefore served to increase the products' margin of safety, but the measurable impact of such testing on the risk of infection from PFC blood products was minimal.[34]

60. In summary: the decision when to introduce the test for HCV was taken in Scotland by the Minister of State. SHHD kept abreast of the deliberations about when testing for HCV should be introduced; they did so in particular by participation in ACVSB. The decision was based directly on advice from SHHD but ultimately on the expert advice obtained from ACVSB.

61. Funding for HCV testing was approved by SHHD for the financial years 1991/92 and was accordingly in place for testing to begin in April 1991.

62. SHHD, in common with DHSS and leading figures in SNBTS and NBTS, took the view that it was appropriate for HCV testing to begin in Scotland at the same time as it began in England.

63. Various factors caused delay in introduction of testing: among them were the need to obtain

[29] PRSE0003692.
[30] NHBT0000188_011.
[31] PRSE0003326.
[32] PRSE0003619.
[33] NHBT0000073_033.
[34] Perry witness statement WITN6920001: see esp. §§ 446-7, 466.

and to evaluate confirmatory tests; to secure adequate supplies of test kits; and, once a second-generation test had been developed, to evaluate it too. A factor that may have contributed to delay in England but not in Scotland was the need to secure funding for the various regional centres that were to carry out the testing.

64. Testing could have started in Scotland earlier than 1 September 1991, since the infrastructure and funding were in place, but the prevailing view in SNBTS and NBTS remained that testing should begin in Scotland at the same time as it began in England. SNBTS did not advise SHHD to adopt any other course.

65. The SHHD submission recommending introduction of the test in Scotland was put to the Minister once there was a firm date for him to approve; the fact that the submission was made only in July 1991 did not delay the starting date, since the funding was already in place. In any event, the inclusion of an item for testing in the 1991 PES constituted de facto ministerial approval, since the minister would have had to sign off on an item in the PES bid for the funding.

66. The Penrose Inquiry[35] concluded that, in retrospect, the meetings of the ACVSB on 24 April 1990 and 2 July 1990 were missed opportunities to recommend the earlier implementation of screening. In particular, the decision on 2 July 1990 to delay implementation to allow for a comparative trial between the Ortho and Abbott tests was found to be unwarranted: local centres could have made their choice of test, and comparisons could have been made once screening had begun. That Inquiry accordingly concluded that a recommendation to ministers that routine screening be introduced should have been made by mid-May 1990, although it was unlikely, having regard to the availability of test kits, that screening could actually have begun much before autumn 1990.

67. The main reason for the delay appears to have been adherence to a decision that screening should be introduced throughout the UK on the same date, even though some areas were ready to begin considerably earlier than others (Scotland was one of them). That conclusion is supported by the reluctance of officials in SHHD to make a submission to ministers about the introduction of testing in Scotland until they could include a date in the submission.[36] The date they were waiting for was evidently the date on which screening was to be introduced in England and Wales.

68. *Scottish Government position.* The government accepts that there was delay in introducing testing. At least with hindsight, the delay is difficult to understand. It appears reasonable to conclude that officials in SHHD could have done more to draw attention both to the fact that Scotland

[35] §§ 31.527-529.
[36] See e.g. PRSE0002817.

could be ready to introduce screening earlier (e.g. by the original target date of 1 April 1991) and that funding problems in England and Wales were leading to delay in Scotland.[37]

69. It is also accepted, as the Penrose Inquiry concluded, first, that SNBTS through Professor Cash effectively determined the policy for Scotland, by agreeing the date of 1 September 1991 with Dr Gunson of NBTS; and second, that the evidence does not allow a conclusion on the question whether the responsible minister in Scotland would in fact have authorized introduction of screening on a date other than that on which it was to be introduced in England and Wales.

Look back

70. Prior to 1994, the attitude to look-back of officials within SHHD was coloured by the view, commonly held among transfusionists, that it was logistically too difficult, and that because there was no real evidence-based treatment for HCV, the exercise would cause patients distress and anxiety for no real benefit.[38] The latter point also convinced Professor Cash that look-back would not be appropriate at that time. Dr Gunson and the English RTDs in particular were unenthusiastic about instituting a look-back programme.

71. The ACVSB committee met on 25 February 1991 and decided that look-back should not be undertaken 'as a service'.[39] Dr McIntyre of SHHD was present at the meeting as an observer. Thus, at this stage, the advice to ministers throughout the UK was that look-back should not go ahead.

72. Some in Scotland felt, however, that look-back should at least be attempted. Dr Gillon had formed an ad hoc working party to develop protocols for HCV testing and donor counselling. The Working Party's report to the National Medical Director, dated 23 November 1990 included a clear recommendation that look-back should be instituted.[40]

73. On 12 March 1991, Professor Cash wrote to Dr Gillon indicating that in his view, there should be no look-back 'in the light of national events'.[41] Dr Gillon disagreed. At some point between March and September 1991 he decided that his region, South-East BTS, would go ahead with look-back in spite of the UK decision not to do so.

74. Matters continued on this basis until 1993, when Professor Cash's interest in the topic was once again piqued when he attended a symposium at which improved treatments for HCV

[37] Cf. the conclusions of the Penrose Inquiry at § 31.530.
[38] PRSE0001781.
[39] PRSE0002280.
[40] PRSE0001944.
[41] PRSE0004416.

were discussed.[42] Meantime, Professor Cash wrote to Dr Gunson on 18 November 1993 indicating that the Scottish RTDs had stepped back from introducing look-back until such time as further UK deliberations had taken place.[43]

75. By the time of the next meeting of the SNBTS MSC on 18 May 1994, the results of Dr Gillon's look-back scheme were available, albeit they were not published until later.[44] The vast majority of the meeting was given over to consideration of the issue.[45] Dr Gillon gave a presentation on look-back which made a powerful impression on Dr Keel, who had recently taken over Dr McIntyre's responsibility for blood transfusion issues at SHHD. In the light of Dr Gillon's work, Dr Keel was convinced that look-back was feasible, and turned to putting the wheels in motion to obtain a policy decision to proceed. On issues of this kind there was a general desire to proceed on a four nation basis; it was recognized that there were significant practical issues that had to be addressed.[46]

76. In Scotland matters took an unexpected turn when Mr McIntosh issued a memo to SHHD dated 19 May 1994 indicating that SNBTS proposed to start look-back on 1 June 1994.[47] A meeting between SNBTS and SHHD representatives took place on 24 May, at which SHHD officials gave SNBTS representatives a sympathetic hearing on look-back.[48] Indeed, it appears clear that SHHD agreed at that meeting – at least in principle - that SNBTS should take steps to implement a look-back exercise, subject to SNBTS producing written details of its mechanics.[49]

77. It appears, however, that at this stage it was envisaged that look-back would be taken forward on a UK-wide basis. As at 30 May 1994 the issue was being taken forward by SHHD and the Department of Health on that basis. This was consistent with the long-held view that in matters related to blood transfusion policy there ought to be a common approach north and south of the border.[50]

78. By the time of its general issues meeting of 21 September 1994, SNBTS had not produced detailed papers on the costs and consequences of a look-back.[51] Mr McIntosh produced a summary document on 23 September 1994 on the costs and consequences of look-back – apparently in response to observations at the general issues meeting. In it he indicated that

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[42] PRSE0000796.
[43] PRSE0003928
[44] PRSE0001046, published 21 July 1994, the study having been completed in 1992.
[45] PRSE0003685.
[46] WITN5736003 §§ 35-36
[47] SNB.008.4779; PRSE0002093.
[48][48] PRSE0004286
[49] SNB.009.9601; PRSE0004756
[50] PRSE0003964.
[51] PRSE0000955.

SNBTS anticipated being able to have their preparations in place within weeks rather than months from being given the go ahead and putting the cost at around £50,000 in respect of which funds had already been set aside from non-recurring sources.[52]

79. At a meeting of the UK government's advisory committee, the ACMSBT, on 29 September 1994, reasons were put forward why a look-back exercise should probably be instituted. It is worthy of note, however, that even at that stage, there was strong dissent from that view. The matter was deferred to the next meeting.[53] At the next SNBTS general issues meeting on 14 October 1994 it was noted that a decision on look-back from the ACMSBT was awaited but that that committee was not expected to consider the matter again until December.[54]

80. In spite of continuing uncertainty about the cost-effectiveness and therapeutic benefits of look-back, SHHD officials were convinced that look-back was appropriate and recommended its implementation in Scotland, despite delays south of the border.

81. At around this point SHHD officials decided that it would be appropriate to obtain legal advice. In broad terms, that advice was to the effect that, standing the feasibility of a look-back exercise, ministers had a duty to begin look-back as soon as possible.[55] However, it seems clear that SHHD officials, and in particular Dr Keel, were already persuaded that a look-back exercise was both feasible and necessary from an ethical point of view. The legal advice obtained confirmed that view and informed the letter which was subsequently issued by Lord Fraser to his English counterpart.[56]

82. On 22 December 1994 Lord Fraser, the Scottish Minister of State with responsibility for health, wrote to Tom Sackville, his English counterpart, making the points that look-back was feasible and practicable; treatment was now available, and failure to act might result in legal liability. Lord Fraser also noted that that the ACMSBT committee had recommended uniform introduction throughout the UK, but indicated that in the light of the legal advice received, he considered that he had little choice but to instruct SNBTS to proceed as expeditiously as possible to take forward look-back for all areas in Scotland.[57] On the same date, Mr Tucker of SHHD wrote to Mr McIntosh of SNBTS instructing him to do so.[58]

83. Lord Fraser's letter recognized, on the one hand, the desirability of proceeding on a UK-wide basis and the sensitivities of doing otherwise and, on the other, that circumstances in Scotland made the decision to carry out look-back necessary now.

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[52] PRSE0002454.
[53] PRSE0003670.
[54] PRSE0003853.
[55] PRSE0001781.
[56] PRSE0001781. Cf. also Dr Keel's oral evidence: 25 July 2022 pp 77-78.
[57] PRSE0001781.
[58] PRSE0000661.

84. *Scottish Government position.* It may be that look-back could have been commenced across the whole of Scotland sooner than it actually was. Dr Gillon's study suggests as much. The desirability of implementing the same arrangements throughout the UK no doubt led to a reluctance to begin look-back in Scotland earlier than elsewhere in the UK.

Ex gratia payments to those infected or affected

85. The position taken throughout the UK prior to devolution was that no compensation should be paid to patients in relation to NHS treatment unless the NHS was at fault. This was, for example, explained to Susan Deacon, Minister for Health and Community Care in the Scottish Executive, in a Health Department paper of July 1999 entitled 'Compensation for Haemophiliacs infected with Hepatitis C'.[59] That paper explained to her that the issue had hitherto been treated as a UK-wide matter on which the four territorial health departments should adopt a consistent line.[60]

86. The same point was discussed by Professor Keel.[61] She explained in her witness statement that both before and after devolution there was a clear and widely held view in government that compensation should not be paid where there was no evidence of negligence; to do otherwise would be to set a precedent which might cause problems in the future.[62] In her oral evidence, she went on to explain that she was not in principle against a no-fault compensation scheme, and her mind was open to exploring that possibility. As she put it, during her time in government the idea was always in the 'too difficult' box to pursue and come out with a scheme that would fit with the NHS.[63]

87. Ms Deacon explained in her witness statement that she took the view that a new devolved administration ought not to accept this position unquestioningly and therefore asked Health Department officials to carry out a fact-finding exercise on the particular issue of the timing of introduction of heat treatment of blood products. She also arranged to meet representatives of the Haemophilia Society. A meeting took place on 14 September 1999.[64]

88. The scope of the exercise was defined by reference to questions raised by the Haemophilia Society (Professor Keel made the same point[65]). The remit was (1) to examine evidence about the introduction of heat treatment in Scotland for Factor VIII in the mid-1980s, and to assess whether patients in Scotland with haemophilia A were exposed to the risks of the hepatitis C

[59] SCGV0000176_118.
[60] WITN4436001 at §§ 18-20.
[61] Keel witness statement § 71.
[62] Keel witness statement §§ 71, 75-6.
[63] Transcript 26 July 2022 pp 131-2.
[64] Deacon witness statement §§ 33-38.
[65] Keel witness statement § 83.

virus longer than they should have been, given the state of knowledge at the time; and (2) to examine evidence about the information given to patients with haemophilia in the 1980s about the risk of contracting the hepatitis C virus from blood products.

89. Ms Deacon regarded this exercise as a step forward, rather than the last word on the subject. Professor Keel was satisfied that the investigation exercise was impartial and objective.[66]

90. The report was shared with the Haemophilia Society and the Health and Community Care Committee of the Scottish Parliament. Ms Deacon envisaged that the debate would continue.[67]

91. The Scottish Executive report published in October 2000 set out the results of this fact-finding exercise.[68] Ms Deacon's statement at the time, which she acknowledged might have been framed more sensitively, noted that the conclusion of the exercise was that the relevant authorities had done their best; that nothing further could have been done; and that compensation should therefore not be payable.[69]

92. In March 2001 Mr Justice Burton handed down judgment in *A v National Blood Authority*, holding that blood was a 'product' for purposes of the Consumer Protection Act 1987 and that the claimants were therefore entitled to damages for injury caused by a defective product.

93. In light of the judgment in *A*, the Scottish Executive accepted that the issue of compensation for those who had been infected with Hepatitis C had to be revisited. Professor Keel remained of the view that the treatment they had been given was not negligent.[70] But the issue of negligence was not relevant under the Consumer Protection Act. Malcolm Chisholm (then deputy minister) advised the Scottish Parliament on 26 April 2001 that the Scottish Executive was considering the implications of the judgment in *A* for a small number of similar cases in Scotland.[71]

94. The Scottish Executive report of October 2000 was indeed not the last word on these issues. In October 2001 the Health and Community Care Committee published its own report on Hepatitis C.[72] As discussed in evidence with Mr Chisholm,[73] the Committee considered some limited evidence beyond that examined in the Scottish Executive report. On the basis of that evidence, it reached the view that, given the state of scientific knowledge at the time, it was not clear that SNBTS should have acted differently. The Committee also considered the issue

[66] Keel witness statement § 82.
[67] See e.g. transcript 29 July 2022 pp 78-82.
[68] GGCL0000010.
[69] Deacon witness statement §§ 95-96.
[70] WITN5736003_0057 § 99.
[71] Chisholm witness statement §§ 15-16.
[72] MACK0001929_001.
[73] Transcript 28 July 2022 pp 27 ff.

of a public inquiry, which it did not support.

95. On the particular issue of compensation, the Committee drew attention to the general principle that compensation was paid only when negligence was demonstrated; but it also referred to the judgment in *A* and to the fact that the Macfarlane Trust already provided financial assistance for individuals who had contracted HIV through blood products. Having regard to this, the Committee recommended that the inconsistency created when the Macfarlane Trust was set up be corrected and that a mechanism for providing financial and other support to those who had contracted Hepatitis C through blood or blood products provided by the NHS in Scotland be set up.[74]

96. Professor Keel, while recognizing the Committee's work in grappling with the complex issues, thought that its principal recommendation of a compensation scheme for all patients infected with Hepatitis C through blood transfusion or blood products was potentially unfair to other patient groups who felt they had been harmed by NHS treatment. She also had concerns about the financial impact of the scheme, since money spent on it would not be available for direct patient care or for risk reduction measures in the field of blood transfusion.[75] As Mr Chisholm explained in evidence,[76] the Committee's proposal would create a precedent which could have enormous financial implications.

97. It was therefore felt important to identify the principles on which any financial assistance should be provided: there must be agreed and publicised criteria.[77] That was the reason for setting up an Expert Group; the Health and Community Care Committee in its October 2001 report had recommended that a commission examine the current system of fault-based compensation and propose alternatives.[78]

98. The Expert Group, chaired by Lord Ross, published its preliminary report on 6 November 2002. The report called for financial help for all those infected with HCV through blood, blood products and tissue.[79]

99. Malcolm Chisholm was conscious that making payments in these circumstances would cut across UK government policy, which was that no such payments should be made. He therefore contacted Alan Milburn, Secretary of State for Health, to advise him that he was minded to provide payments of some kind. Thereafter issues rose between the UK government and the Scottish Executive about whether making such payments was within

[74] Committee report § 98.
[75] WITN5736003_0059 § 103.
[76] Transcript 28 Jul 2022 p 36.
[77] Chisholm witness statement § 20.
[78] Chisholm witness statement § 25.
[79] HSOC0003349.

devolved powers and whether such payments could be left out of account for purposes of any social security benefits paid to prospective recipients.[80]

100. When the preliminary report was published, Malcolm Chisholm made a statement that what must be done now is to think carefully about who needs help and the best way to design a scheme and structure payments so that the individuals benefit fully, while also taking account of the costs in light of other health priorities. Over the next few months work on these issues went ahead.[81]

101. Robert Stock, a Scottish Executive policy adviser, briefed the minister to the effect that the proposals made in the Expert Group's final report would be likely to incur costs which would have an impact on current health service provision and would involve making payments to people who would not have been covered by any similar scheme. He explained that, prior to the establishment of the Macfarlane Trust, the norm had been that compensation would be paid only if a person had suffered harm for which the health service was legally liable. The Macfarlane Trust (along with the Eileen Trust) had extended this to one no-fault situation. The Expert Group proposed to go further, for example by including those who were or had become free of symptoms, those who had not suffered physical harm, and their dependants. Mr Stock proposed revisions to the approach taken by the Expert Group. Statistical methods were used to calculate what level of award could be offered without the cost of the scheme prejudicing other health service provision. These concerns were taken into account in government.[82]

102. The amounts proposed were determined by what was affordable within the health budget; the level of payments was discussed in the Scottish Cabinet, but not with affected communities or with the UK government, precisely because the amounts depended on what could be afforded.[83] This is consistent with Professor Keel's recollection.[84] Although the Health and Care Committee would have preferred that the payments be larger, its response to Malcolm Chisholm's statement on 29 January 2003 was positive.[85]

103. Malcolm Chisholm presented the proposals on 29 January 2003. The scheme he proposed formed the basis of what would become the Skipton Fund.[86]

104. In summary: in 2003 the Scottish Executive departed from the long-standing view that no payments should be made to those infected with or affected by Hepatitis C through blood or

[80] Chisholm witness statement §§ 28-30.
[81] Chisholm witness statement § 31.
[82] WITN7078001_004 §§9-13.
[83] Chisholm witness statement §§ 33-34, 38, 41.
[84] WITN5736003_0061 § 106.
[85] Chisholm witness statement § 36.
[86] Chisholm witness statement § 45.

blood products. It led the way in establishing an *ex gratia* payment scheme.

105. It might be asked: why did this occur so much later than the establishment in 1983 of the Macfarlane Trust for those infected with HIV through blood products? It is clear that the support provided by the Macfarlane Trust represented a major break with the general principle that payments should not be made to patients in respect of NHS treatment unless their treatment had been shown to be negligent. This break with principle was accepted or justified because HIV was regarded as a uniquely terrible affliction. Professor Keel, for example, described it at the time as a death sentence and also referred to the social stigma which HIV carried.[87] Similarly, the Expert Group report explained that the rationale for support provided to those infected with HIV was based largely on the presumption at the time that HIV would inevitably and swiftly progress towards death.[88]

106. Hepatitis C, on the other hand, was identified only in 1989. It took time to appreciate the severity of the infection, not least because in some of those infected it was effectively latent for a period of years. There remained a concern within the health service and in government about further departure from the principle that payments should be made only in respect of negligent treatment. There was serious concern about setting a precedent for payment of no-fault compensation. There was a concern about the effect that such payments might have on NHS service provision more generally. The Expert Group itself found it impossible to identify a general principle underlying the various current schemes in which *ex gratia* payments were made in the absence of legal liability: it noted only that such schemes depended on what appeared to be fair in all the circumstances and covered cases in which there was felt to be a moral obligation on the part of the state to make payments to persons who had been harmed.[89]

107. *Scottish Government position.* Once the severity of HCV infection had been recognized, as it gradually was in Scotland in particular owing to the work of campaigners, the Health and Community Care Committee of the Scottish Parliament, and the Expert Group chaired by Lord Ross, the view that provision ought to be made for those infected with Hepatitis C began to gain ground. The Expert Group formed the view that infection with HCV may bring about adverse effects similar to those of infection with HIV.[90] Its report therefore concluded that it was inequitable that those who had contracted HIV as a result of receiving NHS blood or blood products received compensation while those who had contracted HCV

[87] Keel witness statement § 71.
[88] HSOC0020367 at § 1.3.
[89] Expert Group report § 3.36 (some examples of other such schemes are given in § 3.25).
[90] § 4.2.

in exactly the same way did not.[91] This recognition paved the way for the establishment of the first *ex gratia* payment scheme for those infected by HCV.

HIV Litigation

108. *Scottish Government position*. The Inquiry's own presentation note contains a detailed account of legal actions which from 1988 began to be raised by haemophiliacs infected with HIV through blood products.[92] The actions were raised against health boards, the SNBTS, and the Secretary of State for Scotland. It is unnecessary to repeat that detail here and sufficient to note the following.

109. First, the Scottish Office did not accept liability; the actions were therefore defended.

110. Second, the focus in the Department of Health appeared to be on *ex gratia* compensation for those infected. Only in December 1990 did it emerge that DoH might be contemplating settling the actions which had been raised in England. On 11 December 1990 the prime minister announced that the UK government had agreed in principle to settle the actions.[93]

111. Third, the Scottish Office had not been involved in discussions leading up to this announcement. It was unprepared for dealing with settlement of the Scottish actions. While it was clear that those actions too must be settled, it would take several months before discussions with solicitors representing the Scottish claimants were concluded with a settlement agreement. For most claimants settlement was agreed by August 1991. Some special cases required more time.

112. In this instance, communications between DoH and the Scottish Office were clearly not satisfactory. Lord Forsyth stated that consultation by DoH and the Treasury was inadequate to enable the Scottish Office to fulfil its functions.[94] The consequence is that settlement in the Scottish actions was delayed.

Public inquiry

113. On the advent of devolution, the new health minister in Scotland, Ms Deacon, was advised in a submission from officials that the issue of compensation had twice been examined rigorously by the Department of Health in recent years. It was suggested that nothing further was required.[95] Nonetheless, as noted already, Ms Deacon commissioned a fact-finding exercise. As she explained, her focus was on trying within devolved arrangements to make

[91] Expert Group report § 2.4.
[92] Inquiry presentation INQY0000373 at §§ 608-49.
[93] DHSC0003654_003.
[94] WITN7126001 at § 68.
[95] WITN4436001 at § 20.

progress in addressing the needs of those infected and affected. She explained that she did not think a full public inquiry would be the best way forward: it would take years, incur considerable cost, and would be focused on the past rather than the future.[96] She also drew attention to the context: the powers of a Scottish inquiry would be limited. The few Scottish public inquiries which had taken place had been concerned with events which had taken place wholly within Scotland; whereas the issue of infected blood and blood products was a UK-wide issue. Particularly in the early years of devolution, there was a concern about setting precedents in relation to other issues on which campaigners were seeking a public inquiry. Finally, it was hoped that the committee structure in the new parliament would enable members of parliament to conduct inquiries into issues of concern - as indeed the Health and Community Care Committee did in relation to infected blood.[97]

114. Malcolm Chisholm gave evidence that during his time as Minister for Health and Community Care the issue of a public inquiry had again been considered. He explained the reasons for deciding against this to the Health and Community Care Committee on 9 September 2003. The principal reason was that, having regard to the state of scientific knowledge at the relevant times, it was difficult to see how things could have been done differently. Any inquiry would encroach on reserved matters, given that licensing of blood products had been the responsibility of a UK government agency, although he did not regard this as one of the main reasons. Furthermore, lessons in better communication by clinicians with their patients had been learned already. The Committee itself was not pressing for an inquiry; its priority was securing payment to those infected and affected. He noted, however, that if new evidence emerged, he would be happy to consider it with an open mind.[98]

115. Robert Stock, an official who provided advice to the minister from 2001 to 2004, explained in his witness statement that he regarded the lack of consensus on the risks associated with hepatitis C at the time, coupled with the fact that NHS staff acted in good faith in the light of the evidence available to them, as the principal reason why there was no need for a public inquiry. He emphasized the view in the Health Department that, in order to justify the cost of an inquiry, there must be the prospect of revealing significant new information. The cost implications of an inquiry were always a major consideration, because they would have an adverse impact on the care the Scottish health service could provide to patients.[99]

116. Andy Kerr, who succeeded Malcolm Chisholm as Minister for Health and Community Care

[96] Deacon witness statement § 76.
[97] Deacon witness statement §§ 78-79.
[98] Chisholm witness statement §§ 50-61.
[99] WITN7078001_0010 §§ 32-38

in October 2004 explained in his witness statement that, if there was new evidence to the effect that the NHS could have taken action earlier in light of what was known at the relevant times, this would need to be considered in relation to the issue of a public inquiry.[100]

117. Professor Aileen Keel remained of the view in May 2006 that no new evidence had emerged since 2000 such as to make it appropriate to hold a public inquiry.[101]

118. The SNP manifesto for the 2007 elections to the Scottish Parliament undertook that an SNP government would hold a public inquiry to find out why people were infected with hepatitis C through NHS treatment.[102]

119. The Penrose Inquiry was announced by the then Cabinet Secretary for Health and Wellbeing on 23 April 2008. In her statement to the Scottish Parliament on that day, the Cabinet Secretary emphasized that those who have suffered, and the families of those who have died, deserve answers to the complex questions surrounding their or their loved one's infection with Hepatitis C or HIV as a result of NHS treatment with blood and blood products. The Penrose Inquiry also investigated the deaths of a number of individuals.[103]

120. *Scottish Government position*. The present Scottish Government's understanding is that in the early 2000s calls for an inquiry were resisted substantially on the grounds that the issues had already -and recently- been investigated. Significant weight was placed on the investigation instructed by Ms Deacon, the report of which was published in October 2000. The evidence shows that the scope of that report was limited: it had focused, as urged by the Haemophilia Society, on the issue of heat treatment of Factor VIII as well as on the information given to haemophiliacs. It is fair to say that an investigation with that limited scope might on its own not bear much weight. But it did not stand alone: Andy Kerr, Minister for Health and Community Care from October 2004 to May 2007, explained that, in reaching his views on the utility of a public inquiry, he took account of the October 2000 report as well as other correspondence, SNBTS evidence to the Health and Community Care Committee, the Report of the Expert Group on Financial and Other Support of March 2003, and other briefings and advice.[104]

121. Some might conclude that the refusal to set up a public inquiry before the Penrose Inquiry was set up amounted to a cover up. No evidence has been produced to support such an assertion.

122. The present Scottish Government understands the Scottish Government at the time to have

[100] WITN5753003 at §§ 46-53.
[101] WITN5736003_0069 § 122.
[102] SNP 2007 manifesto p 36.
[103] See § 6 of its Terms of Reference.
[104] See e.g. witness statement of Andy Kerr WITN5753003 at § 39.

placed weight on the following factors.

123. First, given the state of scientific and medical knowledge in the 1980s, it was difficult to see how things could then have been done differently. With the advance of medical science, important lessons had in the meantime been learned, but there was no need of a public inquiry to learn them.

124. Second, there was genuine concern about the cost of a public inquiry, and the adverse impact its cost might have on the provision of NHS services more generally.

125. Third, there was a concern about the value of having a Scottish inquiry which would be unable to grapple effectively with issues which had a UK-wide dimension. That point applies to many of the key decisions in relation, for example, to screening of blood donations. This concern is not fanciful: the Penrose Inquiry was unable to compel the attendance of witnesses from whom it would have wished to take evidence because they were not resident in Scotland.

126. Finally, the issue of holding a public inquiry has to be seen in the wider context of the campaign to obtain *ex gratia* payments for those infected or affected by HCV. So, for example, the Health and Community Care Committee of the Scottish Parliament pressed the government to accept the principle that payments should be made; as long as that was done, the committee was less interested in whether a public inquiry was held.

vCJD

127. vCJD was discovered in 1996. At that time little was known about its transmissibility in humans. The possibility of transmissions through blood transfusion had to be considered. In October 1987 the CMO for England acknowledged the possibility of such transmission.

128. In her witness statement Professor Keel addresses the main issues.[105] In brief summary: first, there was a question whether there should be a ban on UK blood products. Professor Keel's view was that the risk of transmission at this time was hypothetical. There was no diagnostic test. She therefore shared the concern that steps taken to prevent the theoretical risk of transmission could pose a real, quantifiable risk of eroding the donor base and risking the blood supply. She explains that the Scottish Office did not consider deviating from the recommendations of the Committee on the Safety of Medicines, but that she was disappointed by the CSM's decision on 1 April 1998 that UK plasma should be banned from use in medicinal products.

129. Second, the situation raised serious ethical questions. On 6 February 1998 ethical advice was issued to NHS Trust medical directors by Dr Winyard. This advice was adopted in Scotland.

[105] WITN5736003 at §§ 49-66.

It was to the effect that patients who had received blood or blood products implicated with vCJD should not be informed, as the risk of transmission was entirely theoretical; there was no diagnostic test or treatment available; and any individual informed would face a lengthy period of anxiety and uncertainty, owing to the likely long incubation period of the disease. In June 2000 it was decided that further information should be provided to implicated donors if they wanted it. Again, the Scottish Executive did not seek separate advice on this issue. On 29 October 2002 Professor Keel wrote on behalf of the CMO to authorize clinicians to inform patients that they had been exposed to vCJD implicated products. A notification process was commenced throughout the UK in September 2004. In 1999 universal leucodepletion was introduced throughout the UK. Further risk reduction measures were announced throughout the UK in July 2005; the announcement was prompted by advice from the CJD Incidents Panel. Donors who had donated blood to patients who subsequently developed vCJD were to be contacted and were informed that they were potentially at risk.

130. *Scottish Government position*. On these issues the Scottish Executive appears to have taken the view that a UK-wide approach was appropriate. It appears that DoH took the lead. The measures taken appear to have been successful, since no instances of transmission are known to have occurred after universal leucodepletion was introduced in 1999. The ethical issues about the information to be given to those who had been exposed to implicated products were clearly profound. The Scottish Government does not believe that it is appropriate for it to assess what should have been done by earlier administrations. It has no recommendations to propose on this issue.[106]

II Decision-making in Scotland; and relations between relevant bodies

131. The Inquiry team has prepared a *Presentation Note on Scottish Office and SHHD Decision Making*.[107] A presentation on that topic was given at the Inquiry hearing on 21 September 2022. That makes it unnecessary for these submissions to explore these issues in detail.

132. It may, however, be helpful to note the legislative framework at the outset. Section 19 of the National Health Service (Scotland) Act 1972 provided for the establishment of the Common Services Agency ('CSA', now commonly referred to as NHS National Services Scotland), of which the Scottish National Blood Transfusion Service ('SNBTS') is a division. The National Health Service (Functions of the Common Services Agency) (Scotland) Order 1974 delegated to the CSA (among other functions) the provision of supplies of human blood for the purposes of carrying out blood transfusion and related services, including the production of

[106] On the current regulatory position, see below §§ 189-90.
[107] INQY0000373.

blood fractions. The National Health Service (Scotland) Act 1978 Act replaced the 1972 Act. Section 10 of the 1978 Act again provided for delegation to the CSA, and the 1974 Order was preserved.

133. Sections 1(1) of the 1972 and 1978 Act imposed a general duty upon the Secretary of State (now upon the Scottish Ministers) to promote the effective provision of an integrated health service in Scotland. Thus, the principal duty to provide effective health care in Scotland lay upon the Secretary of State for Scotland, and the Scottish Office retained strategic control in matters of health care policy. The day-to-day running of the service was delegated to territorial health boards or to bodies corporate, such as the Common Services Agency.

Relations with the UK government prior to devolution[108]

134. Until the Scotland Act 1998 came into force, the government of the UK was unitary. The National Health Service was a truly UK-wide organization. While the Secretary of State for Scotland (and the Scottish Office) existed to represent Scottish interests within government, his freedom to act independently was limited by the extent to which the doctrine of collective responsibility of the UK cabinet would permit him to do so. There were issues on which it was considered desirable that the UK should act as a whole. Blood policy was one such issue. Differences in the provision of treatment from one part of the UK to another were thought to be difficult to explain from a policy point of view and were in general to be avoided. This was particularly so where the source and content of the expert advice which informed the formation of policy was the same in Scotland and England, as would very often be the case. Nonetheless, as the Inquiry has heard, it was open to those responsible for taking decisions in Scotland to take a line different from that taken in England.

135. Prior to the Scotland Act 1998, responsibility for the health service in Scotland was entirely devolved to the Secretary of State for Scotland and through him to SHHD. DHSS had no oversight role, but SHHD and DHSS kept in touch with one another in relation to developments which might affect the other department. Mr Macniven explained that in relation to each aspect of health policy for which he had responsibility, he took care to establish and maintain communication with his opposite number in the DHSS. But it was for each health department to develop its own policies. Since each department could and did take its own decisions on policies and funding priorities, there were necessarily differences in service delivery in the various countries of the UK. Mr Macniven's assessment was that relations between SHHD and DHSS were cordial if not close.[109] (Professor Keel said the

[108] Covered in Inquiry presentation INQY0000373 at §§ 28 ff.
[109] WITN7064001_014 §§ 24-25, 27, 29.

same and referred to a general desire across all four countries to act on a UK basis in relation to policy in areas such as blood and blood products.[110])

136. One specific example is surrogate testing for NANB hepatitis. There was no reason to think that the problem was any different in Scotland from the rest of the UK; it therefore would have seemed sensible at the time for health departments to take the same decision on introducing testing. Mr Macniven thought that theoretically surrogate testing could have started in Scotland without DHSS agreement, but that the question was hypothetical. That is because the health departments were of one mind: circumstances were similar throughout the UK, and they should therefore co-ordinate the introduction of testing.[111]

137. There appear to have been some instances where communication between DHSS and SHHD could have been better. Lord Forsyth referred to a lack of consultation by DHSS officials with their Scottish counterparts in relation to settling litigation brought by those infected by blood products with HIV.[112]

138. Lord Forsyth explained that, any serious disagreement on policy between SHHD and DHSS would be resolved by discussion between senior officials or, if necessary, ministers.[113]

Ministers and officials

139. As Mr Macniven explained in evidence, only the most difficult or politically contentious decisions would be taken personally by ministers, on the basis of a written submission by officials. There were no set criteria for determining when officials should refer issues to ministers for decision: it was a matter of judgment, which would be exercised by officials at the appropriate level of seniority.[114] A specific example is again the question whether to introduce surrogate testing for NANB hepatitis. As Mr Macniven explained, officials had concluded that the arguments against introducing it were sufficiently decisive that it was unnecessary to refer the question to ministers.[115]

140. Lord Forsyth's evidence was to the same effect: officials were responsible for administering agreed policy and were expected to draw issues of concern to the attention of ministers.[116] He also noted that officials (in SHHD) were extremely effective and diligent.

141. It might be suggested that the absence of set criteria for determining when matters should be referred to ministers was a weakness. That would be a misunderstanding. The untidy realities

[110] WITN5736003_009 § 16.
[111] WITN7064001_35 § 56, 66.
[112] Forsyth witness statement WITN7126001 at §§ 68, 77.
[113] Forsyth witness statement § 27.
[114] WITN7064001_007 §§ 11-13.
[115] WITN7064001_042 § 64 (see also §§ 36-47 above).
[116] Forsyth witness statement § 9.

of life mean that it is not practicable to foresee all eventualities in the form of a prescriptive code which dictates when a matter needs to be referred to ministers. Even a prescriptive code would be in need of interpretation and therefore call for the exercise by officials of their judgment about when to refer an issue to ministers. The system necessarily involves the exercise of judgment.

Relations between SHHD and SNBTS

142. SHHD and SNBTS had a close relationship, their joint aim being to ensure that the health service in Scotland had a sufficient supply of safe and efficacious blood and blood products. Department officials attended the meetings of the CSA's governing body and its blood transfusion service committee as well as the quarterly meetings of SNBTS directors. Apart from these formal contacts, there were frequent informal contacts between the two.[117] Professor Keel regarded communication between SHHD and SNBTS as highly effective.[118]

143. There is some suggestion in the evidence that at times there were tensions in the relationship between SHHD and SNBTS. This is not an issue on which the Scottish Government feels that it can usefully comment, beyond making the following general points. From the evidence it is clear that, so far as there may have been tensions, they largely arose in relations with Professor Cash; the evidence is summarized in the Inquiry's presentation on decision-making in Scotland.[119] Mr Macniven was candid in discussing this issue. In evidence, he described Professor Cash as, in effect, a chief executive and as commendably energetic in seeking to get the best deal for SNBTS. He was also clear that Professor Cash was effective: his approach worked well, and SNBTS grew to meet increasing demand for its products.[120] Since SHHD had to cater for the demands of other parts of the health service too, it was perhaps inevitable that Professor Cash's approach might give rise to some tensions. Nonetheless, taking all of that into account, Mr Macniven's overall conclusion was that SNBTS was in general well supported by SHHD in financial and other terms; and that the difficulties Professor Cash's approach may have caused ultimately came down to diversion of effort, in the sense that Mr Macniven himself devoted more time and energy than he might otherwise have done to acting as a conduit in order to ensure effective communication between SHHD and SNBTS.[121]

Decision-making on medical and technical matters

[117] WITN7064001_018 § 31.
[118] WITN5736003_008 § 15.
[119] INQY0000373_016 §§ 45-55.
[120] Macniven transcript 19 July 2022 pp 51, 52..
[121] WITN7064001_019 § 32; transcript 19 July 2022 pp 53, 59.

144. Advice on matters of health policy was primarily provided to ministers by officials within SHHD who were not medically qualified. They were, in turn, advised by medical colleagues, whose function it was to liaise with key medical personnel in the health service and to convey to administrative colleagues sufficient knowledge about the technical aspects of a topic to allow appropriate policy to be formulated. Within the department the administrative and medical officials worked closely together, exchanging information daily without necessarily holding formal meetings. Medical officers also produced a monthly report, in addition to attending weekly meetings.

145. Government medical advisers were not themselves necessarily expert in any particular field. For the most part, the medical officers had a wide portfolio of responsibilities, and while some clearly gained considerable experience in particular fields, such as blood transfusion, and others might take the lead in relation to a particular issue, all would have had a number of other areas to cover. For example, Dr McIntyre, who became a Principal Medical Officer in 1977, was required to cover communicable diseases and environmental health. This wide brief thus included issues such as outbreaks of food poisoning, water quality and sewage disposal, radiation hazards and the aftermath of the Chernobyl disaster, as well as issues related to the blood transfusion service. Medical advisers contributed to the formation of policy by reporting back on the outcome of meetings they had attended for example with Regional Transfusion Directors, by maintaining a network of contacts with informed clinicians, providing a filter for external expert advice and by providing general advice on medical matters.

146. The small cadre of medical staff in SHHD therefore was not, and could not be expected to be, expert in HIV or hepatitis. They did have access to medical publications and sought to keep abreast of developments. But where specialist knowledge was required they necessarily turned to the experts. They obtained their information about the risks arising from blood and blood products and the various national and international responses to those risks principally through SNBTS. Its staff had the necessary national and international links.[122]

147. One means by which specialist medical or scientific advice was obtained – for example in relation to the appropriate methods of testing for hepatitis or HIV – was through the government practice of establishing advisory committees, composed of acknowledged experts in the particular field. SHHD was reliant on such expert advice in the formulation of medical policy. For reasons of economy and efficiency, and because the medical issues generally bore upon the NHS throughout the UK, such advisory committees tended to be administered by

[122] See e.g. Macniven witness statement WITN7064001_0023 § 40.

the DHSS in London; Scottish interests were represented on such committees by the presence of experts from north of the border, and Scottish civil servants including medical advisers attended as observers and reported back to SHHD. In such cases, it might be said that DHSS were taking the lead on a particular topic. This simply meant that the larger administrative Department was providing the primary support for the particular topic concerned.

148. Another means of keeping abreast of medical and scientific developments and obtaining the advice necessary to respond to them was the participation by SHHD medical officers in the regular meetings of SNBTS. Dr Bell attended the SNBTS directors' meetings religiously; subsequently Dr Forrester carried out a similar role. After these meetings the medical officer would generally write up a note of the key issues and circulate it to administrative and other colleagues as appropriate.

149. In addition, SHHD made routine use of the advice of its consultant adviser, Professor Cash. So, for example, departmental memoranda show that on the anxious questions whether and when to introduce screening for HTLV-III in Scotland SHHD was eager to involve Professor Cash in the discussion. He duly wrote to the CMO with his assessment of the benefits and risks. The documents also show that his advice was accorded significant weight.[123] The same is true of the question when to introduce screening for Hepatitis C.

III Current provision for support in Scotland

Financial support

150. The Inquiry is familiar with the compensation payments and *ex gratia* schemes which have been set up for those infected and affected over the years. It is not necessary to repeat the details here. Those schemes applied within Scotland too.

151. In 2017 the Scottish Government established the Scottish Infected Blood Support Scheme ('SIBSS'). For Scottish beneficiaries, this scheme superseded the existing UK-wide schemes, i.e., the Eileen Trust, Macfarlane Trust, MFET Ltd, Skipton Fund, and Caxton Foundation.

152. SIBSS' policies and its budget were based on the proposals of the Financial Review Group, which the government had set up in 2015.[124] In developing SIBSS policies, the Scottish Government took account of information received from the Alliance House organizations, and also consulted bodies such as Haemophilia Scotland and the Scottish Infected Blood Forum. Fuller details are set out in a witness statement given by Sam Baker.[125]

[123] See e.g. Inquiry presentation INQY0000373 at §§ 355-59 on this topic.
[124] See WITN4508014.
[125] WITN0713015.

153. Since its inception, the SIBSS scheme has been amended in order (a) to give effect to recommendations made in 2018 by the Clinical Review of the Impacts of Hepatitis C Group, as well as feedback from scheme beneficiaries via SIBSS surveys[126]; (b) to increase certain payments in order to achieve greater parity with the other infected blood support schemes in operation in the United Kingdom, in June 2021; and (c) to make cost of living increases in the level of payments under the scheme, most recently in April 2022.

154. Significant efforts have been made to minimize bureaucracy and improve the service provided by the Scheme where possible. The Scottish Government and SIBSS managers will continue to look at areas where the Scheme can be improved in future. While the Scottish Government will of course wish to consider any recommendations the Inquiry wishes to make in relation to this and the associated issue of a compensation scheme, it remains convinced of the benefits for its beneficiaries of a separate Scottish Infected Blood Support Scheme that can be more local and more responsive to its members. The Scottish Government would therefore wish to continue its support for SIBSS using the current approach, whereby the scheme is managed in Scotland by NHS National Services Scotland.

Non-financial support

155. The Scottish Government funds or supports various forms of non-financial support for those infected or affected.

156. *SIBSS*. SIBSS provides general support to those infected and affected in relation to insurance and mortgages by, for example, pointing beneficiaries to useful websites for insurance information or writing to mortgage lenders on their behalf to confirm their receipt of regular payments. It is worth noting that the situation, in terms of access to insurance products specifically, appears to be improving: the Association of British Insurers recognizes that HIV has become treatable (although not curable) and that HCV treatment success rates have improved. Insurance products currently available reflect that recognition.

157. *Psychology services*. The Scottish Infected Blood Psychology Service was set up in May 2021. It provides support to all those infected and their families. The Service is managed by NHS Lothian but is available across Scotland for infected patients and their family members. It is funded by the Scottish Government.

158. The Inherited Bleeding Disorders Psychological Support Service was set up in 2015-16 and is also managed by NHS Lothian, but available to patients across Scotland and their family members. It is also funded by the Scottish Government, jointly with NHS National Services

[126] https://www.gov.scot/policies/illnesses-and-long-term-conditions/infected-blood/, where further references are available.

Scotland's National Services Division.

159. Both services have received positive feedback from those who have used them. The Scottish Government therefore remains committed to continuing to support them as long as there continues to be demand for them.

160. *Palliative care.* The Scottish Government has taken note of the expert report to this Inquiry on palliative care in advanced liver disease, as well as recommendations made on behalf of those infected and affected in Scotland.

161. The Scottish Government has made a commitment to develop a new national strategy in order to provide the very highest standards of care up to the end of life and to ensure that everyone can access seamless, timely and high-quality palliative care. To that end, it has appointed a National Clinical Lead supported by a small expert Clinical and Practice Advisory Group (including a Consultant in Palliative Medicine and a Palliative Care Consultant Nurse) and in October 2022 established a new Strategy Steering Group for Palliative and End of Life Care. Representation on the steering group is broad: it reflects delivery of palliative care by staff from many disciplines and across sectors for people at home, in care homes, community hospitals, acute hospitals and hospices.

162. Initial discussion at the steering group has identified the need to develop a strategy which delivers palliative care for people with all illnesses. This will provide an opportunity to address local arrangements for delivery by Health Boards and Health and Social Care Partnerships, as well as looking at the potential for a new National Care Service. It will also address public health approaches to promoting a shared understanding of palliative care, so that Scotland is a place where citizens and communities are able to support one another and talk openly about planning ahead, serious illness, dying, and bereavement. Development of the strategy will be informed by the experiences of, and engagement with, service users and their families and carers.

IV The Framework study: *Compensation and Redress for the Victims of Infected Blood Recommendations for a Framework* (March 2022)

163. The Cabinet Office commissioned this study from Sir Robert Francis. It is for the Cabinet Office to lead on considerations on how any compensation framework for the UK would operate. There is a lot of work still to be done to consider the details of Sir Robert Francis' proposals. The Scottish Government would hope to reach agreement on any framework on a four nations basis and so does not plan to comment in significant detail while the Cabinet Office continues to consider Sir Robert's report. However, at the outset the Scottish Government has some general observations about the context for the proposed framework

which may assist the Inquiry.

164. First, it is crucial to acknowledge the suffering of those infected and affected. The Scottish Government does so willingly and without reservation. It profoundly regrets what they have suffered and continue to suffer.

165. Second, the observations that follow in no way detract from that acknowledgment.

166. Third, the Framework Study concludes that, without prejudging the outcome of the Inquiry, there would be a strong moral case for compensating those infected and affected, independent of any issues of legal liability or culpability (§ 2.5). As these submissions have noted already, the Scottish Government has long accepted the principle of making payments to those infected and affected without legal liability being established. That is the objective of the various earlier *ex gratia* payment schemes and now SIBSS.

167. Fourth, although it does not consider issues of legal liability or culpability, the Framework Study proposes awards of compensation which in a number of respects go beyond the long-established framework which underpins awards of compensation in the courts, including compensation paid in cases of medical negligence. That is in spite of the fact that, by definition, in those cases legal liability has been established or admitted.

168. Fifth, the Framework Study discusses briefly the rationale for payment of compensation to those infected and affected as a result of receiving infected blood or blood products. In essence it is twofold: that their case is a special one, in which there is a moral obligation on the state to pay compensation; and that their claims are not of a kind which readily lend themselves to resolution in conventional litigation.[127]

169. The Scottish Government accepts those points in general.

170. The Scottish Government also accepts the recommendation that the proposed scheme be UK-wide. In his oral evidence to the Inquiry, Sir Robert Francis recognized that his recommendations with regard to the award of compensation had drawn more on the position in England than in Scotland. When his attention was drawn to differences between the legal position in Scotland compared with England and Wales, his suggestion was that differences between the jurisdictions should be 'ironed out' and that there should be parity between the different nations. The objective, as he saw it, was to have a UK-wide scheme funded by the UK Government, with local administration to take account of local conditions.[128] He noted that some points of detail might require further reflection, but overall his view was that within a UK-wide scheme there should be some give and take about what was reasonable in making

[127] See in particular §§ 4.14/15; 4.48/49; 4.64.
[128] Transcript 11 July 2022 p 62; 12 July 2022 pp 54, 71/2.

an award, so that a fair solution was reached for the whole of the UK.[129]

171. While the Scottish Government supports this approach in principle, it suggests that there will need to be further consideration of how such a scheme might work in practice. In particular, the Framework Study proposes, on the one hand, that the scheme should be locally administered in each of the four nations of the UK, and, on the other, that there should be parity in compensation levels across the UK. The following are some of the issues which may arise from that framework and are therefore likely to need further examination.

172. *The discount rate.* The Framework Study proposes (paragraph 2.59) that future losses should include a discount for acceleration of receipt. When calculating future loss in a personal injury claim, it is normal to apply a discount rate to account for accelerated receipt. However, the discount rate in Scotland differs from those which apply in England & Wales and in Northern Ireland. The discount rate in England & Wales is -0.25%, in Northern Ireland -1.5%, and in Scotland -0.75%. The rates across the UK are all, currently, negative which has the effect of increasing, not decreasing, the award and as such, the term 'discount rate' is misleading.

173. *Aggravated damages.* Framework Study recommendation 7 is that the compensation scheme should allow for an award equivalent to aggravated damages. Aggravated damages are not, currently, a concept that exists under Scottish personal injury law. Although the Scottish Government suggested that it would be helpful if the Inquiry explored this point in oral evidence, that did not occur. The evidence instead (i) recognized that a claimant would probably not obtain an award on this basis in litigation; and (ii) indicated that the level of award would be 'relatively modest', by which sums in the tens rather than hundreds of thousands were said to be intended.[130]

174. *Interest.* Framework Study recommendation 13 refers to the application of interest on awards for past financial loss and past provision of care, or alternatively, an uplift for inflation. In relation to the application of interest, while the official judicial rate across the UK is currently the same (8% per year), in practice, different rates are often applied when calculating past loss. In Scotland, a rate of 4% for past loss is not uncommon but it is understood that in England and Wales the rate could be as low as 0.05%. This could result in a significant difference in the ultimate sum awarded.

175. *Awards for bereaved family members or dependants.* The Framework Study recommends that these awards are made with reference to the Fatal Accidents Act 1976. That Act does not apply in Scotland, where the governing legislation is the Damages (Scotland) Act 2011.

[129] Transcript 12 July 2022 pp 91-4, 145.
[130] Transcript 11 July 2022 pp 131/2, 134/5.

176. *Payments made under previous schemes.* The Framework Study recommends (recommendation 15) that no account should be taken of payments made under the current support schemes or previous schemes (although payments made under future infected blood support schemes should be taken into account in cost of living awards). The basis for this recommendation is (1) that the payments made were *ex gratia* and/or charitable; (2) it is anyway not easy to work out to what type of loss they relate; and (3) it is suggested that it would be burdensome or in some cases impossible to establish what support payments have already been made.[131]

177. The Framework Study develops the point regarding the *ex gratia* nature of the payments under reference to the general principles which the courts apply, namely (i) that as a general rule a claimant is entitled to recover the full extent of his or her loss but not more; (ii) that in quantifying that loss benefits received should be deducted but only if they are 'like for like', that is, they relate to a head of loss for which the claimant is claiming; and (iii) that there is an exception to the rule of deduction of 'like for like' benefits when the payments made were made for reasons of benevolence. (§§ 9.79-84). It notes in § 9.85 that in Scotland, but not elsewhere in the UK, the relevant legislation, the Administration of Justice Act 1982 s 10(c) and (iii) requires deduction from damages of benefits paid from public funds to an injured person in order to support his or her subsistence, provided they were paid before the date of the award of damages. In § 9.86 the Study observes that it is 'challenging' to apply these principles in a UK-wide scheme. The conclusion reached is that payments made under the support schemes to date should not be set off against any award made under the proposed framework.

178. The Scottish Government respectfully submits that none of these reasons is compelling. More importantly, all are outweighed by important considerations of equity: that is, that those in materially similar circumstances should be treated in the same way.

179. The underlying rationale of the proposed framework is that payments should be made to those infected or affected on what might be called a 'bespoke' basis, a scheme specifically designed for the present circumstances. Instead of applying the ordinary rules on quantification of damages used by the courts, the proposed framework would provide for awards under the various headings set out in chapter 9 of the Framework Study. Special medical and legal panels would determine eligibility. Payments would be made not because legal liability had been established but because there was a moral obligation to make them.

180. There is no clear reason why this framework for making payments could not take account of earlier *ex gratia* payments. Both the existing (and predecessor) schemes and the proposed

[131] §§ 2.70, 9.79-93, 10.3; recommendation 15 was mentioned only briefly in oral evidence: Transcript 12 July 2022 p 63.

framework are intended to recognize and redress harm suffered by the infected and affected. That being so, it would be relevant for the proposed framework to take account of payments which had already been made to individual applicants, for example to contribute towards living costs in a particular year. Indeed, some of the payments made were compensatory in nature, particularly the HIV settlements first made in 1991 and 1992 for those infected via blood products and blood transfusions respectively.

181. As the Framework Study observes, the relevance of the 'benevolence exception' to the present circumstances is unclear. It is an exception to an otherwise clear principle that claimants should not obtain double recovery, so payments they receive as a result of their injury should be deducted from any award of damages. If the relevance of the exception is unclear, the correct conclusion is that it should not apply rather than, as the Framework Study concludes, that all past payments should be left out of account.

182. The details of the payments made under the various current support schemes, as well as past payments by the Skipton Fund and MFET, are available.. In any case if, as the Study contemplates, disproportionate effort or difficulty might be involved in tracking down 'relatively small payments' (§ 9.79), the proposed framework could adopt a view of disregarding certain types of payments or those below a certain level as de minimis. But it will be clear from what has been said already that that is not an apt description of the level of payments some of those infected have received. While some past charitable discretionary payments from the Alliance House organizations would be difficult to establish, it is straightforward to establish what an individual has received from SIBSS. It will also normally be possible to establish what lump sum and annual payments have been received from the Alliance House organizations, based on when the person first applied to a scheme.

183. Accordingly, the Scottish Government does not believe that the various reasons given for ignoring payments made under existing support schemes to be adequate.

184. For the Scottish Government, however, the primary consideration is fairness to all concerned. Significant payments have been made under the existing and previous schemes. For example, some of those who are coinfected will over the years have received sums amounting to about £590,000 up to March 2023 (not including charitable payments from the Macfarlane or Eileen Trusts or the £100,000 interim payments made in October 2022). Others have yet to make any claim on the support schemes (or may only just have done so) and have yet to receive anything. If all past payments are left out of account, it is clear that individuals in otherwise similar circumstances may be treated differently, in some cases very differently.

185. The Scottish Government considers that unequal treatment of this kind cannot be regarded

as either fair or equitable. It therefore submits that the Inquiry may wish to consider closely this particular aspect of the Francis proposals. The impact on the working of the proposed framework need not be substantial. At the very least, however, it would be equitable for panels under the proposed scheme, when considering the level of award, to be required to consider and to take appropriate account of sums which a claimant has already received under the existing or previous support schemes.

V The current position in Scotland

186. For the assistance of the Inquiry, this section sets out the up-to-date position in Scotland in relation to various issues relevant to the Inquiry's terms of reference.

Patient Safety Commissioner.

187. During 2021 the Scottish Government ran a public consultation on instituting an office of Patient Safety Commissioner, independent of the Scottish Government and the NHS and having statutory powers. There was strong public support for the proposal. On 6 October 2022 the Scottish Government introduced the Patient Safety Commissioner for Scotland Bill into the Scottish Parliament. The Bill as introduced provides for a Commissioner who will be directly accessible to patients, their families and the wider public. Key functions of the Commissioner will be to act as an advocate for patients; to hold healthcare providers to their responsibility to listen to patients' concerns about safety; to work with patient safety organizations to identify systemic patient safety issues and promote better coordination; and to consider and make recommendations on anything else to do with the safety of healthcare in Scotland. Among other things, the Bill as introduced confers power on the Commissioner to require health care providers to provide information which is relevant to his or her work; and to carry out formal investigations into health and safety issues and report the findings and resulting recommendations to the Scottish Parliament. Those to whom recommendations are addressed will be required to respond to them within a specified period.

The current regulatory position

188. This section provides a brief note of the current regulatory position.

189. First, since late 1999 UK plasma has not been used in the manufacture of medicinal products owing to the risk of transmission of vCJD. In 2020 a review by the Commission on Human Medicines and the Medicines and Healthcare Products Regulatory Agency concluded that the use of plasma from UK donors for these purposes would expose the patient population to no

or minimal additional risk of vCJD in the future.[132] Based on that advice the Scottish Government and the other UK governments announced in February 2021 that UK plasma could in future be used for production of immunoglobulins. (MHRA is to carry out a further review on the question whether UK plasma can also be used for production of albumin.)

190. Second, in order to give effect to vCJD risk reduction measures, it had been the practice that individuals born in or after 1996 do not receive UK plasma; instead they receive imported plasma or apheresis platelets. (The significance of 1996 is that from that year onwards individuals would not have been exposed to BSE through ingestion of food.) In September 2019 SaBTO reassessed the risk-reduction measures appropriate for such individuals (as well as those with TTP (thrombotic thrombocytopenic purpura)) and in light of a revised risk assessment recommended that those measures be withdrawn. That was done from September 2020. Other risk reduction measures remain in place.[133]

The current testing regime

191. The testing regime has recently been extended. Following recommendations from SaBTO in 2021, SNBTS introduced in April 2022 testing for anti-Hepatitis B core antibodies as an additional measure, as well as the existing HBV testing which was already being undertaken. This has allowed the identification of donors who have previously had Hepatitis B. It is anticipated that only a small number of donors will be in that position, but those who are will no longer be able to donate blood.[134] Other UK blood services have also started such testing.

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132 https://www.gov.uk/government/publications/critical-risk-assessment-report-use-of-uk-plasma-for-the-manufacture-of-immunoglobulins-and-vcjd-risk#:~:text=The%20Commission%20on%20Human%20Medicines,medicinal%20products%20would%20be%20negligible.

133 https://www.gov.uk/government/publications/risk-reduction-measures-for-variant-creutzfeldt-jakob-disease-pcwg-report

134 https://www.scotblood.co.uk/news/hepatitis-b-virus-hbv-core-testing/