Presentation on Financial Assistance Internationally

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Introduction

1. This presentation sets out the position in relation to the financial assistance schemes that were implemented in a variety of countries, to address HIV and or hepatitis C infection from infected blood or blood products. The presentation is necessarily selective but seeks to address in broad outline the provision that was made by some other countries. The position in Ireland has already been explored through the evidence of Brian O'Mahony.

Australia

Mark Fitzpatrick Trust

2. The Haemophilia Foundation of Australia (HFA) campaigned during the mid-1980s, through various means including newsletters, for the introduction of no-fault compensation for HIV infection.¹ In 1984 the National Advisory Committee on AIDS (NACAIDS) was established during a special meeting of the Australian Health and Medical Council (AHMC).² NACAIDS was established to act as an educational advisory body. A Compensation Working Party within NACAIDS was established in early 1986.³ In 1987, the Compensation Working Party published a report setting out various compensation options:

 $^{^{1}\,\}mathrm{HSOC0016703}$ p.4; NHBT0004024_003 p.7, HSOC0023206 p.1

² RLIT0002014 p.20; RLIT0000456 p.267

³ RLIT0000456 p.270

- A lump sum payment to anybody who satisfied an authority that they had contracted AIDS through blood products, organ transplants or artificial insemination. The sum would not be means tested and where the infected person had died, the payment would be made to their personal representatives.⁴
- A limited compensation scheme based on needs, with a cause-based test of liability. "Types of benefits" that might be covered included those concerning "Deprivation or impairment of earning capacity", death benefits, and household help or other expenses. However, there would be no provision for non-pecuniary loss.⁵
- A statutory cause-based compensation scheme related as closely as possible to common law benefits. Such a scheme might include an income adjustment benefit, i.e. periodical payments for 18 months after contraction of the virus reimbursing the individual for "most of his earnings" at the time of the accident which had been lost, defined as 80% of pre-injury earnings where the person had a full income loss up to a maximum of \$500 per week, or 85% of the difference between actual and pre-injury earnings. These payments would be "intended to provide the individual with the means to adjust to the consequences of AIDS". In addition, it might include an "impairment benefit", assessed 6 months after diagnosis with the sum dependent on the degree of impairment and age of the person, to cover costs associated with the disease, including quality of life changes, lifestyle costs and the loss of the ability to provide services to others. The payment would be part lump sum, related to pain, suffering and loss of amenity, and part annuity to a maximum value of \$50,000 for those aged 18 to 25, declining by 2% per annum to zero at age 75 and above. Finally, there might be death benefits, paid to dependants in a sum equivalent to a total incapacity sum that would otherwise have been paid. However, the payments relating to loss of earnings would be restricted to a period of five years after the date of death, or until the retiring age of the spouse if that was earlier because of "the opportunity over the long term for the spouse of the

⁴ HSOC0001487 p.19

⁵ HSOS0001487 p.19-20

deceased person to build a new life and the availability of Commonwealth benefits such as widow's pension".⁶

3. In 1989, the HFA submitted an outline proposal for financial assistance as part of their lobbying of the Minister of Health and Community Services. The proposal set out the service provision and financial needs of people with haemophilia and HIV/AIDS, together with the costings.⁷ It was submitted that the government should provide this assistance by setting up a special fund to make payments to people with haemophilia and their infected spouses or children.⁸

4. In 1989, \$13.2 million was set aside by the Australian Government to establish an independent Trust Fund to meet the financial needs of all those who were medically infected with HIV, and not just people with haemophilia. The interest and investment return from that initial funding was to be used to provide "financial assistance" (which was explicitly not compensation). 10

5. From the outset, it was expressly understood that the sum of \$13.2million would be reviewed in two years "and supplemented if necessary". ¹¹ An additional \$1million was given to the Trust in 1999. ¹²

6. The Trust, called the Mark Fitzpatrick Trust, could make discretionary payments to people "infected as a consequence of medical procedures prior to the protection of the blood supply and blood products". ¹³ In addition, payments could be made to people who were a dependent, parent or guardian of a person "who had medically acquired HIV" or of a person who had died from an HIV related illness as a result of medically acquired HIV.

⁶ HSOS0001487 p.23-25

⁷ HSOC0004453 p.12

⁸ HSOC0004453 p.12

 $^{^9}$ £6,256,149.68 at adjusted value for currency (1 AUD = 0.474 STG) on 01 Jan 1989. Accounting for inflation, £17,699,332.47 on 17 Nov 2021: HSOC0004453 p.12. See also HSOC0016703 p.4, SCGV0000230_063 at p.1 and MACK0002565 p.90

¹⁰ HSOC0004453 p.12 and DHSC0002848 p.17

¹¹ HSOC0004453 p.12

¹² MACK0002565 p.90

¹³ SCGV0000230 063 p.1

- 7. The board of the Trust making decisions about payments included "representatives of the affected groups". ¹⁴ Payments were made "based on need and hardship". ¹⁵ Annual payments were to beneficiaries, with a final payment on the death of a beneficiary to assist with funeral and associated expenses. ¹⁶
- 8. It appears that in the event that a claimant was later successful in any litigation, they would have to repay any amount paid out to them by the Trust.¹⁷
- The Mark Fitzpatrick Trust was wound up in May 2001 after 423 beneficiaries received \$20.16 million.¹⁸

Compensation for Hepatitis C Infection

- 10. No Australian Government financial assistance was provided for those with hepatitis C infection; their involvement was limited to contributing to legal costs and settlements in litigation. ¹⁹ The only State / territory to establish any financial assistance was the Australian Capital Territory (ACT).
- 11. In the ACT, financial assistance was available to "persons infected between 1 January 1985 and February 1990" where it was "more probable than not that the blood transfusion was the source of infection". ²⁰ The level of assistance was based on the impact of the disease on a person's health and life. No payments were available to spouses of the deceased person "as any individual who is deceased as a result of hepatitis C is likely to have contracted the virus at least two decades ago and outside of the compensable period". ²¹ The Scheme was primarily "owned" by the Australian Red Cross Blood Service ("ARCBS") but each proposed settlement required agreement with the Commonwealth Department of Health and Family Services.

¹⁴ SCGV0000230 063 p.1

 $^{^{15}}SCGV0000230_063~p.1$ and MACK0002565 at p.90

¹⁶ MACK0002565 p.90

¹⁷ DHSC0002848 p.17 and DHSC0046951 068 p.3

 $^{^{18}}$ £7,146,440.83 at adjusted value for currency (1 AUD = 0.35 STG) on 01 May 2001. Accounting for inflation, £18,690,290.77 on 17 Nov 2021. See MACK0002565 p.90

¹⁹ MACK0002565 p.92

²⁰ MACK0002565 at p.83

²¹ MACK0002565 at p.83

- 12. In New South Wales, the Government indemnified the ARCBS for claims made against it in relation to those who contracted hepatitis C from transfusion of a fresh blood product. However, no scheme was established in either New South Wales or other territories.²²
- 13. In 1994, the Haemophilia Federation Australia decided not to launch a campaign or take any special action for people with haemophilia infected with hepatitis C.²³ It had previously been seeking no-fault compensation at the state and federal level with poor results.²⁴
- 14. In the late 1990s, the Federal Government had a policy of contributing 40% of any hepatitis C related legal costs and settlements incurred by the States.²⁵ By 2000, the States and Federal Government set up the National Management Fund to provide coverage towards the Australian Red Cross Service to pay any valid claims arising from its work.²⁶
- 15. In 2004 the Senate Community Affairs Committee considered the circumstances surrounding hepatitis C infection in Australia and how hepatitis C affected people with haemophilia. The Committee concluded that "extending the current compensation arrangements is not in the best interests of those people who have acquired hepatitis C through blood and blood products". Furthermore, despite compensation via litigation being extremely difficult and uncertain particularly for those receiving "many pooled donations", they considered that it would be effective instead to focus on better access to services, improve the education of medical personnel, and support research efforts to develop more effective treatment of hepatitis C.²⁸

²² MACK0002565 at p.85

²³ HSOC0028440 p.3

²⁴ HSOC0028440 p.3

²⁵ MACK0002565 p.83

²⁶ MACK0002565 p.90-91

²⁷ MACK0002565 p.92

²⁸ MACK0002565 p.92

Denmark

Ex gratia compensation

- 16. In 1987 a coordinated public campaign by the Danish Association of Haemophiliacs together with litigation that the Association had commenced put significant pressure on the Danish government.²⁹ By Executive order (2 September 1987 General Compensation for HIV Infected Haemophiliacs), Parliament authorised the Minister of the Interior to award DKK 100,000 to people who were infected with HIV through blood or blood products.³⁰ This amount was increased to DKK 250 000 in 1988 and payment could also be made to certain relatives³¹ and then to DKK 750 000 in 1992.³² These sums could also be paid to heirs in certain circumstances.
- 17. The payments were made ex gratia and were not taken into account in the determination of taxable income, nor would the financial return on the sums result in a reduction in state benefits. Individuals had to apply to the Danish Health and Medicines Authority by 1 January 1987 in order to be considered for the payment.³³

Litigation

18. In 1987, the Danish Haemophilia Society filed a lawsuit against Nordisk Gentofte, the Statens Seruminstitut, the National Board of Health and the Ministry of the Interior over the use of infected blood products from unscreened donor blood after 1 January 1986. In 1995, the Danish Haemophilia Society lost the case in the Eastern High Court, except in relation to one claimant.³⁴

²⁹ RLIT0000538 at p.1

³⁰ See RLIT0002015. £8,716.83 at adjusted value for currency (1 DKK= 0. 0.087 STG) on 02 Sept 1987. Accounting for inflation, £21,823.45 on 18 Nov 2021. See HSOC0004453 at p.7

 $^{^{31}}$ £21,887.67 at adjusted value for currency (1 DKK= 0.088 STG) on 01 Jan 1988. Accounting for inflation, £53,829.49 on 18 Nov 2021. See HSOC0004453 at p. 7.

 $^{^{32}}$ £67,733.29 at adjusted value for currency (1 DKK= 0.090 STG) on 01 Jan 1992. Accounting for inflation, £141,375.45 on 18 Nov 2021. See RLIT0000532 at p. 2.

³³ RLIT0000534 at p.1

³⁴ RLIT0000538 at p.1

19. After the domestic litigation, on 22 February 1995 the Minister of Health issued a press release expressing the Government's sympathy with those infected with HIV but noted their respect for the court decision rejecting the negligence claim. However, the Government stated that they considered they had a moral duty towards those infected and agreed to create a fund ("the HIV Compensation Fund"), to be administered by the Association to ensure that the "special and individual needs" of people with haemophilia infected with HIV could be better met.³⁵

20. The Government provided DKK 20 million to the fund.³⁶

21. In parallel, the Association brought a case before the European Court of Human Rights for a breach of Article 6 of the European Convention on Human Rights which entitles everyone to a fair trial because the domestic litigation had taken so long. The European Court of Human Rights upheld the claim and awarded DKK 100,000 to the applicants for non-pecuniary damage.³⁷

Establishment of trust or scheme

22. The Danish Haemophilia Society is responsible for the administration of two funds designed to support individuals with haemophilia who were infected with HIV through the use of blood and blood products: the Support and Research Fund and the HIV Compensation Fund noted above.³⁸ The Support and Research Fund was established independently by the Society in 1980 and supports people with haemophilia as well as research in haemophilia.³⁹

The HIV Compensation Fund

23. As noted above, the HIV Compensation Fund was established by statute in 1995 with an initial sum of DKK 20 million being provided by the Government. It was designed for the

³⁵ RLIT0002015.

 $^{^{36}}$ HSOC0004453 at p.7. £2,294,222.58 at adjusted value for currency (1 DKK= 0.115 STG) on 01 Feb 1996 . Accounting for inflation, £3,517,854.72 on 18 Nov 2021. See RLIT0000538 at p.1

³⁷ RLIT0002015 and RLIT0000456 at p.192

³⁸ RLIT0000528

³⁹ RLIT0000536 p.1

benefit of 91 people. ⁴⁰ It was initially established for a period of 15 years. ⁴¹ However, as at 2010, 27 individuals of the original 91 individuals remained alive and so the Fund was extended indefinitely, with additional capital of DKK 10 million being provided. ⁴² The Fund continues to provide benefits to date.

- 24. The Compensation Fund is governed by a board, constituted of five members appointed by the Minister of the Interior and Health on the recommendation of the Danish Bleeding Association. ⁴³ Board members are appointed for four years at a time. The Board of Directors then elects its own Chairperson from amongst its members, and thereafter establishes its own procedures for the work that must be undertaken. The rules of procedure must however be approved by the Minister of the Interior and Health. ⁴⁴
- 25. The Fund provides financial assistance in the form of both lump sum and fixed amounts.⁴⁵ Up to 20% of the Fund was permitted to be used for lump sum payments to meet the "special individual needs" of both the infected individual as well as family members of the infected individual. The remaining 80% of the fund is for lump sums or annual amounts to individuals to cover any lost earnings, shortened-life expectancy and a reduced quality of life experienced by the infected individual.⁴⁶ These payments can only be made to the infected person themselves, spouses or cohabitants of over 2 years, or their children to age 21.
- 26. The infected individual must have applied for reimbursement to the Danish Health and Medicines Authority no later than 1 January 1988.⁴⁷ This is done by a two page application form downloaded from the Foundation website. The form is completed with the relevant supporting documentation and it is then submitted to the Secretariat of the Foundation. The Foundation Secretariat is responsible for assisting with applications. The fund covers

 $^{^{40}}$ £2,103,820.60 at adjusted value for currency (1 DKK= 0.105 STG) on 01 Jan 1995 . Accounting for inflation, £3,574,904.78 on 17 Nov 2021. All calculations for this entry and all infra done using https://fxtop.com

⁴¹ RLIT0000528

 $^{^{42}}$ £1,193,394.07 at adjusted value for currency (1 DKK= 0.119 STG) on 01 Jan 2010 . Accounting for inflation, £1,314,526.80 on 17 Nov 2021. See RLIT0000527

⁴³ RLIT0000527

⁴⁴ RLIT0000527

⁴⁵ RLIT0000527

⁴⁶ RLIT0000527

⁴⁷ RLIT0000534 at p.1

subsidies for medicine expenses, dietary supplements, vitamins and alternative preparations, psychological assistance, travel, assistance with accompaniment, establishment in one's own home, etc. The fund only in special cases provides assistance to cover the full cost: the fund generally covers 50%. All applications are assessed individually.⁴⁸

Hepatitis C compensation

- 27. No direct, individual compensation scheme was established for individuals who became infected with hepatitis C through use of contaminated blood and blood products in Denmark. Attempts to establish a similar fund to the HIV Compensation Fund were officially abandoned at the Annual General Meeting of the Association in 1999.⁴⁹
- 28. However, in 2000, the Ministry of Health approved the payment of DKK 50,000 to the Association to be used for grants for support and encouragement in the form of recreation for hepatitis C-infected persons. With that funding, the Association set up a fund for people infected by hepatitis C. In 2008, there were between 50 and 80 infected persons with hepatitis. In 2008, the Danish Bleeding Association received an additional four-year grant, which was used to help those with HIV and/or hepatitis for psychological assistance, coaching, financial services assistance as well as a personal development course. It does not appear that the funding was renewed thereafter. However there does not appear to have been any direct financial compensation for those infected with hepatitis C or B.

France

1989 Solidarity Funds

29. By 1988, the French Association of Haemophiliacs (AFH) had officially asked infected haemophiliacs to initiate legal action against blood transfusion centres, with the aim of

⁴⁸ RLIT0000530

⁴⁹ RLIT0000525

 $^{^{50}}$ £4,176.24 at adjusted value for currency (1 DKK= 0.084STG) on 01 Jan 2000. Accounting for inflation, £8,014.15 on 18 Nov 2021. See RLIT0000531

⁵¹ RLIT0000531

securing financial compensation.⁵² The AFH also approached Parliament with this objective. The French Ministry of Health maintained that it was not responsible for the use of infected blood products, however, it allocated approximately FF 300,000 to commence activities relating to financial assistance.⁵³

- 30. Compensation was first discussed in the French Parliament in 1987. In July 1989, the first financial assistance schemes were approved in France under the Évin Agreement, named after the Minister of Health.⁵⁴ Payments were to begin in September 1989.
- 31. As State responsibility had not been proven in courts, the schemes were presented by the Government as an act of "solidarity" rather than compensation for injury. Those who accepted payments from the funds, were barred from litigating in the courts. 55 Two funds were introduced, the Public Solidarity Fund and the Private Solidarity Fund.
- 32. The Public Solidarity Fund was financed by the Ministry of Health. It was reserved for haemophiliacs who were confirmed AIDS sufferers. Victims could receive between FF 30,000⁵⁶ and FF 170,000⁵⁷ depending on their personal and family circumstances. In the event of death, the widow of an infected haemophiliac could submit an application for payment.
- 33. The Private Solidarity Fund was managed by private health insurance companies, blood transfusion centres and the AFH. Payments were made by the insurance companies, which in turn received tax benefits to partially offset the financial burden.⁵⁸ The Fund was limited to HIV seropositive haemophiliacs. Payments were also available to spouses who became infected. They were each eligible for a lump sum of FF 100,000.⁵⁹ Additionally, if an

⁵² NHBT0004024_003 p.2

⁵³ HSOC0004453 p.13

⁵⁴ RLIT0000540 p.1

⁵⁵ RLIT0000540 p.2

⁵⁶ RLIT0000541. £2,884.73 at adjusted value for currency (1 FRF= 0.096 STG) on 01 Sept 1989. Accounting for inflation, £6,254.56 on 18 Nov 2021

⁵⁷ RLIT0000541. £16 346.79 at adjusted value for currency (1 FRF= 0.096 STG) on 01 Sept 1989. Accounting for inflation, £35,442.48 on 18 Nov 2021

⁵⁸ RLIT0000541

⁵⁹ £9,615.76 at adjusted value for currency (1 FRF= 0.096 STG) on 01 Sept 1989. Accounting for inflation, £20,848.52 on 18 Nov 2021. HSOC0004453 p.13

infected haemophiliac was deceased, a lump sum of FF 170,000 could be granted to the widow⁶⁰ and FF 40,000 per dependent child. ⁶¹ To qualify for payment, HIV seropositivity must have been discovered before December 31, 1989.⁶²

- 34. It appears that 1,037 individuals received payments.⁶³ All payments were tax-free.⁶⁴
- 35. There is a lack of information detailing the application process and how the amount of funding was determined. It is also unclear how recipients of the Private Solidarity Fund were further compensated if they later developed AIDS.
- 36. Both Solidarity Funds came under criticism from infected individuals, the press and opposition parties, particularly regarding "the reliance, at least in part, on private financing". ⁶⁵ The AFH actively pushed for a new compensation scheme, sending letters and petitions to politicians. Transfusion recipients, organised into the Association de Défense des Transfusés, also demanded the introduction of a general compensation law which included all victims of infection via blood and blood products. ⁶⁶
- 37. The Public and Private Solidarity Funds ceased activity in 1992 when they were replaced by the Compensation Fund.⁶⁷

Compensation Fund

38. On 31 December 1991 the Compensation Fund was established by Article 47 of Act No. 91-1406. A Compensation Commission was set up to deal with the thousands of claims

 $^{^{60}}$ £16 346.79 at adjusted value for currency (1 FRF= 0.096 STG) on 01 Sept 1989. Accounting for inflation, £35,442.48 on 18 Nov 2021

 $^{^{61}}$ £3,846.30 at adjusted value for currency (1 FRF= 0.096 STG) on 01 Sept 1989. Accounting for inflation, £8,339.41 on 18 Nov 2021

⁶² HSOC0004453 p.13

⁶³ RLIT0000540 p.2

⁶⁴ HSOC0004453 p.13

⁶⁵ RLIT0000544 p.29

⁶⁶ RLIT0000544 p.29

⁶⁷ RLIT0000543 p.9

received⁶⁸ and was to be chaired by the President of the Chamber of the Court of Cassation.⁶⁹

- 39. The scheme began to operate on 2nd March 1992.⁷⁰ It was financed mainly by the Government, with a one off contribution of FF 1.2 billion⁷¹ made by insurance companies.⁷² This scheme was also created on the basis of showing "national solidarity" with victims.⁷³
- 40. The Fund provided compensation for "all people infected with HIV through medical treatment or actions, including transfusion patients, their infected partners (for unmarried partners, the question remains open, but these cases are generally accepted), their children, and their heirs."⁷⁴ It covered infection occurring in French territory up to 1 January 1990, when the blood transfusion insurance group (Groupement d'assurance de la transfusion sanguine) took out a policy covering "the liability risks inherent in blood transfusions."⁷⁵
- 41. To apply for compensation, infected people had to provide proof of HIV seropositivity and details of their blood transfusion. The burden of proof then passed to the Fund and there was a "simple, not irrebuttable, presumption [of entitlement] capable of being contradicted to the contrary". The Compensation Commission could then carry out further investigations if necessary. It was not mandatory to present proof of culpability. There is no evidence to suggest a time-limit between the discovery of the infection and being eligible to apply for compensation. Offers of compensation were awarded within six months of the application being received. This process was inspired by pre-existing

⁶⁸ DHSC0004409 044 p.1

⁶⁹ RLIT0000543 p.4

⁷⁰ RLIT0000543 p.6

⁷¹ £122,654,345.30 at adjusted value for currency (1 FRF= 0.102 STG) on 02 March 1992. Accounting for inflation, £231,621,033.21 on 18 Nov 2021

⁷² DHSC0004409 044 P. 1

⁷³ RLIT0000543 p.16

⁷⁴ RLIT0000544 p.30

⁷⁵ DHSC0002587 006 p.1

⁷⁶ RLIT0000543 p.10

⁷⁷ DHSC0004409 044 p.2

⁷⁸ RLIT0000543 p.14

⁷⁹ DHSC0004409 044 p.2

French compensation schemes, in particular the Fund for the Guarantee of Traffic and Hunting Accidents and the Guarantee Fund for Victims of Terrorism and Other Crimes.⁸⁰

- 42. The amount of compensation provided to victims is unclear, however, a paper published by the European Consortium for Political Research states that it was "much higher than previously established sums". The paper also gives the example that an adult man diagnosed with AIDS and earning an average income could be compensated in the range equivalent to US\$ 150,000⁸¹ and US\$ 400,000⁸². From 1992 to 1993, compensation for economic loss is said to have varied from the equivalent of \$3,000 to \$500,000⁸³ per case. Victims who had previously received payments from a Solidarity Fund could increase their level of compensation through the Compensation Fund. The Compensation Fund is estimated to have cost the French Government FF 6 to 7 billion. The Compensation Fund is
- 43. The Compensation Commission focused on a personalised assessment of each victim instead of adopting the solution of a lump sum. Factors which were taken into consideration included economic loss, damage to health, emotional distress and disruption of family and social life. The age of a victim was considered to be particularly relevant, with younger victims being entitled to a higher level of compensation.⁸⁷
- 44. Once a victim accepted compensation from the Fund, it was unclear for a period of time whether they were legally bound not to make any further claims against the Government, on the basis that the Fund would provide "full compensation for damage".⁸⁸ It appears that

⁸⁰ RLIT0000543 p.13

 $^{^{81}}$ £85,294.99 at adjusted value for currency (1 USD = 0.569 STG) on 02 Mar 1992. Accounting for inflation, £221,232.14 on 18 Nov 2021

 $^{^{82}}$ £227,453.31 at adjusted value for currency (1 USD = 0.569 STG) on 02 Mar 1992. Accounting for inflation, £589,952.39 on 18 Nov 2021

 $^{^{83}}$ £1,977.59 - £329 598.23 at adjusted value for currency (1 USD = 0.659 STG) on 31 Dec 1992. Accounting for inflation, £4,337.29 - £722,881.20 on 18 Nov 2021

⁸⁴ RLIT0000544 p.31

⁸⁵ RLIT0000540 p.2

 $^{^{86}}$ RLIT0000544 p.31; £688,004,616.41 - £802,672,052.48 at adjusted value for currency (1 FRF = 0.115 STG) on 31 Dec 1993. Accounting for inflation, £1,119,954,889.28 - £1,306,614,037.49 on 18 Nov 2021

⁸⁷ RLIT0000544 p.31 and RLIT0000543 p.7

⁸⁸ RLIT0000543 p.11

the Court of Cassation ultimately held that litigation could only relate to "heads of damage for which they have not already been compensated by the Fund".⁸⁹

- 45. Other circumstances when a victim could take further legal action were: where their application was rejected by the Compensation Fund, where they rejected the offer made to them by the Compensation Fund or where they had not received an offer from the Compensation Fund within 6 months of their application. Victims who pursued compensation through litigation but failed in the courts were not barred from applying to the Compensation Fund thereafter. 91
- 46. According to the Compensation Fund's 1998 Annual Report, by February of that year, they had received a total of 4,241 claims. Of these claims, 61 per cent (2,587) were from transfusion patients, 28.3 per cent (1,201) from haemophiliacs, 1.9 per cent (81) from von Willebrand's disease patients and the remaining 8.8 per cent (372) from people who were infected through their partners or born to HIV-positive mothers. A total of 3,778 separate offers were made, representing 89% of the claims submitted. Rejected cases almost exclusively concerned transfusion patients and were based on the proven sero-negativity of donors. 92
- 47. After 6 years of operation, the Compensation Commission had made a total of 15,542 offers of payment, including the 3,778 noted above plus a further 1,425 for economic costs and 10,339 for non-pecuniary loss and "disturbance of living conditions" suffered by a relative.⁹³
- 48. It is unclear exactly when the Compensation Fund ceased operating, however, its activities were in "serious deceleration" by 1998.⁹⁴ 91.4% of haemophiliacs who received compensation before 1998 had done so by the end of 1993.⁹⁵

⁸⁹ RLIT0000543 p.12

⁹⁰ DHSC0004409 044 p.2 and RLIT0000543 p.5

⁹¹ RLIT0000544 p.31

⁹² RLIT0000543 p.16

⁹³ RLIT0000543 p.16

⁹⁴ RLIT0000543 p.18

⁹⁵ RLIT0000543 p.19

Compensation for Hepatitis C Infection

- 49. In relation to hepatitis C, despite pressure from the AFH, the State declined to establish a financial assistance or compensation scheme for individuals with haemophilia who were infected with hepatitis C. ⁹⁶
- 50. The French Government is said to have been reluctant to establish a compensation scheme due to the scale of infection, particularly when transfusion victims were included. An estimated 150,000-200,000 people were believed to have been infected with hepatitis C via transfusion, meaning the creation of a compensation fund would require "exorbitant sums". French legal experts also argued against a compensation fund akin to that for HIV on the basis that "two of the fundamental components of the prejudice caused by AIDS do not exist in the case of hepatitis C: social isolation and the risk of death (which is said to be very remote)."
- 51. To obtain compensation, those infected with hepatitis C therefore had to litigate on an individual basis. ⁹⁹ To sue a blood transfusion centre, a victim had to prove that they received blood products from the centre before the date of hepatitis C seroconversion. The blood centre could refute claims if they were able to prove that the transfused products were not contaminated, by testing the donors. If such proof could not be established the blood transfusion centre would be held liable and required to indemnify the victim through their insurer. Legal action could also be brought against the State for negligence of their supervisory duties, but this was rarely successful. ¹⁰⁰
- 52. A news article published by the British Medical Journal in 1995 reported that only around 20 people had received compensation through the courts for hepatitis C infection in France. One such claimant had received an immediate sum of FF 80,000¹⁰¹ while the full amount

⁹⁶ RLIT0000544 p.31

⁹⁷ HSOC0026135 p.15

⁹⁸ ARCH0002131 p.2

⁹⁹ DHSC0002419_035 p.2

¹⁰⁰ HSOC0026135 p.15

 $^{^{101}}$ £9,611.21 at adjusted value for currency (1 FRF = 0.120 STG) on 01 January 1995. Accounting for inflation, £14,701.08 on 18 Nov 2021

of compensation was decided, another received compensation reaching FF 1 million¹⁰² and a third victim received FF 1 million¹⁰³ for hepatitis C infection and a further FF 2 million¹⁰⁴ for HIV infection.¹⁰⁵ In October 1997, a payment of FF 2.5 million¹⁰⁶ was granted to two brothers who were infected with both hepatitis C and HIV.

Germany

Statutory scheme

- 53. On 24 July 1995 Germany set up a single, no-fault statutory scheme to provide support and to compensate for financial, physical and emotional suffering.¹⁰⁷ The statutory scheme applies to the entirety of the Federal Republic of Germany, incorporating the geographic areas of the former German Democratic Republic (East Germany) and the former Federal Republic of Germany (West Germany).¹⁰⁸ The scheme applies to individuals who were infected with HIV through the use of infected blood and blood products.
- 54. In October 1994, the Bundestag (the German Parliament) parliamentary committee of inquiry into "HIV infections through blood and blood products", which was established in 1993, presented its final report. ¹⁰⁹ The report included a proposal that financial assistance should be provided to those infected with HIV. The Federal Ministry of Health, through the law on humanitarian aid for people infected through blood products (HIVHG), established the Humanitarian Aid Foundation, a legal federal foundation based in Bonn,

 $^{^{102}}$ £120,140.12 at adjusted value for currency (1 FRF = 0.120 STG) on 01 January 1995. Accounting for inflation, £183,763.54 on 18 Nov 2021

 $^{^{103}}$ £120,140.12 at adjusted value for currency (1 FRF = 0.120 STG) on 01 January 1995. Accounting for inflation, £183,763.54 on 18 Nov 2021

 $^{^{104}}$ £240,280.25 at adjusted value for currency (1 FRF = 0.120 STG) on 01 January 1995. Accounting for inflation, £367,527.07 on 18 Nov 2021

¹⁰⁵ ARCH0002131 p.1 and p.2

 $^{^{106}}$ £261,175.89 at adjusted value for currency (1 FRF = 0.104 STG) on 01 October 1997. Accounting for inflation, £438,366.18 on 18 Nov 2021

¹⁰⁷ RLIT0000603 p.10

¹⁰⁸ RLIT0000604 and RLIT0000603 p.10

¹⁰⁹ RLIT0002016

Germany. 110 The Foundation was established as the means through which the financial assistance would be provided. 111

- 55. The Foundation's funds were raised by the Federal Government (contributing 40% of the initial endowment), the Federal States (contributing 20% of the endowment), the German Red Cross (contributing 3.7% of the endowment), the pharmaceutical companies (contributing 36.3% of the endowment)¹¹²: Bayer AG, Immuno GmbH, Behringwerke AG, Baxter Deutschland GmbH, Armor Pharma GmbH and Alpha Therapeutics GmbH. The original statute indicates that the Foundation's assets amounted to 3 million DM.¹¹³
- 56. In 2017, the source of funds was changed to prevent the Foundation's assets being used up and the Foundation being dissolved in accordance with its legislative framework; funds were raised exclusively from the federal budget to ensure life-long continuity of benefits. 114

 The Foundation is entitled to accept donations from third parties.

Benefits

57. Initially, benefits were limited in amount and duration as follows: according to Section 16 of the HIVHG, those infected with HIV received a monthly benefit of EUR 766.94¹¹⁵; people with AIDS a sum from EUR 1,533.88 without checking their income or other economic circumstances. ¹¹⁶ After the death of the infected person, children received EUR 511.29 per month until they completed their vocational training, or when they reached the age of 25, whichever was sooner. ¹¹⁷ Spouses received EUR 511.29 per month if the infected person died when the HIVHG came into force. ¹¹⁸ The payments ended after five years from

¹¹⁰ RLIT0000604

¹¹¹ RLIT0000604

¹¹² RLIT0000604

¹¹³ RLIT0000604

¹¹⁴ RLIT0002017 at p.10

 $^{^{115}}$ £687.60 at adjusted value for currency (1 EUR= 0.897 STG) on 30 June 2019 (date chosen as last day before rule change). Accounting for inflation, £666.22 on 18 Nov 2021

¹¹⁶ £1,375.20 at adjusted value for currency (1 EUR= 0.897 STG) on 30 June 2019 (date chosen as last day before rule change). Accounting for inflation, £1,332.44 on 18 Nov 2021

¹¹⁷ £458.40 at adjusted value for currency (1 EUR= 0.897 STG) on 30 June 2019 (date chosen as last day before rule change). Accounting for inflation, £444.15 on 18 Nov 2021

¹¹⁸ £458.40 at adjusted value for currency (1 EUR= 0.897 STG) on 30 June 2019 (date chosen as last day before rule change). Accounting for inflation, £444.15 on 18 Nov 2021

the start of the payments. In 2017, with effect from July 1, 2019, benefits were dynamically linked to the pension level and some time restrictions were lifted. However, funding provided by the Foundation is not offset against the provision of other sources of public funds.

58. More specifically, persons who are directly entitled to benefits from the Foundation are those who, through blood products placed on the market before January 1, 1988, have been infected with HIV or have been infected with HIV and contracted AIDS as a result. AIDS is to be assumed if either a CD4 helper count of less than 200 or a CD4 helper count of regularly less than 400, combined with an opportunistic infection, is detected. Benefits from the foundation are also paid to persons who have been infected as spouses, fiancés or life partners of those receiving infected blood products, or a person infected with HIV at birth if the mother was infected with HIV from blood products and would themselves be entitled to benefits from the Foundation. Uninfected children and spouses of people who are infected or sick are also entitled to benefits. Children of their spouse who are taken in by the infected or sick person in their household are also considered as children.

59. All payments are made without recognition of any legal liability and do not exclude future claims being brought. However, parties are excluded if they had by its establishment in 1995, received more than DM 200 000¹²⁰ in compensation from litigation. The burden is placed on the applicant to prove that this reason for exclusion did not exist.

60. In the event of an application being rejected, the applicant can appeal in writing to the arbitration board within three months. This board consists of two doctors and a qualified lawyer. The members of the arbitration board and their representatives are appointed by the Federal Ministry for Health at the suggestion of the haemophilia associations and the haemophilia treatment centres.¹²¹

Governance and supervision of the Foundation

¹¹⁹ RLIT0000618

 $^{^{120}}$ £82,815.03 at adjusted value for currency (1 DEM= 0.414 STG) on 01 Jan 1995. Accounting for inflation, £128,200.81 on 18 Nov 2021

¹²¹ RLIT0000604

61. The Foundation governance is constituted by a foundation board, a foundation council as well as a medical commission. The Board of Trustees consists of seven members. One member is appointed by the Federal Ministry of Health. Two members are nominated by the German Bundestag. The Federal Ministry of Health appoints two members on the proposal of the pharmaceutical companies (as they are named in *Section 5(1) of the Act*) and the blood donation services of the German Red Cross. The Federal Ministry of Health appoints two further members on the recommendation of the regional haemophilia associations. 122

62. The Foundation is subject to the supervision of the Federal Ministry of Health. The Foundation must draw up a budget before the start of each financial year. The budget requires the approval of the Federal Ministry of Health, and the statute regulates the details of the budget. The Foundation is obliged to submit accounts to the founders. The auditing authority is the Federal Audit Office. 123

Application procedure¹²⁴

63. When applying for benefits, the infected person must prove their eligibility by a medical certificate, which must show that the administered blood product caused their HIV infection. To demonstrate causation, it is sufficient that a blood product has been used in the course of a treatment which may have caused an HIV infection. Applicants who do not have haemophilia must also provide a certificate from the treating facility to prove when it administered the blood product to them. Any costs incurred for issuing the certificates will not be reimbursed.

64. In relation to an infected partner or spouse, a medical certificate must be provided to prove that an HIV infection or AIDS disease is present and that the infection was most likely transmitted by the spouse, fiancé or life partner, as well as the cause of the HIV infection in the spouse, fiancé or life partner. It must be proven that the marriage, engagement or civil partnership existed at the time of infection. Similarly, in relation to children who have

¹²² RLIT0000604

¹²³ RLIT0000604

¹²⁴ RLIT0000604

contracted the infection from their mother a medical certificate is required addressing their, and their mother's, HIV infection as well as their relationship with their mother.

65. Where there are any doubts about the evidence provided, the application documents are submitted to a committee consisting of three members, which is to be set up at the request of the foundation's board of directors. The foundation board will then decide on the basis of the opinion of the commission. The chairing member of the commission must be qualified to hold the office of judge; in addition, the commission must consist of two people with a medical licence.

Nature and level of support¹²⁵

66. In 2016, the total number of beneficiaries in 2016 was 553 individuals. This was made up of 140 HIV-infected individuals, 384 with AIDS-related illnesses and 29 children of deceased individuals, resulting in an annual sum of €8 534 507.16 being paid. 126

Hepatitis C financial assistance

67. There has been no provision of financial assistance for individuals with hepatitis C, except for those who contracted hepatitis C from Anti-D immunoglobulins. Enacted with retrospective effect on 1 January 2000, the Act on Assistance for Patients Infected with the hepatitis C Virus by Anti-D Immunoglobulins makes provision for financial assistance to women infected by administration of anti-d immunoglobulins in 1978 and 1979. 128

68. The Act provides for: 129

- a. Annuities, of a maximum amount per month of DM2,000. 130
- b. Reimbursement of health care costs.
- c. Lump sum payments for infected patients, "contact persons" most likely infected by them, and dependants where the infection has reduced the person's ability to

¹²⁵ RLIT0000606

 $^{^{126}}$ £6,263,901.53 at adjusted value for currency (1 EUR= 0.734 STG) on 01 Jan 2016. Accounting for inflation, £7,822,311.27 on 18 Nov 2021

¹²⁷ RLIT0000602

¹²⁸ RLIT0000602 and RLIT0000602

¹²⁹ RLIT0000602

^{130 £860.74} at adjusted value for currency (1 DEM= 0.430 STG) on 18 Nov 2021

- work. Lump sum compensation may range from DM7,000¹³¹ to DM30,000¹³², the amount being contingent on the extent to which the individual's working ability has been impaired.
- d. Pensions of between DM600¹³³ and DM1,000¹³⁴ per month may be claimed by dependents (spouses or children) of deceased infected patients. In the case of spouses they must be claimed within 60 months of the infected person's death. Children will be supported until the age of 18 or until they have completed their education, at the latest by their 27th birthday.
- e. The costs of compensation under the act are borne jointly by the Federal Republic of Germany (50%), the states in which the immunoglobulin was administered (12.4%) and the former western states (37.6%), with the exception of lump sum payments, which are borne by the Federal Republic of Germany alone (approximately DM15 million in total).

Italy

Establishment of the Scheme

- 69. In 1988, the Italian Haemophilia Foundation wrote an open letter to the Minister of Health, requesting financial means to be allocated to "those affected with AIDS, and also to parents, wives, and children of those who died from AIDS." Several political parties were lobbying for legislation to provide some kind of compensation. They hoped to establish a fund for all those who had contracted HIV-infection from blood and/or blood products. 135
- 70. On 13 January 1990, an article, in the British Medical Journal, reiterated the wishes of the 1988 letter but added, "Given the speed at which parliament moves in Italy, any relief will be a long way off... Solicitors are believed to be discouraging patients and their families from taking... legal action against the Ministry of Health or any pharmaceutical company,

^{131 £3.012.59} at adjusted value for currency (1 DEM= 0.430 STG) on 18 Nov 2021

¹³² £12,911.09 at adjusted value for currency (1 DEM= 0.430 STG) on 18 Nov 2021

¹³³ £258.23 at adjusted value for currency (1 DEM= 0.430 STG) on 18 Nov 2021

¹³⁴ £430.37 at adjusted value for currency (1 DEM= 0.430 STG) on 18 Nov 2021

¹³⁵ HSOC0004453, p.5

hospital or other authority."¹³⁶ Usually in Italy, any civil litigation would require proof of negligence and causation.¹³⁷

- 71. However, the political groups advocating for legislation to provide financial assistance were successful and in January 1992, as the result of a Senate Assembly vote, the compensation plan that had been designed for vaccine-related injuries absorbed other legislative proposals that had been drafted in order to compensate blood victims. On 25 February 1992, Law 210/1992 was promulgated. Consequently, a patient infected with an HIV, HBV, or hepatitis C-contaminated blood product could receive monetary compensation in 2 ways: the "national solidarity" fund (Law 210/1992) or the usual principles of civil liability.
- 72. Law 210/1992 orders that the State must compensate for an event such as post-transfusion impairment, "not because the State itself has any responsibility for the damage, but because, under the principle of distributive justice founded on social solidarity, the burden of the consequences of the damage is converted to a collective responsibility." ¹³⁹
- 73. Law 210/1992 was the first social-security type of intervention in Italian legislative regulation. It "recognises a public responsibility in the production, preparation, and administration of biological materials (blood and hemoderivatives) in which there exists a serious risk of the transmission of infective agents that it is not always possible to destroy." As a result of its application, Law 210/1992 establishes (at least partial) lifelong economic indemnity for persons infected with (and permanently impaired by) HBV, hepatitis C or HIV via transfusion or the administration of hemoderivatives in a way that is unrelated to any medical malpractice or third-party responsibility. Despite the provision made by this law, the impaired patient "is free to pursue the normal procedures that regulate the responsibility of the single medical practitioner or the hospital under third-party responsibility." 141

¹³⁶ SCGV0000230 063

¹³⁷ RLIT0000557

¹³⁸ RLIT0000553, RLIT0000615 and HSOC0026106, p.1

¹³⁹ RLIT0000556

¹⁴⁰ RLIT0000556, p.1

¹⁴¹ HSOC0026106, p.1

- 74. The articles of Law 210/1992 pertinent to the provision of financial assistance of those infected with HIV and hepatitis are summarised below.
- 75. The indemnities awarded by this law are paid for by the Italian Ministry of Health. Five years after its enactment, the 210/1992 compensation scheme created difficulties for the Italian Treasury. In March 1997, the press reported on the Government's inability to find budget resources for the payments of the claims brought under the 1992 Act. 142

Nature and level of support

76. Article 3 of Law 210/1992 outlines the amounts eligible victims are entitled to: 143

- a. A "non-joint monthly life pension" ¹⁴⁴ amounting to approximately \$700, ¹⁴⁵ "calculated according to the legal criteria applied for the disabled exservicemen" pensions, paid to the claimants starting from the month following the filing of the claim.
- b. If the claimant dies, "a lump sum of approximately \$35,000¹⁴⁶ is to be awarded to the relatives (but solely if they are financially dependent on the deceased person) in the following order: spouse, minor son, major disabled son, parents, minor brothers and sisters, major disabled brothers and sisters." ¹⁴⁷
- 77. The financial relief envisaged was limited, even for covering the everyday needs of those living with HIV. Both the Associazione dei Politrasfusi Italiani (API) and the Italian Haemophilia Foundation (IHF) raised their discontent publicly: the lump-sum award set to compensate for the death of the victim of infected blood was called a "mite from the State", to signify its inadequacy to compensate for the death of a loved one.

¹⁴² RLIT0000546, p.41

¹⁴³ RLIT0000615, p.7

¹⁴⁴ 'Non-joint' refers exclusively to the ex-servicemen, and only if the serviceman dies will the spouse receive money.

¹⁴⁵ RLIT0000546, p.39; £373.83 at adjusted value for currency (1 USD= 0.534 STG) on 01 Jan 1992. Accounting for inflation, £1,044.77 on 22 Nov 2021

 $^{^{146}}$ £18,691.58 at adjusted value for currency (1 USD= 0.534 STG) on 01 Jan 1992. Accounting for inflation, £52 238.84 on 22 Nov 2021

¹⁴⁷RLIT0000546, p.39

- 78. After three years of protests by the API and the IHF, the Italian Government amended the Act. In August 1995, a Decree was issued which raised the lump-sum to approximately \$100,000. 148
- 79. On 25 July 1997, Italy introduced Law 238/1997 which was inserted as part of Article 2 of Law 210/1992.¹⁴⁹ It provided that:
 - (a) Infected persons are entitled to a "compensation reversible" for 15 years; this means that if the person who is receiving the compensation dies, the relatives can continue to receive it for 15 years. The amount paid is calculated in accordance with table B set out in Law 177/1976¹⁵⁰ as amended by article 8 of Law 111/1984.¹⁵¹ This compensation is additional to any other amount the infected person would have earned or received but for the infection; the amount will be revalued annually in accordance with inflation.
 - (b) The compensation is supplemented by a sum corresponding to the amount of the special supplementary allowance pursuant to the Law of 27 May 1959, n. 324. ¹⁵² In 1959 this amount was set to 2,400 Lire ¹⁵³, tax-free. The supplementary sum can be combined with a special supplementary allowance or other similar indemnity linked to the change in the cost of living following infection.
 - (c) If a person has already been indemnified in accordance with the Law 210/1992, they can still receive, upon request, a one off payment for the period in between the event that caused the damage and when the indemnity is received.

 $^{^{148}}$ RLIT0000546, p.39; £62,617.25 at adjusted value for currency (1 USD= 0.626 STG) on 01 Aug 1995. Accounting for inflation, £134,783.25 on 22 Nov 2021

¹⁴⁹ RLIT0000554 and RLIT0000615, p.4

¹⁵⁰ RLIT0000552

¹⁵¹ RLIT0000550

¹⁵² RLIT0000555

 $^{^{153}}$ £1.38 at adjusted value for currency (1 ITL = 0.000573 STG) on 27 May 1959. Accounting for inflation, £30.51 on 22 Nov 2021

- (d) If the infected person dies, the eligible family member may choose between the reversible payment or a one-off 150 million Lire lump sum payment. ¹⁵⁴ The eligible person is, in the following order: the spouse, children, parents, minor siblings, siblings or adults unable to work.
- (e) Free healthcare treatment is available for the diagnosis and treatment of HIV and hepatitis caused directly by blood or blood products: the same is also guaranteed to any subsequently infected spouse or child infected during gestation.
- 80. In March 1999, Dr Paul Giangrande of the UK Oxford Haemophilia centre, wrote to Karin Pappenheim, CEO of the UK Haemophilia society confirming that in Italy, "All those who have been infected with hepatitis C are potentially eligible for long term financial support (currently set at 900000 Lire¹⁵⁵ per month) if they are *actually ill* due to chronic hepatitis. In other words, the money is not made available to all those who are merely hepatitis C positive, although they can get funds in future if they do fall ill. I will write to (Professor) Mannucci for further details." After meeting with Mannucci, Giangrande wrote again to Ms Pappenheim stating, "It is certainly true that all recipients of blood products (not just people with haemophilia) are eligible for monthly benefits for both hepatitis C and HIV. Indeed, it is possible to receive compensation for both infections." 157
- 81. In 2010, the Italian Government enacted Law 78/2010 which removed the annual uprating of the special supplementary allowance, in line with inflation. This was challenged in the courts and in 2011, the Italian Constitutional Court declared this law unconstitutional. ¹⁵⁸ In spite of this, the Italian State bodies failed to address this. ¹⁵⁹ Consequently, a complaint was lodged at the European Court of Human Rights on behalf of 162 victims. ¹⁶⁰ The Court upheld the complaint in *MC and others v Italy* (Appln No. 5376/11) as a breach of Article

 $^{^{154}}$ £50,496.41 at adjusted value for currency (1 ITL = 0.000337STG) on 25 July 1997. Accounting for inflation, £97 181.47 on 22 Nov 2021

 $^{^{155}}$ £317.42 at adjusted value for currency (1 ITL = 0.000353 STG) on 01 Mar 1999. Accounting for inflation, £574.32 on 22 Nov 2021

¹⁵⁶ HSOC0026115

¹⁵⁷ HSOC0019749 007

¹⁵⁸ RLIT0000549, p.3

¹⁵⁹ RLIT0000549, p.3

¹⁶⁰ RLIT0000549, p.3 and RLIT0002020

6, Article 1 Protocol 1 and Article 14. As a result, payments to the infected increased by 40%. ¹⁶¹

Eligibility

- 82. Article 1 of Law 210/1992¹⁶² outlines who is eligible to receive the financial assistance, namely those who become infected with HIV as a result of the administration of blood and its derivatives, and those presenting with irreversible damage from post-transfusion hepatitis.
- 83. The August 1995 Decree, which raised the lump-sum to approximately \$100,000, ¹⁶³ also introduced other amendments for the beneficiaries of the Act. These new provisions were kept in force by the Government by re-enacting the Decree every two months until December 1996 when finally, these new provisions were also converted into law under Article 2 of Law 210/1992 by Parliament. ¹⁶⁴
- 84. Article 2 of Law 210/1995 provides that:
 - (a) The lump-sum is payable to relatives of the deceased party even where they did not depend financially on the original claimant.
 - (b) In the case of death, the life pension and the lump-sum can be claimed by a spouse infected through sexual intercourse with the infected partner, and also by a child infected at birth.
 - (c) Claimants who suffer from more than one disease (as in the case of HIV and hepatitis C co-infection), where each infection is recognised as having a distinct disabling outcome are entitled to receive supplementary awards, of up to 50% of that provided for under Article 2a above.

¹⁶¹ RLIT0000549, pp.3-4

¹⁶² RLIT0000615

¹⁶³ Converted to £73,052 (1 USD = 0.730504 GBP)

¹⁶⁴ RLIT0000546, p.40

(d) The administrative task of determining the claim was given to civil health facilities, instead of military medical commissions.

Process

85. In determining the claim, the onus is on the claimant to produce medical documentation in order to establish when, how, and from which transfusion or blood product administration the HIV contamination stemmed. In order to receive economic indemnity from Law 210/1992, a causal link between the event and infection has to be established. Regional military medical bodies were initially appointed to examine the documents and evaluate the existence of this causal link in each case. As mentioned above, this responsibility was handed over to the civil health facilities in 1995.

86. The claimant must do the following:

- (a) File a claim within three years of knowledge of infection in the case of post-transfusion hepatitis or within ten years in cases of HIV infections. The Ministry is given 90 days from the date of submission of the application to investigate and form a judgement.¹⁶⁷
- (b) For HIV infections, the application must be accompanied by documentation proving the date of the transfusion or the administration of blood products, as well as the date of HIV infection and date of death if applicable.
- (c) Obtain from a physician who performs transfusions or administers blood products, a transfusion data sheet or confirmation of the date of administration.

Hepatitis C and HIV Litigation

- 87. In 2011, the Italian courts held that compensation paid in civil claims should be reduced by the payment that the infected blood victims may have already received pursuant to Law 210/1992.¹⁶⁸
- 88. A significant number of lawsuits against the Ministry of Health were won by applicants and the State was ordered to pay considerable damages to the infected blood victims. 169

¹⁶⁵ Article 3, Law 210/1992

¹⁶⁶ RLIT0000546, p.39

¹⁶⁷ Time ran from the date of the law entering into force where the person was already infected at that date.

¹⁶⁸ RLIT0000553

¹⁶⁹ In Italy, class actions were introduced in the legal system only in 2007

Consequently, the Italian Government enacted Article 27-bis of the Law 114/2014 with the aim of reducing litigation. Pursuant to this provision, all the legal actions that have been initiated before 31 December 2017 can be settled with a sum of €100,000¹⁷⁰ upon request submitted by the lawyer and the client.¹⁷¹

89. This payment is granted by the Ministry of Health as compensation to the victim, who in turn waives any action that is pending against the State. That is paid in addition to the indemnification payment described above.¹⁷²

Statistics/data

Law 210/1992

- 90. By May 1995, 2,511 claims had been dealt with, and many heirs had received financial relief (604 claimants had died by that time). At the same time, the number of claims received by the ad hoc bureau had risen to 20,140. By 1 April 1996, there were 26,978 claims, with 3,408 pensions and 514 lump-sums awarded totalling an expenditure of 171,966,164,290 lire¹⁷³ by the Treasury.¹⁷⁴
- 91. In 1998, the Department of Forensic Sciences at the University of Siena published the results of their study which looked at the requests for compensation presented in the central Italian region of Tuscany from the promulgation of Law 210/1992 to 31 December 1998.¹⁷⁵
- 92. Out of 428 requests for financial indemnity made in the region of Tuscany during this time period, 372 were granted and 56 denied. Post-transfusion infections (286 cases) were more prevalent than those due to blood products (141 cases). Cases of hepatitis, particularly hepatitis C, constituted the great majority of the infections for which

 $^{^{170}}$ £88 723 at adjusted value for currency (1 EUR=0.88723 GBP) on 31 December 2017. Accounting for inflation, £95 557.56 on 6 December 2021, RLIT0000549 p.6

¹⁷¹ RLIT0000549

¹⁷² RLIT0000549

 $^{^{173}}$ £73 312 318.82 at adjusted value for currency (1 ITL=0.000426 GBP) on 1 April 1996. Accounting for inflation, £ 121 253 656.4 on 6 December 2021

¹⁷⁴ RLIT0000546, pp.40-41

¹⁷⁵ HSOC0026106, p.1

indemnity was sought, while cases of HIV infection were scarce and in sharp decline according to the data from 1995 and 1996.¹⁷⁶

93. In 48 (86%) of the 56 cases for which the right to economic indemnity was denied, the impairment reported was hepatitis C.¹⁷⁷ Of these 56 cases, either a connection of causality between the transfusion or the administration of blood products and impairment was missing, or there was incomplete documentation regarding the transfusion (10 cases), or there was a history of other risk factors such as drug use (8 cases). In 11 cases, a negative judgment was expressed on the basis of data, supplied by the transfusion centre, demonstrating the donor's negativity years after the donation, while in 10 other cases, previous seropositivity for hepatitis B and hepatitis C antigens was demonstrated in the applicant.¹⁷⁸

94. In October 1995, the Italian Board of Health had specified that the average lapse of time between exposure to a virus and the first rise in transaminase (liver enzyme) levels or demonstration of hepatitis C positivity, is up to one year. Therefore, they said that the causal connection between the two could be excluded after an interval of one year. Based on this rigid adherence to this one-year time limit, 17 applicants were denied causal connections and hence, financial indemnity.¹⁷⁹

Spain

95. Two funds were set up in Spain to provide support for the health, psychological, social and economic effects experienced by those in their population who had been infected with HIV through blood and blood products. The first fund was the Victoria Eugenia Royal Foundation. It was established in 1989 as a channel for both private and public economic aid and was in part supplemented by the pharmaceutical industry. The second fund was the Spanish Decree-Law 9/1993 28 May - established through legal fiat - and came about as a result of negotiations between a committee created by the Spanish Federation of Haemophilia and the pharmaceutical industry in Spain.

¹⁷⁶ HSOC0026106, p.1

¹⁷⁷ HSOC0026106, p.4

¹⁷⁸ HSOC0026106, p.3

¹⁷⁹ HSOC0026106, p.1 and p.4

¹⁸⁰DHSC0002587_005, p.1

96. In June 1989 the Spanish Parliament initially rejected any effort to introduce a statutory compensation scheme for people with haemophilia who became infected with HIV through the use of infected blood products¹⁸¹, citing the need not to discriminate between people with haemophilia and other people who had contracted HIV differently.¹⁸²

97. However, later in 1989 the political mood changed and the Victoria Eugenia Royal Foundation was established in order to mitigate the health, psychological, social and economic effects of persons infected with HIV and families impacted by this infection. The Foundation was declared as "Scientific, Assistance and Private Beneficence Useful" (sic). The Foundation was the channel for both private and public economic aid until 1993.

98. A total amount of £3,125,263.94 was given from 1989 to 1993 from both private support and government grants. ¹⁸⁴ The Inquiry has been unable to identify details of the application process or criteria for acceptance by the Foundation to date.

99. In 1993, the Spanish Decree-Law 9/1993 (BOE No.130, 1.6.1993)¹⁸⁵ was passed as a result of compensation agreements between the Spanish government and pharmaceutical companies. It was promulgated in order to acknowledge the effects on individuals and their families infected and affected by HIV infection through the use of infected blood or blood products. The law "concedes help to people affected by the Human Immunodeficiency Virus due to the actions of the Spanish Public Health System." (sic)¹⁸⁷ The law provided economic compensation as well as making an admission of the damage caused to people with haemophilia in Spain.

100. Payments were available to people who had been infected by blood transfusion or blood products where infection occurred before the establishment of compulsory HIV testing. ¹⁸⁸

¹⁸¹ SCGV0000230 063, p.2

¹⁸² SCGV0000230_063, p.2

¹⁸³HSOC0026102, p.4

¹⁸⁴HSOC0026102, p.4

¹⁸⁵ RLIT0002018

¹⁸⁶HSOC0026102, p.7

¹⁸⁷HSOC0026102, p.7

¹⁸⁸ DHSC0002848

In addition, payments were available to their spouse or children where they were infected, to children, under the age of 24, of living or deceased infected people, adult dependents over the age of 65 and disabled adult dependents who were unable to work. In addition, to receive the funds they had to waive their right to make a claim against the Public Administration or its personnel. Those who had obtained a judgment against the Public Administration could not apply for the financial assistance (arts 3.2 and 3.3)¹⁸⁹.

- 101. The law acknowledges that:
 - (a) HIV infection in people with haemophilia was a result of therapeutic treatment;
 - (b) HIV/AIDS further aggravates the clinical situation of people with haemophilia;
 - (c) A high prevalence of HIV infection is recorded (50%) among people with haemophilia;
 - (d) An infected person's health deteriorates quickly;
 - (e) Infection became a serious social problem.
- 102. The law was understood to have been long awaited and to be based on solidarity with those affected. 190
- 103. The Law describes an affected person as:
 - (a) Any individual with haemophilia infected with HIV through blood products;
 - (b) Any person infected with HIV through blood transfusion;
 - (c) Any partner infected through the epidemiological chain;
 - (d) Any children infected through the epidemiological chain. 191
- 104. The Law provides both a lump sum payment (described as "gross economic compensation") and an updateable lifelong State payment. The Law defines "updateable" as providing for annual increases to cover rising cost of living. 193
- 105. The aim of the updateable lifelong State payment is to economically help families impacted through infection. Payment is given to the infected person as well as to dependent

¹⁸⁹RLIT0002018 at p.4

¹⁹⁰HSOC0026102, p.8

¹⁹¹HSOC0026102, p.9

¹⁹²HSOC0026102, p.10

¹⁹³HSOC0026102, p.11

family members. A pension for young dependent children was given to encourage those children to study instead of entering the job market prematurely. This pension is payable regardless of other income streams. It is possible, in one family, to receive more than one pension.¹⁹⁴

106. The Law extends coverage of state payment to an infected person's children under 24 years of age, as well as lifelong state payment to an infected person's disabled dependent children and lifelong state payment for an infected person's dependent over 65 years of age. 195

107. In 1993 the first instalment to be paid was €30050.50, and in 1994 the second instalment to be paid was €30050.50.¹⁹⁶

108. In addition to the state payment, an agreement on compensation was reached between the pharmaceutical companies Baxter and Immuno, the Spanish Federation of Haemophilia and the Victoria Eugenia Foundation.¹⁹⁷ The resolution established a gross economic compensation package which applied to all viral infections.¹⁹⁸ For every infected person, Baxter pharmaceutical paid out €13164.45¹⁹⁹ in 1996 and Immuno paid out €16628.80²⁰⁰ in 1998 and in 1999.²⁰¹ The Inquiry has been unable to identify any further information in relation to these payments.

Compensation for those infected with hepatitis C

109. By a law 14/2002, BOE No. 135, 6.6.2002, social aid was provided for people infected with Hepatitis C, or their relatives in case of death (namely, children, a spouse or parents).²⁰² However, the amount of compensation to be paid was limited to €18030.36.

¹⁹⁴HSOC0026102, p.12

¹⁹⁵HSOC0026102, p.11

¹⁹⁶£23807.8 at adjusted value for currency (1 GBP=1.262212 EUR) on 28 May 1993. Accounting for inflation, £ 42713.7 on 14 February 2022. All calculations for this entry and all infra done using https://fxtop.com

¹⁹⁷HSOC0026102, p.15

¹⁹⁸HSOC0026102, p.15

¹⁹⁹£9952.7 at adjusted value for currency (1 GBP=1.322701 EUR) on 1 December 1996. Accounting for inflation, £ 16600.41 on 14 February 2022

²⁰⁰£10482.8 at adjusted value for currency (1 GBP=1.586294 EUR) on 1 December 1998. Accounting for inflation, £ 16730.2 on 14 February 2022

²⁰¹HSOC0026102, p.16

²⁰² RLIT0002019 at p.3

²⁰³ In addition, to obtain this financial aid, those who had been infected had to waive the right to bring any type of claim against the Public Administration or its respective staff for medical negligence or other forms of liability. The Inquiry has been unable to identify any further information in relation to these payments.

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March 2023

²⁰³ HSOC0026102, p.17. £11366.34 at adjusted value for currency (1 GBP=1.586294 EUR) on 1 December 1998. Accounting for inflation, £18140.3 on 14 February 2022