

Neutral Citation Number: [2022] EWHC 2269 (Admin)

Case No: CO/3319/2020

IN THE HIGH COURT OF JUSTICE QUEEN'S BENCH DIVISION ADMINISTRATIVE COURT

<u>Cardiff Civil Justice Centre</u> 2 Park Street, Cardiff, CF10 1ET

Date: 01/09/2022

Before:

THE HON. MRS JUSTICE STEYN DBE

Between:

THE QUEEN (On the application of CAROLYN

CHALLIS)
- and -

THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

- and -

NATIONAL HEALTH SERVICE BUSINESS SERVICES AUTHORITY

Interested Party

Claimant

Defendant

David Lock QC and Hannah Gibbs (instructed by Leigh Day) for the Claimant Rory Dunlop QC and Benjamin Tankel (instructed by Government Legal Department) for the Defendant

The Interested Party did not appear and was not represented

Hearing dates: 20 and 21 June 2022

Approved Judgment

This judgment will be handed down by the Judge remotely by circulation to the parties' representatives by email and release to The National Archives. The date and time for handdown is deemed to be 10.30 AM on Thursday 1 September 2022.

Mrs Justice Steyn:

A. Introduction

- 1. The English Infected Blood Support Scheme ('EIBSS'), set up by the Secretary of State for Health and Social Care ('the Secretary of State'), makes provision for payments to be made, subject to certain eligibility criteria, to those who contracted Human Immunodeficiency Virus ('HIV') or hepatitis C virus ('HCV') from or via NHS contaminated blood or blood products. It is administered by the National Health Service Business Services Authority (the interested party). The eligibility criteria for primary beneficiaries with HCV provide that to be eligible "the individual must have been infected ... with hepatitis C through treatment with NHS blood or blood products prior to September 1991 ['the cut-off date'], or have acquired it from someone who was" (emphasis added).
- 2. By this application for judicial review, the claimant challenges a decision of the Secretary of State made on 10 January 2022 to maintain the cut-off date rule pending the outcome of the Infected Blood Inquiry ('IBI'). The sole issue (aside from the question of the appropriate relief, if it arises) is agreed in these terms:

"Was the decision taken by the Defendant on 10 January 2022 ("the January Decision") to maintain, pending the outcome of the IBI, the cut-off date rule irrational?"

B. The claimant

- 3. Ms Carolyn Challis was diagnosed with Hodgkin's disease in April 1992. In her first statement to the IBI she has given evidence that between 3 March 1992 and 1 July 1993 she received three blood transfusions from the National Health Service ('the NHS'), during the course of her diagnosis and treatment for Hodgkin's disease. In August 1993, she was diagnosed with HCV.
- 4. On 10 December 2004, Ms Challis made an application for an ex gratia payment to the scheme, known as the Skipton Fund, which had been established that year for the benefit of those infected with HCV through treatment with NHS blood or blood products. The eligibility criteria for the Skipton Fund introduced the rule that the individual must have been infected with HCV through treatment with NHS blood (or blood products) prior to the cut-off date of September 1991 (or have acquired it from someone who was). On 14 December 2004, Ms Challis's application was rejected on the grounds that "your doctor has advised us that the date of infection was in February 1992 and accordingly outside the scheme guidelines".
- 5. On 18 February 2005, the Scheme Administrator for the Skipton Fund wrote to Ms Challis's doctor:

"As I am sure you will appreciate when the Department of Health established the fund last year expert, specialist advice was taken regarding the mechanical aspects of the fund and this included the screening of blood products for Hepatitis C. In this respect the information provided to the fund by the Blood Transfusion Service was that all blood products after 5th

September 1991 [sic] used within the NHS will have been screened for Hepatitis C.

In the case of Ms Challis the application completed by Dr Cramp shows that her operations requiring blood products were dated February 1992 onwards, which is within the screened period. ..." (Emphasis added.)

6. On 1 September 2006, the Skipton Fund established an appeal panel to which Ms Challis applied. On 26 March 2007, the appeal panel refused her appeal, observing:

"the treatment which you believe gave rise to your infection with Hepatitis C took place after 1 September 1991. Unfortunately this takes your application outside the terms of the Skipton Fund and we have no discretion to change the time limits"

- 7. On 1 November 2017, the Secretary of State established the EIBSS which brings together and replaces five earlier ex gratia payment schemes, including the Skipton Fund. In September 2019, Ms Challis made an application for an ex gratia payment to the EIBSS. Her application was rejected on 22 October 2019. Ms Challis appealed on 31 December 2019. On 17 June 2020, the EIBSS Appeals Panel rejected her appeal ('the 17 June 2020 decision'). In doing so, the panel accepted the evidence of Ms Challis's treating clinicians that she was infected with HCV "as a result of the transfusions received during 1992 and 1993". Nonetheless, her appeal was rejected on the ground that her application fell outside the scheme rules as she had contracted HCV after September 1991.
- 8. Although the eligibility criteria exclude Ms Challis from the ex gratia payment scheme, her individual situation is not the focus of this claim. She does not contend that the terms of any rational scheme must be such as to include her. Her complaint is that the Secretary of State made an irrational decision to exclude *anyone* infected on or after 1 September 1991 from the HCV payment scheme.
- 9. Mr Rory Dunlop QC emphasised at the outset of his submissions that the Secretary of State is acutely aware of the human context in which a large number of people have lost their lives or suffered debilitating illnesses. Whatever the causes, which are not a matter for this judgment, that is terrible. Mr Dunlop disavowed any intention, through the legal arguments presented in this case, to minimise her suffering. Ms Challis has undoubtedly suffered greatly. Nothing in this judgment should be taken to indicate a lack of sympathy for her suffering.

C. <u>Procedural history</u>

10. In her original claim form, the claimant sought to challenge the 17 June 2020 decision, which was described in the claim form as a "decision by the secretary of state to bring into force and/or maintain the cut-off date as a rule within the EIBSS scheme". The claimant advanced five grounds. On 22 March 2021, Mostyn J granted permission on grounds 2 and 3, refused permission on grounds 1, 4 and 5; and granted an extension of time to bring the application on ground 2. In respect of ground 2, by which the claimant contended the decision was irrational, Mostyn J observed:

"I am satisfied that Ground 2 is arguable. Whenever a point in time is used to define an entitlement there will always be hard cases that fall on the wrong side of the line. However it seems to me to be arguable that where the claimant does not know when she was infected, or whether she was infected by old blood, that the operation of the bright line in this case is arbitrary and irrational."

- 11. The claimant filed a renewal notice in respect of grounds 1 and 5. Following the grant of permission by Mostyn J, and prior to the oral renewal hearing, the Secretary of State made a fresh decision to maintain the cut-off date pending the outcome of the IBI. A submission dated 19 November 2021 ('the November Submission') invited the Secretary of State to choose between two options: (i) maintain the cut-off date, at least until the IBI reports or (ii) start the process of reconsidering the cut-off date. Officials recommended the Secretary of State choose option (i) and he did so on 30 November 2021.
- 12. At a hearing before Jay J on 7 December 2021, the reasoning in the November Submission was criticised by the claimant. The defendant was ordered to file and serve a witness statement and to provide proportionate disclosure. The claimant was granted permission to amend her statement of facts and grounds to address the Secretary of State's fresh decision and evidence; and the claimant's renewed application for permission was re-fixed.
- 13. The criticisms of the November Submission prompted officials to ask the Secretary of State to reconsider the two options, and make a fresh decision, based on a further submission dated 6 January 2022 ('the January Submission'). Officials again recommended the Secretary of State choose option (i) and he did so on 10 January 2022 ('the January 2022 decision').
- 14. At a hearing on 4 February 2022, Jay J granted permission on ground 4C and refused permission on grounds 1, 1A, 4A, 4B, 4D and 5. Although, overall, the claimant was granted permission on three grounds, the sole ground pursued is the rationality challenge in respect of the January 2022 decision (ground 4C). The head of challenge raised by both grounds 2 and 4C was rationality, and the claimant accepts that the January decision should be the focus of this judicial review. The claimant has chosen not to pursue her claim based on ground 3, having been refused permission on the parallel ground raised in respect of the January 2022 decision (ground 4D).

D. The facts

- 15. The government set up a series of ex gratia payment schemes starting in 1987 to provide support to those infected with HIV or HCV from NHS contaminated blood. The schemes cover some dependants of victims. The schemes commenced in 1987 with the Macfarlane Trust which made payments to people with haemophilia who had contracted HIV from NHS blood or blood products. From 1993, a new scheme, the Eileen Trust, was created to make payments to non-haemophiliacs who contracted HIV from NHS blood or blood products.
- 16. At that time, no equivalent payments were made to people who contracted HCV from blood and blood products provided by the NHS. During the 1990s, those infected with

- HCV from NHS blood campaigned for a similar scheme to the Eileen and Macfarlane Trusts.
- 17. Some claimants infected with HCV brought a group civil action. In *A v National Blood Authority* [2001] 3 All ER 289, Burton J held that blood which contained HCV was a 'defective product' and the defendant was liable, pursuant to the Consumer Protection Act 1987, to anyone infected with HCV by that product. However, many of those infected with HCV from NHS blood were unable to take advantage of the judgment, in some cases because they were infected before the Consumer Protection Act 1987 came into force on 1 March 1988, and in others because the ten-year limitation period for bringing a claim had passed (often in circumstances where the potential claimant only became aware that they were infected many years after the event).

The Ross report and the establishment of the Skipton Fund

- 18. The first ex gratia payment scheme for those infected with HCV from NHS blood or blood products, the Skipton Fund, was established in 2004. It is common ground that a significant factor prompting the UK government to create the Skipton Fund was a report, known as the Ross report, which was written by a group of experts ('the Expert Group') commissioned by the Scottish Executive on the recommendation of the Health and Community Care Committee of the Scottish Parliament, and published in March 2003.
- 19. The background to the creation of the Expert Group is related in the Ross report:
 - "1.6 Having considered a petition calling for compensation for 'HCV in blood' patients, the Health and Community Care Committee of the Scottish Parliament recommended ex gratia financial and other appropriate practical support should be made available for this group of patients. ...
 - 1.7 The Committee's recommendation was based on the following principles:
 - HCV patients were morally entitled to the same compensation as HIV patients;
 - HCV patients were morally entitled to similar support to that given in the support package provided for people who had contracted vCJD from food;
 - The unfairness of some people being able to benefit from the CPA judgement [i.e. A v National Blood Authority] but not others."
- 20. The Scottish Executive did not agree with this recommendation. But it accepted the Committee's recommendation to establish "an Expert Group to look at the current compensation system and propose alternatives". The Scottish Executive "agreed that the situation of 'HCV/HIV in blood' patients should form part of its wider

considerations". The Ross report was the work of the expert group chaired by Lord Ross which was established in accordance with this recommendation.

21. The Expert Group noted (Ross report, §3.25):

"We considered the provisions of some existing schemes that provide assistance, including the Macfarlane and Eileen Trusts, the vCJD scheme, the Criminal Injuries Compensation Act, the Pneumoconiosis etc (Workers' Compensation) Act 1979, the Vaccine Damage Payments Act 1979 and the compensation scheme in operation in the Republic of Ireland for persons infected with HCV through administration of infected blood and blood products. The evidence we considered on these schemes is set out in more detail in Annex F. We noted that all of these compensation schemes retain some test of causation or some limit on compensation." (Emphasis added)

- 22. The Expert Group did not "feel able to recommend the introduction of a no-fault scheme in Scotland", finding the "existing principle that 'the NHS does not pay compensation when it has no legal liability for the harm suffered by the patient' to be generally sound". But they "felt that special circumstances do arise from time to time where it is legitimate to make an exception". (Ross report, §3.34)
- 23. The Expert Group concluded:

"People who have contracted HIV or HCV as a result of receiving blood, blood products or tissue transfer from NHS Scotland

- 2.3 We considered the arrangements already in place to provide financial support for those infected with HIV through blood, blood products or tissue transfer via the Macfarlane and Eileen Trusts and are impressed by the principles underlying these schemes.
- 2.4 We conclude that the fact that people who contracted HIV as a result of receiving blood, blood products or tissue transfer from the NHS received compensation while people who contracted Hepatitis C virus (HCV) in exactly the same way did not, is inequitable. We are of the view that this inequity should be addressed by introducing new arrangements."
- 24. The Expert Group made four recommendations. Recommendation 1 stated (so far as relevant):

"The Scottish Executive should agree to make compensation payments as a matter of urgency to all people who can demonstrate, on the balance of probabilities, that they received blood, blood products or tissue from the NHS in Scotland before the dates when they were made HCV-safe and who were

subsequently found to be infected with Hepatitis C virus, as follows:

- A an initial lump sum of £10,000 to cover inevitable anxiety, stress and social disadvantage;
- B an additional lump sum of £40,000 to those who develop chronic hepatitis C to cover pain and suffering;
- C in addition, those who subsequently suffer serious deterioration in physical condition because of their Hepatitis C infection e.g. cirrhosis, liver cancer or other similar serious condition(s), should be entitled to full compensation. This compensation should be calculated on the same basis as common law damages taking account of the payments made under A and B above;

D ...

- E people who receive any payment under legal liability arising from alleged negligence or breach of statutory duty, from the Scottish Ministers, or any of the constituent authorities of the NHS in Scotland, in respect of having been infected with Hepatitis C should not qualify for these arrangements;
- F people who are already in receipt of payments linked to HIV infection from the Macfarlane Trust, Macfarlane Trust Special Payments Trust, Eileen Trust or the associated government Scheme of Payments should have these payments taken into account when compensation is assessed for the purposes of C;
- G people who have become infected with Hepatitis C as a result of the virus being transmitted from a person infected by blood, blood products or tissue from the NHS in Scotland shall be entitled to compensation on a similar basis to those who have been infected directly in this manner." (Emphasis added.)
- 25. The Expert Group explained their thinking as follows:
 - "3.35 Ex gratia schemes already exist to provide assistance in various circumstances, and these have been listed in paragraph 3.24. The Group has recommended the introduction of compensation payments for the benefit of people who can demonstrate, on the balance of probabilities, that they have received blood, blood products or tissue from the NHS in Scotland before the dates when they were made HCV safe, and who were subsequently found to be infected with HCV. We recognise that all these constitute exceptions to the general rule

that the NHS does not pay compensation when it has no legal liability for the harm suffered by the patient.

3.36 We asked ourselves whether there is any general principle covering all these schemes which could be applied to particular situations not yet identified but which might arise in the future. However, we have not succeeded in discovering such a principle. The existing schemes were all adopted for a particular purpose only, and all that can be said is that they appear to be fair in all the circumstances, and to cover situations where there was felt to be a moral obligation on the part of the State to make payments to persons who had been harmed. These are the considerations which have led to the Group's recommendation for compensation payments to HCV patients. Beyond that, we have been unable to identify any general principle applicable to such schemes and to other situations that might arise in the future, but it may be that, from their very nature, all such cases can only be dealt with on an ad hoc basis.

. . .

4.2 Presently people who have contracted HIV through receiving blood, blood products or tissue from the NHS benefit from the arrangements via the Macfarlane and Eileen Trusts, whereas people who contracted HCV under exactly similar circumstances do no. We believe that infection with HCV brings about adverse effects for the people involved similar to those experienced by people infected with HIV. Furthermore, the way in which people were infected with HCV was exactly the same as those who became infected by HIV. We feel that this represents an inequity that should be addressed by introducing new arrangements.

. . .

- 4.5 ... The proposed arrangements address an inequity between two groups of patients who were harmed by exactly the same set of circumstances (i.e. the inadvertent provision of blood, blood product or tissue contaminated with a virus). ..." (Emphasis added.)
- 26. Discussions between the respective administrations for England and Scotland concerning the scheme appear to have begun shortly before the final Ross report was published in March 2003. On 20 November 2002, an official in Scotland sent an official in England details of options for the eligibility criteria for schemes. The table attached to the email proposed:

"Basic eligibility criteria: Recipients of payments likely to have been infected with Hepatitis C as the result of receiving blood products or tissue from the NHS in Scotland before the

NHS introduced measures to make these 'Hepatitis C-safe'." (Emphasis added)

27. Mr William Vineall, Director of NHS Quality, Safety and Investigations at the Department of Health and Social Care states in his witness statement for this case:

"This is the first reference we have been able to find to the eligibility criteria limiting the scheme to those who were infected with HCV by NHS blood prior to the introduction of screening."

- I note that the *preliminary* recommendation published by the Expert Group chaired by Lord Ross did not limit the proposed ex gratia payments to those who received blood, blood products or tissue "before the dates when they were made HCV-safe" (Ross report, Annex G): those words were added at some point between publication of the preliminary and final reports. The Ross Report made no express reference to the fact that there was no cut-off date in the ex gratia schemes for those infected with HIV, and gave no express reasons for recommending that, in contrast to the Macfarlane and Eileen Trusts, the proposed HCV scheme should be limited by reference to the date(s) when blood, blood products and tissue "were made HCV-safe".
- 29. The outcome of the discussions was that a scheme along the same lines as proposed by the Scottish Executive would be introduced in England, and by the devolved administrations in Wales and Northern Ireland. On 29 August 2003, the (then) Secretary of State for Health, John Reid, announced that a financial assistance scheme for people infected with HCV as a result of being given blood products by the NHS would be established. By January 2004, the basic eligibility criteria and payment structure had been agreed across all four administrations.
- 30. The Skipton Fund was established in 2004. The eligibility criteria for the scheme include the requirement that the individual was infected through treatment with NHS blood or blood products *prior to September 1991*. This cut-off date appears to have been chosen because 1 September 1991 was the official roll out date for routine HCV testing of blood components by Regional Transfusion Centres.

The English Infected Blood Support Scheme (EIBSS)

- 31. In 2017 new support schemes for England and, separately, for each of the devolved nations, were established, replacing the five existing UK-wide infected blood support schemes (that is, the Macfarlane and Eileen Trusts, the Skipton Fund, the Caxton Foundation and MFET Ltd). The scheme for England is the EIBSS which brings together the administration of the various predecessor HIV and HCV schemes, replacing them from 1 November 2017.
- 32. The Department of Health and Social Care carried out two consultations on reform of the support offered by the previous five schemes. The main consultation was launched in January 2016 with a follow up consultation on the proposed higher payments for certain beneficiaries with HCV in March 2017. The decision made in 2004 to introduce a cut-off date of 1 September 1991 for those suffering with HCV was not changed in the EIBSS. Mr Vineall states that, as far as he is aware, no issue with the

cut-off date was raised during the consultations or identified in the equality impact assessment.

33. The Department of Health and Social Care Specification for the EIBSS sets out the eligibility criteria for primary beneficiaries in Annex A. So far as material, it states:

"Eligibility for those with hepatitis C

Stage 1 Payment

The criteria for qualifying for stage 1 payments are: the individual must have been infected, in England or overseas if the infection occurred while serving in the armed forces, with hepatitis C through treatment with NHS blood or blood products prior to September 1991, or have acquired it from someone who was. All applications should be assessed on the Balance of Probabilities of whether NHS blood or blood products, used in treatment in England (except for those in the armed forces), were the source of infection.

. . .

The key indicators for a qualifying application are:

 That on the Balance of Probabilities the individual received hepatitis C from NHS blood or blood products or from someone who did

and

• That blood test results show that the individual is currently infected with hepatitis C virus

or

• That the individual has received or is currently receiving treatment for hepatitis C

Or

• That the individual showed symptoms of hepatitis C after the acute phase of infection (first 6 months) was over.

Stage 2 Payment

The criteria for qualifying for stage 2 payments are that: the individual is eligible for stage 1 payments and their hepatitis C has advanced. ...

Eligibility for those who contracted HIV

The criteria for qualifying for HIV payments are:

On the Balance of Probabilities the individual was infected, in England or overseas if the infection occurred while serving in the armed forces, with HIV through NHS blood or blood products:

- a) Blood transfusion, this is the transfusion of whole blood, red cells, platelets or plasma;
- b) Tissue transfer;
- c) Infection through treatment with blood products
- d) Or acquired HIV directly from someone who meets these criteria.

Note: all NHS blood in England was being screened for HIV from October 1985 onwards so it is very unlikely (although not impossible) that HIV was transmitted through infected NHS blood after October 1985" (underlining added).

34. The "*Note*" was first introduced in the version of the Specification published on 23 December 2021, but the eligibility criteria in respect of HCV and HIV remained the same as under the predecessor schemes.

The Infected Blood Inquiry (IBI) and the Francis Report

- 35. In July 2017, the UK government set up the Infected Blood Inquiry (IBI) under the Inquiries Act 2006, with Sir Brian Langstaff as its Chair. The IBI is ongoing. It is not expected to report until 2023. Ms Challis is a core participant and has given evidence to the IBI.
- 36. The IBI's first term of reference is:

"To examine the circumstances in which men, women and children treated by national Health Services in the United Kingdom (collectively, the 'NHS') were given infected blood and infected blood products, in particular since 1970..."

As the Francis report notes at §1.4:

"The Inquiry is required to look at many aspects of the provision of this treatment, and the aftermath, and to examine issues of responsibility and culpability for what is widely acknowledged to be a disastrous episode in the history of the NHS."

37. The IBI's Terms of Reference include the following:

"Treatment, care and support

- 8. To consider the nature and the adequacy of the treatment, care and support (including financial assistance) provided to people who were infected and affected (including the bereaved), including:
 - a. whether and to what extent they faced difficulties or obstacles in obtaining adequate treatment, care and support;

b. ...

- c. the actions of the various Trusts and Funds set up to distribute payments;
- d. the differing criteria for eligibility for financial assistance applied by the various Trusts and Funds, the justification (if any) for such differences and whether such differences were or are equitable;
- e. the appropriateness of preconditions (including the waiver in the HIV Haemophilia Litigation) imposed on the grant of support from the Trusts and Funds;
- f. the extent of any differences in the arrangements made for financial assistance between England, Wales, Scotland and Northern Ireland;
- g. a broad consideration of the extent to which support is and has been comparable with support for those similarly infected and affected in other countries, for example, Canada and EU nations, such as France and Ireland.

. . .

Recommendations

- 11. <u>If the Inquiry considers it appropriate</u>, to make interim recommendations.
- 12. To report its findings to the Minister for the Cabinet Office, and to make recommendations, as soon as practicable." (Emphasis added.)
- 38. On 8 July 2021, Sir Robert Francis QC was appointed by the then Paymaster General to conduct the Infected Blood Compensation Study. The outcome of that study, a report entitled "Compensation and Redress for the Victims of Infected Blood Recommendations for a Framework" ('the Francis report'), was published on 7 June 2022 (that is, after the decision under challenge). Sir Robert's terms of reference are set out in Appendix 1 to the Francis report. The matters he was asked to consider included the rationale for compensation and "the scope of eligibility for such compensation (including the appropriateness or otherwise of any conditions such as 'cut-off' dates)". Sir Robert was asked to give "independent advice to the Government regarding the design of a workable and fair framework for

compensation for individuals infected and affected across the UK to achieve parity between those eligible for compensation regardless of where in the UK the relevant treatment occurred or place of residence."

39. The Francis report explains the "status of the Study" at §1.9:

"The understanding is that one I have submitted my report, and the Government has decided its response to my recommendations, both will be submitted to the Inquiry for its consideration and will be in the public domain. It is, therefore, important that I do not purport to prejudge the findings or recommendations of the Inquiry under its terms of reference. It follows that any recommendations I make have to be highly conditional on the outcome of the Inquiry, and that I am considerably limited in the conclusions I can safely draw about many matters relevant to the context of a possible compensation scheme. ..."

- 40. The Francis report concludes that there is a "strong moral and social justification" for compensating those infected and affected by the infected blood tragedy: see the Francis report §§4.64-4.74. The Francis report makes the following recommendations in respect of eligibility for compensation of directly infected persons:
 - "6.5 Condition 1: The applicant has been diagnosed as being infected with either or both of:
 - HCV
 - HIV

[the relevant diseases]

. . .

- 6.7 Condition 2: the applicant received one or more blood transfusions or blood products known to be capable of transmitting one or more of the relevant diseases. [the relevant treatment] ...
- 6.8 <u>Condition 3</u>: the patient received the relevant treatment between defined dates, namely during the period when no effective screening for infection/contamination of blood or blood products was applied to blood or blood products used for the relevant treatment, or alternatively after that period using blood or blood products likely to have been collected or produced during that period. [the relevant period]
 - The eligibility criteria under the EIBSS are (the other devolved schemes use the same or very similar criteria):
 - Those infected with HCV before September 1991;

- o Those infected with HIV before October 1985.
- Cogent submissions have been made to the Study that
 the currently used end date for eligibility does not take
 sufficient account of the later use of stocks which were
 produced during the period and retained. The Inquiry
 may wish to consider the evidence concerning that issue
 to establish whether a later cut off date should be
 defined for that or some other reason.
- The defined period should be that during which the administration of infected blood or blood products was avoidable, whether in the light of the knowledge of the time or retrospectively, subject to the relevant technology or science being available at the time. It is difficult to identify such a strong moral case for compensation for treatments received before, for example, HCV or HIV were known to exist.
- Consideration should be given to extending eligibility to patients who received the treatment before the defined period but at a time when it was known or knowable that the blood or blood products could be infected and there were other effective infection free treatments available for the patient's condition.
- 6.9 *Condition 4*: The applicant's infection was likely to have been caused by the administration of a relevant treatment." (Underlining added.)
- 41. In suggesting that there is a cut-off date of October 1985 for those infected with HIV, the Francis report is consistent with the landing page of the EIBSS website which, under the heading "Who can apply to join the scheme" states:

"People infected with HIV

You can apply to join EIBSS if you were infected with HIV as a result of treatment with NHS blood, blood products or tissue prior to October 1985.

If you were infected with HIV by someone who was infected through treatment with NHS blood, blood products or tissue <u>prior to October 1985</u> you can also apply for this payment." (Emphasis added.)

42. However, it was common ground before me – reflecting the terms of the DHSC Specification - that the eligibility criteria for those who contracted HIV do not include a cut-off date. It may be that in practice the eligibility of those who contracted HIV has been assessed on the basis that blood and blood products were HIV-safe from October 1985 onwards, and so that date has been used as if it were a cut-off date in the administration of the various HIV schemes. But the eligibility criteria are such

that, in principle, an individual applicant for an ex gratia payment would not be precluded from seeking to establish that, on the balance of probabilities, they contracted HIV from NHS blood or blood products as a result of treatment in, say, November 1985.

- 43. The Francis report addresses the question of interim payments in §§9.128-9.137. Sir Robert observed:
 - "9.128 Sadly, many of the infected community fear that they have not got long to live. ...
 - 9.129 This fear, and the need for early resolution as a result, is perfectly understandable and indeed realistic. It is generally understood that the full detail of a compensation scheme cannot in practice be finalised until the conclusion of the inquiry. ...
 - 9.130 In any event, it seems unlikely that the scheme could become operational until after the publication of the Inquiry report and a process of discussion and consultation, although some elements of the scheme could possibly be set up in advance. This Study has been set up in part to mitigate the risk of delays for these reasons, but as will be clear from the text of this report, the time necessary to set up a complex scheme such as this cannot be eliminated entirely. In the meantime, the risk increases that infected persons will die without the reassurance of knowing of the financial benefits available to pass on to their families and what may be many cases of hardship will continue without certain remedy.
 - 9.131 <u>Unfortunately</u>, it is not possible to eliminate this problem for all potential beneficiaries of the scheme. There will be potential beneficiaries in categories which have yet to be accepted as eligible for compensation. Others may qualify for existing categories in the support schemes but they have yet to apply or be accepted. It is difficult to see how they can be offered any immediate compensation scheme before the scheme is fully operational.
 - 9.132 There is, however, one category where not only is the need for immediate assistance the most clear, but who are the most easily identifiable, namely the infected persons who have already been accepted as eligible for regular payments under the existing support schemes. Further, the support schemes provide an organisation through which a paid payment could be made if the funds to do so were made available." (Emphasis added.)
- 44. Recommendation 14 of the Francis report states:
 - "I recommend that the Government should immediately consider offering a standard figure by way of substantial

interim payments, on account of awards likely to be made under the scheme, to infected persons currently in receipt of support under any support scheme. The figure offered should represent broadly the minimum amount an infected person could be expected to receive by way of a final award."

At §9.135 Sir Robert advised that "very few if any of the eligible infected persons could expect to receive an award of less than £100,000".

The January Decision

- 45. The November ministerial submission advised that officials had not been able to find a clear contemporaneous statement explaining the reasons for the cut-off date adopted in 2004, but they believed they could infer the reasons for it:
 - "6. The date chosen in the cut off was the date when screening of all blood used in NHS treatment for Hepatitis C (HCV) started. The Skipton fund was intended to offer support to those who contracted Hepatitis C after treatment with unscreened blood. By contrast, those who contracted Hepatitis C after routine screening was introduced would need to bring a civil action (e.g. in negligence).
 - 7. The latter category are, therefore, in the same position as anyone else who suffers harm after treatment in the NHS they will only be compensated where the law requires it. Normally that requires proof of fault on the part of the NHS. Any departure from that norm is liable to be hugely expensive to the public purse. It may also have other unintended consequences, such as overly conservative treatment.
 - 8. After September 1991, the NHS had set up a system to screen blood for HCV to safeguard patients receiving treatment with blood or blood products. The small number of claims that might be brought after September 1991 could be managed on a case-by-case basis. Further the screening system meant that it was easier to trace in individual cases whether donated blood had been infected. . . .
 - 9. We believe that this is likely to have been the reasoning, or very close to the reasoning, of the decision-makers at the time the scheme was set up. We consider that these would be good reasons for maintaining the status quo pending any recommendations of the IBI."
- 46. In the January submission officials drew attention to the claimant's submission that:
 - "i) There was a roll out of testing from 1 September 1991 but the date when the roll out finished and it could be said with confidence that all NHS blood was tested for HCV was unclear (see §5 of Reply);

- ii) NHS blood was frozen for later use (as per evidence to the Public Inquiry) ...
- iii) The '35 days' was guidance for some blood products (but not others) from the Regional Transfusion Centres but evidence from the Inquiry confirms that it is wholly unclear if that guidance was always followed."

47. The January submission states:

"The September 1991 date

- 9. The 22 November submission advised on what we believe we can infer to be the reasons for the cut off and acknowledges that we have not been able to find a clear contemporaneous statement explaining it. The Claimant does not agree with our inferences and considers that the scheme was simply for the general purpose of assisting the small number of people who suffered harm (infections) as a result of something introduced for the public good (blood donations and transfusions) (paragraph 6 of the skeleton reply).
- 10. The date chosen as the cut off was the date when screening of all blood used in NHS treatment for HCV started. <u>Using a cut-off date is a very simple way to ensure that the ex gratia scheme only captured those who received blood before screening was introduced.</u>
- 11. The last submission advised that, after September 1991, the NHS had set up a system to screen blood for HCV to safeguard patients receiving treatment with blood or blood products. However, as previously advised, we know that a small number of patients, treated with NHS blood products after September 1991, have been infected with HCV. That is, it is acknowledged that there remains a residual risk, but this is minimised after the introduction of screening.
- 12. Most of the evidence of which we are aware confirms that all blood was screened from 1 September 1991 and that fresh blood in general was stored for a maximum of 35 days. The Claimant refers to other evidence given at the IBI suggesting that 1 September 1991 may have been the start of the roll-out and not the end; hospitals still had stocks of unscreened blood to use up; and that pre-September 1991 unscreened NHS blood could have been frozen for later use.
- 13. We consider that there remains evidence to support using the September 1991 cut-off date as a reasonable point for when blood was screened. However, the IBI is looking at all of the evidence relevant to these points and we await its findings and the recommendation in the previous submission was to

maintain the status quo until we have the benefit of the IBI's report." (emphasis added)

- 48. I note (as Mr Dunlop emphasised) that the underlined admission in paragraph 11 is not an admission as to *how* the small number of patients treated with NHS blood products on or after 1 September 1991, and who have been infected with HCV, came to be infected: it is not an admission that they were treated with blood or blood products that were not screened for HCV.
- 49. The January submission continues:

"Consideration of the cut-off date

16. The 22 November submission advises why we recommend that you maintain the September 1991 cut-off date for application to be considered by the EIBSS support scheme, at least until the Inquiry reports. In summary, the moral and legal case for an ex gratia compensation scheme is weaker for anyone who received screened blood. Also, removing the cut-off date would effectively open up the scheme to those who would fail in a legal claim i.e. no fault compensation, which could set a difficult precedent. There is merit in maintaining the status quo until the Sir Robert Francis report (expected Spring 2022) and the IBI report (expected 2023 – to be confirmed) are available. This will ensure that direction of travel is consistent over the next few years."

50. Officials asked the Secretary of State to choose between two options:

"Option 1 – Maintain the September 1991 cut-off date for applications to be considered by the EIBSS support scheme, at least until the Inquiry reports.

Option 2 – Start the process of reconsidering the cut-off date. The first step would be to open discussions with the Devolved Administrations as we have committed to consulting on any changes."

51. In the January submission, officials reiterated the following advice which had been given in the November submission:

"Para 15. There appears to be no reason, therefore, for changing the wording of the cut off. Although there might have been other ways of drafting the cut off, so as to try to make sure (so far as possible) that the ex gratia scheme only captured those who had received screened [sic] blood, the one chosen had the significant advantage of being very simple and drawing a clear bright line on a particular date. For example, if inclusion in the scheme turned on whether blood was 'unscreened' rather than on the date of the infection, then it would have been necessary to investigate, in every given case (even cases after 1

September 1991), whether blood had been screened. It was is [sic] much easier and simpler to presume that everyone infected after the introduction of routine screening would have received screened blood.

Para 23. We recommend Option 1, for the following reasons

- For anyone who received screened blood, the moral and legal case for an ex gratia compensation scheme is weaker because (a) the NHS introduced appropriate screening; (b) there were fewer cases; and (c) numerically and evidentially these cases could be dealt with, without any excessive burdens, on a case-by-case basis as ordinary negligence claims.
- Removing the cut-off date would effectively open up the scheme to those who would fail in a legal claim i.e. no fault compensation. This could set a difficult precedent for people in a similar position to the claimant such as those infected with Hepatitis B. We are defending a challenge from someone infected with Hepatitis B on the basis that all blood was screened.
- The IBI, and the Francis report, will make their recommendations with the benefit of the fullest possible context, and without focussing only on legal arguments. There is merit in maintaining the status quo for the relatively short period until the IBI concludes so that any decision on whether to maintain or change the cut-off can be taken on a fully informed basis.
- Amending the status quo would require consultation with the other devolved administrations because of the agreement to work in lockstep on any changes to the scheme. Such a consultation process is likely to be lengthy and, if change were needed, it would be better to do it only once, when we have the benefit of the Francis report, commissioned by the Cabinet Office to look at a possible compensation framework, and the IBI report. These reports will allow us to have full facts before making a decision." (Emphasis added.)
- 52. The Secretary of State accepted the recommendation to adopt Option 1.

E. The parties' submissions

- 53. In short, the claimant contends that maintaining the cut-off date of 1 September 1991 is irrational because:
 - i) The intention in establishing an ex gratia fund for those infected with HCV was to create equity between those infected with HCV and those infected with

HIV: see the citations from the Ross report in paragraphs 23. and above. However, there is inequity between the two groups because the eligibility criteria for those infected with HIV contain no cut-off date rule, unlike the eligibility criteria for those infected with HCV: see paragraphs 33. and 40.-above.

- ii) In any event, the cut-off date first adopted in 2004 in the Skipton Fund, and maintained since then, was intended to reflect the date when NHS blood and blood products were "HCV-safe" i.e. the point at which patients were only treated with blood and blood products which had been screened for HCV. However, there is at least a real possibility indeed, the claimant submits there is overwhelming evidence that stocks of blood and blood products which had not been screened for HCV were retained to be used by the NHS on and after 1 September 1991. Consequently, the cut-off date does not accurately reflect the point in time when NHS blood could rationally be described as "HCV-safe".
- 54. Mr Lock submits that the court should apply the following legal principles:
 - "1. The domestic law of this country does not recognise equal treatment as a distinct principle of administrative law: Lord Carnwath in *Gallaher* [*Group Ltd v Competition and Markets Authority* [2019] AC 96] at §24.
 - 2. Public body decision makers have a public law duty to act rationally and an irrational exclusion of a person from an ex gratia scheme can make the exclusionary rule unlawful: see *Gurung v Ministry of Defence* [2002] EWHC 2463 Admin at §35.
 - 3. The starting point is that it is a 'principle of public administration that all persons in a similar position should be treated similarly': see Lord Donaldson in R (Cheung) v Hertfordshire Council quoted by Lord Carnwath in Gallaher at §28.
 - 4. 'Treating like cases alike and unlike cases differently is a general axiom of rational behaviour': see Lord Carnwath in Gallaher at [§26] quoting from Matadeen v Pointu [1999] 1 AC 98. Hence, a failure to do so can lead to a finding that the administrative decision can be irrational.
 - 5. Public law decision-makers are entitled to draw differences between individuals, even if they are in similar positions, providing they do so on a rational basis for reasons which are capable of objective justification: see Lord Carnwath in *Gallaher* at §27.
 - 6. A difference in treatment must be based on the facts at the date of the decision; it cannot be based on an assessment made at a prior date when the decision was made within a different factual or legal context: see *Gurung* at §56.

- 7. The assessment of the rationality of differences in treatment between persons in similar positions is a matter for the Court, not the decision maker: see Lord Carnwath in *Gallaher* at \$27 relying on $R(A) \ v \ SSHD \ [2005] \ 2 \ AC \ 68$ and Gurung.
- 8. In conducting that review, there is a sliding scale of intensity of review. If a decision is made for the distribution of finite resources, there is substantial restraint on the part of the decision maker. If the financial impact of the measure has not been addressed, the level of restraint is less: see *In Re Brewster* [2017] 1 WLR 519 at §64.
- 9. If there are persons in similar positions, a decision maker is required to recognise the fact of similarity of position and a decision to treat those in similar positions differently requires the decision maker to formulate reasons for the difference in treatment: see *In re Brewster* at §65.
- 10. However, even if differences are drawn between persons in similar positions, a difference in treatment still has to be objectively justified and there can come a point where the justification for a policy is so weak, or the line has been drawn in such an arbitrary position, that, even with the broad margin of appreciation accorded to the state, the court will conclude that the policy is unjustifiable: see Lord Carnwath in *Gallaher* at §27."
- 55. In support of the submission that the cut-off date rule is inequitable as between those with HIV and those with HCV, the claimant draws attention to evidence given to the IBI on 11 May 2022 by Dr Andrzej Rejman, a Senior Medical Officer in the Department of Health responsible for Haematology between 1989-1997. Dr Rejman was taken to a ministerial submission dated 20 February 1992 in which an official advised against imposing a cut-off date in the scheme which became the Eileen Trust, stating:

"Most HIV infections from blood/tissue will have occurred between 1979 and October 1985 when testing was introduced but it would be difficult to apply a cut-off date. It is still possible that infection could be transmitted from a donor who was in the 'window period' at the time of testing. Moreover, one of the reported tissue cases was infected in 1986."

"Apart from that one tissue case there have been no reports of infection transmitted since 1985 but we think it would be better to leave the scheme open rather than fix a closing date which might result in hard cases. However, claims of infection from blood or tissue after 1985 would have to be examined particularly closely in view of the safeguards then in place."

56. Dr Rejman agreed that this reflects the rationale for the absence of a cut-off date in this HIV scheme. The claimant submits the rationale applies with equal force to the

HCV scheme.

- 57. Given the absence of any reason in the Ross report for introducing a cut-off date in the HCV scheme where there had been none in the HIV scheme, Mr Lock submits it is probable this point of distinction was overlooked. He draws attention to the way in which eligibility for those infected with HIV is described on the landing page of the EIBSS website (see paragraph above) and contends that, if this was transposed from the website for the Macfarlane and Eileen Trusts, the Expert Group may have been led to believe that eligibility for those infected with HIV was subject to a cut-off date rule.
- 58. Mr Lock submits that, in circumstances where the January submission (and the earlier November submission) failed to draw the Secretary of State's attention to the inequity between the eligibility criteria for those infected with HCV and those infected with HIV, no reason for this unequal treatment has been given and so the decision is irrational.
- 59. As regards the introduction of screening for HCV, it is common ground that such screening began nationwide from 1 September 1991, although some centres began testing for the presence of HCV antibodies from around May 1991. However, the claimant submits there was no system to recall or screen existing stocks of blood and blood products which had been taken from donors prior to the introduction of testing, delivered to hospitals (and elsewhere), and then used after 1 September 1991. It is clear, the claimant submits, from evidence disclosed to the IBI that blood that had not been screened for HCV continued to be used within the NHS after 1 September 1991. Eligibility criteria that conclusively presume that from 1 September 1991 blood and blood products were screened are not rational.
- 60. The claimant has adduced an extract from a presentation note that is before the IBI regarding the late Professor John Cash, who at the material time was the National Medical and Scientific Director of the Scottish National Blood Transfusion Service. The presentation note refers to a letter from Professor Cash dated 15 February 1991 in which he raised the question as to how "start date" was being defined:

"Whatever the 'start date' will be, do we mean that by 9 a.m. on that day all RTC products and those in associated hospital blood banks will be HCV (screen) negative? ... If we adopt this definition, then clearly testing will have to commence well in advance of the 'start date'."

61. The presentation note records at §175:

"The start date was discussed at a meeting of the UK Advisory Committee on Transfusion Transmitted Diseases which Professor Cash attended on 25 March 1991. At that meeting, 'It was agreed that testing of blood and plasma donations would commence on a specified date. There would not be retrospective tests carried [out] on donations collected prior to that date."

- 62. On 27 March 1991, Professor Cash wrote to Dr McIntosh that the "definition of a start date now proposed will be exactly as stated the date when routine HCV donation testing will commence". On 3 April 1991, the proposed start date for anti-HCV testing was moved from 1 July to 1 September 1991 "to allow for a 'second-round' comparative evaluation of anti-HCV test kits at the Newcastle, North London and Glasgow RTCs". Dr Huw Lloyd at Newcastle RTC decided to commence anti-HCV testing in advance of the planned national roll-out, explaining in a letter dated 2 May 1991 that "By Ist July, all units of blood for transfusion in the Northern Region will be negative for Hepatitis C antibody".
- 63. The claimant has put in evidence an extract from the transcript of the IBI on 11 November 2021 in which Sir Brian Langstaff referred to Professor Cash's query as to what "start date" means, and observed:

"So he's raising the possibility that after – if, as we've seen, it is likely that on 1 September what was happening was testing of all new supplies, the supplies currently in the system might very well have been infected because they hadn't been tested.

. . .

That has repercussions – if it's right it may have repercussions for the accuracy of the start date adopted for Skipton."

- 64. While the recommended expiry period for whole blood and red cells (when unfrozen) was 35 days, the claimant asserts that different components have vastly different recommended expiry periods, up to ten years for frozen red cell concentrates. Consequently, unscreened blood products may have remained available for use by the NHS for years after 1 September 1991.
- 65. Mr Lock submits that it is no answer to the charge of irrationality that the decision was only to maintain the cut-off date rule pending the (now published) Francis report and the outcome of the IBI, given the urgency of the situation. The decision was a binary one, to maintain the cut-off date or to seek to devise and consult on a better solution. The fact that the decision was, in effect, a holding decision does not make it rational if the cut-off date is irrational.
- 66. The Secretary of State, contends that it is manifestly rational to wait for the outcome of the IBI before consulting on any amendment to the eligibility criteria, not least given the need to consult with the three devolved administrations on any proposed amendments.
- 67. Mr Rory Dunlop QC, leading Counsel for the Secretary of State, takes issue with the legal principles put forward by Mr Lock (paragraph above):
 - i) The first principle is agreed and relied on by the Secretary of State.
 - ii) Mr Dunlop does not take issue with the second principle, so far as it goes, but submits it is uninformative as it effectively states that it is irrational to act irrationally. Moreover, the claimant's reliance on *Gurung*, a case in which the

- exclusionary rule was found to be irrational because it was racist, does not assist because it is so far removed from the facts of this case.
- iii) As to the third principle, Mr Dunlop contends that *Gallaher* is authority for the proposition that there is no general principle in public law that public authority decision-making must always be consistent (see principle 1), and Lord Carnwath did not say the principle that all persons in a similar position should be treated similarly was the "starting point".
- iv) Mr Dunlop accepts that principle 4 is "accurate so far as it goes", but submits that it omits the important qualification added by Lord Hoffmann in Matadeen v Pointu that where the "reasons for not treating people uniformly" involve "questions of social policy", the question whether that reason is "valid" is one that "the elected representatives of the people have some claim to decide for themselves". Where a social policy distinction is not one that is plainly incapable of rational justification (as, for example, in Gurung and R(A)), the court should defer to the elected government to make the decision on where to draw lines as they have democratic authority and the information to make such decisions.
- v) Mr Dunlop disputes principle 5, submitting that the effect of Lord Sumption's judgment in *Bank Mellat* [2014] AC 700 (which Lord Carnwath cited in *Gallaher* at [27]), is not that the government must provide reasons why it is providing an ex gratia payment to one group, but not others, every time it sets up a new ex gratia payment scheme.
- vi) Principle 6 is disputed. Mr Dunlop submits that in the context of a racist exclusionary rule, in *Gurung* McCombe J was saying that rationality should be judged by reference to today's *standards* (rather than today's *facts*); it was irrational to perpetuate a difference in treatment that, on analysis, was rooted in racism. That does not mean that in a case like this the historical context of why a comparator scheme was set up in a particular way must be ignored.
- vii) In relation to principle 7, Mr Dunlop submits that the proposition does not reflect what Lord Carnwath said and it ignores the need for judicial caution when assessing political judgements.
- viii) The eighth proposition is also disputed, on the basis that "financial decisions are not the only kinds of decisions in which judges exercise 'restraint'".
- ix) Similarly to principle 5, Mr Dunlop takes issue with principle 9, submitting that "Brewster is not authority that, every time the executive creates a new policy, rationality requires it to 'formulate reasons' as to why the policy benefits some but not others in an arguably similar position. This would impose an impossible burden because every time a policy decision is taken there are an indefinite number of ways in which people who do not benefit may say 'why not me?'."
- x) Although principle 10 is not an accurate reflection of what Lord Carnwath said in *Gallaher* at [27], Mr Dunlop accepts the point is uncontroversial.

- 68. The Secretary of State contends for three further propositions:
 - i) The question where to draw lines when creating, extending or amending ex gratia payment schemes is a political one which the court cannot second guess: *R (CN) v Secretary of State for Health and Social Care* [2022] EWCA Civ 86, Sir Geoffrey Vos MR at [43].
 - ii) The general principle that like cases should be treated alike does not require a public authority to perpetuate a decision of policy indefinitely even when the public authority's views on that policy change. A public authority can change its mind and decide to be less generous than it has been in the past.
 - When a line is drawn, it inevitably means that hard cases will fall on the wrong side of the line. Neither the existence of hard cases, nor the fact that the line may have been drawn imperfectly, invalidate the rule if, judged in the round, it is beneficial and rational.
- 69. Mr Dunlop acknowledges that the ministerial submissions did not address the distinction in the eligibility criteria for those infected with HCV compared to those infected with HIV. He contends there was no requirement to do so. In circumstances where Mostyn J had given permission on two grounds, the Secretary of State took the reasonable approach of considering the options in light of the judge's observations in granting permission on two grounds. Mostyn J made no reference to the lack of a cut-off date for those infected with HIV. That was unsurprising in circumstances where the claimant had not relied on the disparity between HCV and HIV sufferers in her grounds of claim, albeit she had raised it in a letter before claim and in her reply to the summary grounds.
- 70. He draws attention to the observations of the Expert Group that the rationale for offering financial support via the Macfarlane and Eileen Trusts to people who contracted HIV from blood and blood products provided by the NHS was "largely based on" or "linked to" "the presumption made at the time that HIV would inevitably and swiftly progress to death" (Ross report, §1.3 and Annex F, emphasis in the original). Subsequent advances in the treatment available for those infected with HIV changed the prognosis, but the understanding when the Macfarlane and Eileen Trusts is likely to have informed the decision, Mr Dunlop submits, not to make eligibility subject to a cut-off date rule. Although by 2004 the prognoses for those infected with HIV or HCV were broadly similar, it is understandable and reasonable, he submits, that a cut-off date was introduced into the new HCV scheme while the eligibility criteria for the already long-established schemes for those infected with HIV were left unchanged.
- 71. As regards the point in time at which blood and blood products were screened for HCV, Mr Dunlop submits that the advice given in the January submission that "there remains evidence to support using the September 1991 cut-off date as a reasonable point for when blood was screened" was not irrational. The IBI is investigating this issue and it was rational for the Secretary of State to choose to wait for the outcome of that in-depth investigation. In circumstances where the cut-off date rule has been in place since 2004 and is only now being challenged, it is anticipated that Sir Brian Langstaff will report next year, and the Secretary of State is committed to consulting

- with the devolved administrations on any proposed changes to the eligibility criteria, it was rational to wait for his report with a view to consulting once.
- 72. The relief sought prior to the hearing included an order quashing the cut-off date rule. However, at the hearing, Mr David Lock QC, leading Counsel for the claimant, made clear that the claimant seeks a declaration that the January Decision is irrational and an order quashing that decision, with a view to the matter being reconsidered, not an order quashing the cut-off date rule.

F. Analysis and decision

- 73. In circumstances where the sole ground of review is rationality, I consider that the legal principles can be addressed shortly. It is well established that it is for the court to determine whether, viewed objectively, the decision is outside the range of reasonable decisions open to the decision-maker. The Supreme Court made clear in *Gallaher* that unequal treatment is not a distinct ground of review. In assessing the claimant's allegation of unequal treatment, the question is whether irrational distinctions have been drawn between different groups. "Consistency ... is a 'generally desirable' objective, but not an absolute rule": Gallaher, Lord Carnwath at [24], citing R (O'Brien) v Independent Assessor [2007] 2 AC 312, Lord Bingham at [30].
- 74. I agree with the Secretary of State's submission that the distinctions drawn in this case are far removed from those which were found to be irrational in *Gurung*. McCombe J found that the line drawn between persons governed by one military code as opposed to another, originally derived from 19th century United Kingdom and colonial legislation, was "*racial in nature*" (albeit it was far from clear that was apparent to the decision makers in 2000), and so irrational: [19], [28]-[29].
- 75. Closer to the facts of this case is *CN* in which the Court of Appeal rejected as unarguable a claim challenging the exclusion from the EIBSS of those infected with hepatitis B virus ('HBV'). I accept the Secretary of State's submission that the propositions cited in paragraph above are well-founded and supported by *CN* at [43]-[44].
- 76. I reject the claimant's contention that the decision to maintain the cut-off date rule, pending the Francis report and the outcome of the IBI, is irrational by reason of the disparity between those infected with HCV and those infected with HIV.
- 77. A cut-off date constitutes a clear, bright line rule which limits the cost of payments under the ex gratia scheme and of the administration of the ex gratia scheme. Although the Francis report had not been published when the January decision was made, the recommendation in that independent report of an eligibility criterion that "the patient received the relevant treatment between defined dates" supports the reasonableness, in principle, of including a cut-off date in the scheme.
- 78. The fact that the eligibility criteria for the HIV schemes introduced in 1987 and 1993 had not included a cut-off date does not make it irrational for the Secretary of State to maintain the narrower eligibility criteria adopted in 2004 for those infected with HCV pending the outcome of Sir Brian Langstaff's consideration of (amongst other matters), the justification (if any) for any differences in the eligibility criteria and "whether such differences were or are equitable".

- 79. Whereas the Ross report described the way in which people were infected with HCV as "exactly the same" as for those infected by HIV, the adverse effects for the people involved were described as "similar" (see paragraph above). Moreover, the Ross report twice observed that at the time when the eligibility criteria were determined for those infected with HIV, the understanding was that the virus would "inevitably and swiftly progress to death"; and it is implicit in the Ross report that that was not the understanding in 2004 in respect of HIV or HCV.
- 80. Although the Secretary of State's January decision involved a choice between the options of maintaining the cut-off date rule pending the IBI or starting the process of reconsidering the cut-off date, the underlying issue is not binary. The possibilities include: (i) maintaining the current eligibility for those infected with HCV or HIV; (ii) removing the cut-off date rule for those infected with HCV; (iii) introducing a cut-off date rule for those infected with HIV; (iv) moving the cut-off date for those infected with HCV to a different date (potentially chosen from a number of options); (v) moving the October 1985 presumption in respect of those infected with HIV (again, potentially chosen from a number of options); (vi) changing the criteria (in respect of HCV and/or HIV) to limit eligibility to those who received unscreened blood or blood products, rather than by reference to a cut-off date. It is reasonable for the Secretary of State to wish to consider the recommendations that Sir Brian Langstaff will make, given that he will have "the benefit of the fullest possible context", before starting the process of reconsidering the cut-off date.
- 81. It seems at least probable that the eligibility criteria for the EIBSS (not necessarily limited to the cut-off date rule in respect of those infected with HCV) will need to be reconsidered in light of the outcome of the IBI. It is far from irrational for the Secretary of State to consider that it is better to wait for the IBI report (which is expected within what may fairly be described as a relatively short period in the context of eligibility criteria that have been in place for 18 years), rather than go through the process twice of reconsidering the eligibility criteria (including consulting each of the devolved administrations), and potentially changing the criteria, within a short timeframe.
- 82. Although it is common ground that there is no cut-off date in the scheme for those infected with HIV, the way in which the presumption that blood and blood-products were HIV-safe from October 1985 has operated may, perhaps, mean that the difference between the schemes has been somewhat less marked in practice than it might appear on the face of the eligibility criteria (see paragraphs 40.-above). The way in which the various schemes have operated is also a matter being considered by the IBI.
- 83. The fact that the November and January submissions did not address the distinction between the eligibility criteria for those infected with HCV compared to HIV does not alter my conclusion that the decision to maintain the cut-off date rule pending the outcome of the IBI is not rendered irrational by reason of the differing eligibility criteria for the two groups. It is understandable that the November and January submissions did not address this distinction given that the issue was raised only in the claimant's reply, not her statement of facts and grounds, and the disparity was not the reason Mostyn J gave for granting permission. Moreover, no reasons challenge is brought.

- 84. The second aspect of the claimant's challenge focuses on the rationality of the particular cut-off date adopted, rather than the *principle* of adopting a cut-off date in one scheme and not another. On the evidence before me, it is plain that there is a serious question as to whether 1 September 1991 fairly reflects the point at which all NHS blood and blood products with which patients were treated could be said to have been "*HCV-safe*" i.e. screened for HCV antibodies.
- 85. Nevertheless, I am not persuaded that the January decision is irrational on the ground that it does not reflect the point at which only blood and blood products that had been screened for HCV were used by the NHS for these reasons:
 - i) The Secretary of State's decision was, in effect, a holding decision. The cut-off date of 1 September 1991 is maintained pending the outcome of the IBI. The points made in paragraphs 80.-above apply with equal force to this aspect of the claim.
 - ii) On the evidence before me - recognising that it is only a fraction of that available to the IBI, and without insight into the evidence that is scheduled to be given - it is not possible to say that the Secretary of State's conclusion that (pending the findings of the IBI) "there remains evidence to support using the September 1991 cut-off date as a reasonable point for when blood was screened", was irrational. 1 September 1991 was the date on which HCV screening was formally rolled out nationwide. The correspondence in 1991 to which I have referred indicates that, at least when the intended start date was July 1991, the start date was defined to mean that new blood and blood products would be screened from that date, not that old stocks already delivered to hospitals (and elsewhere) would be recalled or screened. On the other hand I note that the Skipton Fund wrote on 18 February 2005 that the Blood Transfusion Service informed the fund that "all blood products after 5th [sic] September 1991 used within the NHS will have been screened for Hepatitis C". The IBI may find that is wrong, but I accept Mr Dunlop's submission that, at this stage, the Secretary of State does not know that is wrong.
 - The point made in paragraph above also applies. Although it appears that the bright line drawn in the current eligibility criteria for those infected with HCV is imperfect that does not render it irrational to maintain it pending a report following an in-depth inquiry which is currently considering (amongst other matters) whether the cut-off date of 1 September 1991 is justified, equitable and appropriate.
 - Although the Francis report was published after the January decision, the independent advice given to government on the approach to take to interim payments, in particular that it is difficult to see how those who are not current beneficiaries under the scheme can be offered an interim payment before any revised scheme is fully operational (see paragraph above), provides support for the reasonableness of the Secretary of State's approach in the January decision. Moreover, the IBI has the power, if it considers it appropriate, to make interim recommendations.

v) The cut-off date rule was introduced in 2004. The IBI was set up in 2017 and it is anticipated it will report next year. Although I do not underestimate the urgency for those, such as Ms Challis, who would be potential beneficiaries of a revised scheme, it was not irrational for the Secretary of State to take the view that any reconsideration of the eligibility criteria should wait for the findings and recommendations of the IBI.

G. <u>Conclusion</u>

86. For the reasons I have given, the claim is dismissed.