World Federation of Hemophilia WFH Information Clearinghouse
c/o Medizinische Klinik LMU Klinikum Innenstadt
Ziemssenstrasse 1 D-80336 München
Germany

Director: Prof. Dr.Dr. h.c. W. Schramm
Assistant to the Director: Jutta Etzler
phone: GRO-C
fax:
e-mail: Jutta.Etzler@ GRO-C

Status of

Financial Assistance for HCV-infected Persons With Hemophilia

in WFH Member Countries

UPDATE Spring 2000

This document is an Update of the information given on HCV compensation in the 1997 Update of the Status of HIV / HCV Financial Assistance Schemes in WFH Member Countries, which was done by the WFH Information Clearinghouse in October 1997 and was then published and distributed from the WFH Headquarter in Montréal.

To gather the information for this document no systematic survey of National Member Organizations (NMOs) was carried out, as had been done for the previous reports, but only those countries were followed up where efforts to obtain HCV compensation had been commenced and the results were pending.

We thank all who provided information for this Update.

Jutta Etzler
Assistant to the Director
WFH Information Clearinghouse

Prof. Dr. Wolfgang Schramm
Director
WFH Information Clearinghouse

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

Table of Contents

This Report comprises information for the following countries:

For the follow-up information has been requested from a total of 37 countries - 25 (68%) of these have responded.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

OVERVIEW

Country	HCV	HBV	status of efforts	payment	HCV litigation
Australia	> 38%		The Haemophilia Foundation Australia (HFA) is seeking a „no-fault" compensa-tion settlement with the federal and State governments		
Austria	90 %	>90 %	The Austrian Hemophilia Society (ÖHG) is seeking a „no fault" settlement with the Ministry of Health and is requesting that a HCV fund be established similar to the HIV Fund		
Belgium	97 %		Belgium is still seeking a settlement for HIV compensation and has recently made a new approach towards the government - for fear that they would get nothing at all the Society is refraining from also asking for HCV compensation		under the product liability law possible for new HCV infections after 1991
Canada	**81%**	**82%**	A global Settlement Agreement has been reached with the government on June 15, 1999; the full text of the Agreement can be downloaded from website www.hepc8690.com	yes	class actions have been settled by the Agreement
Croatia	88 %		NO financial assistance		
Estonia	**69%**	**11%**	NO financial assistance		
France	**29%**	**nk**	In principle, action against the State can be taken		possible
Germany	83 %		The German Hemophilia Society (DHG) is seeking a political solution		planned
Greece	95% estimated		The issue of HCV compensation has not been discussed		
Ireland	**18%**	**2%**	The Irish Haemophilia Society (IHS) has achieved a 2-component package, including payments and assistance services	yes	possible
Israel	50 %		The Israel Hemophilia Society does not see any chance of convincing authorities to grant financial assistance for HCV infection		
Italy	about 75%	about 2%	General legislation (legge 210 and legge 238) which allows compensation payments for HCV infection as for HIV	yes	yes
Japan	**41%**	**no data**	NO financial assistance		
Latvia	0 %		NO financial assistance		
The Netherlands	90 % estimated	no data	NO financial assistance		yes - but unsuccessful
New Zealand	**70%** estimated	**no data**	Claims for compensation can be made under the regular Accident Compensation Act - but as claims have been assessed differently under the old law and the amended 1992 Act the Society is seeking a general settlement to correct such injustice	yes	yes

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

Country	HCV	HBV	status of efforts	payment	HCV litigation
Norway	**44%**	**very low**	In autumn of 1999 the Norwegian Parliamant decided to make compensation payments - the Norwegian Hemophilia Society is fighting for an increase of the envisaged payments		
Poland	60%		NO financial assistance		possible
South Africa	**27%**	**38%**	NO financial assistance - the South African Haemophilia Society is still struggling for adequate HIV compensation from government	no	no
Spain	**65%**	**nk**	The Ministry of Health is carrying out a survey - all those HCV-infected individuals who comply with prefixed criteria will receive HCV compensation from the government		
Sweden	**G 55%** **M 46%** **S 30%**	**98%** **1%** **no data**	The Swedish Hemophilia Society is seeking HCV compensation from the government - a decision of the Court of Arbitration is pending		- -
Switzerland	90 %		The Swiss Hemophilia Society is seeing no chance for also obtaining HCV financial assistance and will, therefore, make no approach towards the government		
Turkey	**° 83%**	**° 54%**	NO financial assistance		
United Kingdom	47 %		The government is refusing any financial assistance - the Haemophilia Society is continuing its campaign for HCV compensation and has demanded an inquiry into the contamination of the blood supplies		possible
United States	85 %		NO financial assistance		no

Note: **HCV litigation** "possible" means that product liability or other legislation exists that allows litigation.

° = data refer to patients registered with the Hemophilia Society
G = Göteborg hemophilia treatment center
M = Malmö hemophilia treatment center
S = Stockholm hemophilia treatment center
nd = no data - country reported that data are not available
nk = not known - country provided no data

Bold printed infection rates have been derived from the 1998 Hemophilia Statistics Survey done by the WFH Information Clearinghouse, Munich.

AUSTRALIA

as of February 15, 2000

HCV infection rate: 38% *
HBV infection rate: no data available

Patient population:
In Australia, an average of 38% * of the patient population with hemophilia/VWD are infected with HCV. The majority of those who are HIV-infected are also HCV-infected.

For the various disease groups HCV infection has been reported as follows:

hemophilia A	57% *
hemophilia B	48% *
VWD	8% *

* this may be higher as the National Registry is being built up and covers presently only 66% of the patient population

Efforts of the Hemophilia Society to obtain financial assistance:
In 1994, the Council of the Haemophilia Foundation Australia (HFA) unanimously decided against taking any specific action or launch a special campaign to obtain compensation for hepatitis C. This decision was based on legal advice.
HFA is seeking „no-fault“ compensation from the federal and State / Territory governments. But there is poor response so far.

Support for HCV-infected people provided by the Hemophilia Society:
Persons who may be involved in any way in litigation regarding hepatitis C will be provided with relevant legal information by HFA.
In 1996, HFA received funds for the employment of a Hepatitis C Project Officer who developed a variety of educational resources for HCV-infected people with hemophilia and their families. This was a one-year project.

Availability of treatment:
In Australia, health care is covered by the Australian Medicare scheme and includes hemophilia care in general. Interferon treatment, which costs A$ 3,500 per year, is also covered by the Australian Medicare scheme, as well as combination therapy with ribavirin.

In Victoria, combination therapy (interferon/ribavirin) was authorized under the Pharmaceutical Benefits Scheme on October 1, 1999. However, such subsidized combination therapy is only available to patients who have already been treated with interferon monotherapy and relapsed. Treatment response is monitored by PCR testing, if a patient remains HCV-PCR-positive after a treatment course of three months subsidized therapy is withdrawn.

Litigation:
Litigation for medically acquired HCV infection is nearly nil as the governments have settled compensation for people who became infected through blood transfusion. But as the legal grounds for this settlement were not also applicable to people with hemophilia the governments and their lawyers refused to also include people with hemophilia.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

AUSTRIA

as of February 14, 2000

HCV infection rate: 90%
HBV infection rate: >90%

Patient population:
In Austria, 90% of regularly treated patients with hemophilia are HCV-infected. And the HBV infection rate reported for the hemophilia treatment center in Vienna is over 90%.

Efforts of the Hemophilia Society to obtain HCV compensation:
Since 1996 the Austrian Hemophilia Society (ÖHG) is seeking a global „no fault" compensation settlement for any damage that patients with hemophilia/VWD may incur in the future as a result of possible viral contaminations of blood products.
For HCV-infected people with hemophilia/VWD the ÖHG is requesting that a fund be established which is similar to the HIV compensation fund. In this direction the ÖHG has made several approaches towards the health authorities and the pharmaceutical industry, but the outcome of these negotiations leaves little hope for a solution. The efforts made by the ÖHG are supported by the Austrian organization for hepatitis C („Hepatitis Liga").
As there was a change of government early in 2000, the ÖHG is planning a new approach.

Financial assistance:
There is no regular financial assistance, but in case of severe hardship HCV-infected people can apply for some individual financial assistance from a special Emergency Fund which is maintained by the ÖHG. Such financial assistance is provided in the form of lump-sum payments or loans.

BELGIUM

as of February 11, 2000

HCV infection rate: 97%
HBV infection rate: no data available

Patient population:
In Belgium, nearly 97% of the population with hemophilia/VWD are HCV-infected. They became HCV-infected through treatment with blood products before 1990.

Efforts made by the Hemophilia Society to obtain HCV compensation:
The Belgian Hemophilia Society (AHVH) is still seeking a settlement with the Ministry of Health to obtain compensation from the government for those 40 patients who are HIV-infected and has recently made a new approach.
For fear that they would get nothing AHVH is abstaining from an additional request also for HCV compensation.

HCV litigation:
The product liability law, which was enacted in 1991, is not retroactive. Therefore, litigation is only possible for later infections that may occur.

CANADA

as of February 1, 2000

HCV infection rate: 81%
HBV infection rate: 82%

Patient population:
In total, over 12,000 Canadians have been primarily or secondarily infected with HCV through contaminated blood or blood products.
Regarding the hemophilia community Canadian studies on HCV infection and hepatitis C presented in 1992 showed that in a patient population of 884 male patients with hemophilia 64 % were HCV-infected. Extrapolated from an estimated total population of 2,200 patients with hemophilia this meant that 1,408 patients were HCV-infected.

A study on the quality of life of persons with hepatitis C, which was conducted by the St. Paul's Hospital in Vancouver, has shown that 68% have a long-term disability and are no longer able to work.

Time of infection:
The majority of patients became HCV-infected through blood products they had received prior to 1989.

Negligence on the part of the Canadian Blood System is documented by the facts that surrogate testing for hepatitis non-A, non-B was rejected in 1977 and the introduction of heat-treatment was rejected in 1982. Products used in Canada were partly manufactured from high-risk plasma collected in U.S. prisons - Canadian regulators took no steps to prevent the sale of plasma that was contaminated with HIV and HCV.

In 1986, when other countries were already testing for HCV antibodies, the Canadian Blood System refused to introduce this test and rather decided to conduct a study, in which half of the patients received screened and the other half unscreened blood, to find out about the efficacy of the test. This study is fully documented in the Krever Report. Testing for HCV antibodies was introduced much later than in other countries.

Chronology of events and efforts made by the Hemophilia Society to obtain financial assistance:
In May 1995, the Ministers of Health of Provinces/Territories and the federal Minister of Health decided against compensation payments to persons who became infected with HCV through blood transfusion or blood products. In September 1996 the Ministers reconfirmed this decision.
The Canadian Hemophilia Society (CHS) and its chapters started campaigns against this ministerial decision, some approached the Minister of Health of their Province/Territory. Letter writing campaigns were started and the International Hemophilia Day (April 17th) was successfully used for media pressure.

CHS set up a special Task Force for Hepatitis C and developed an "advocacy document" which was circulated to the federal and provincial governments.

In September 1996, following the Interim Report on the "Inquiry into the Canadian Blood System" the therein proposed Task Force on the Blood System was established, the work of which led to the creation of "Transfusion Canada", the new agency for the blood supply system for Canada.
In the Final Report on the „Inquiry into the Canadian Blood System" (Krever Report) it was proposed to compensate all HCV-infected people who became infected through contaminated blood or blood products.

To find out about the opinion held by the Canadian people regarding the issue of HCV compensation CHS launched a nation-wide Public Opinion Survey of over 1,600 Canadians which showed that 4 out of 5 Canadians believed that there is a „moral and compassionate obligation" to compensate all HCV-infected people irrespective of the date when the infection occurred. 92% believed that there is an urgent need that the government settles this matter.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

On March 27, 1998, the Ministers of Health of the federal and the provincial/territorial governments

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

announced a compensation package for all persons who became HCV-infected between 1986 and 1990, including „secondarily infected persons". CHS continued to fight for the inclusion also of those who were infected before 1986, but a ministerial meeting in May 1998 brought no further commitment, except for the Provinces of Ontario, Québec, and British-Columbia (see below).

In June 1998, the Canadian Senate made an unanimous resolution to widen the compensation scheme for those with HCV infection, but a year later in spring of 1999 HCV compensation was still outstanding. Only a few people had received some compensation on very special grounds.

Finally, on **June 15, 1999, the „1986-1990 Hepatitis C Settlement Agreement" was approved** by government.

Financial assistance scheme:
The „1986-1990 Hepatitis C Settlement Agreement" comprises the following three Schedules:
Schedule A: Transfused HCV Plan
Schedule B: Hemophiliac HCV Plan
Schedule C: Federal / Provincial / Territorial Assistance Program for HIV Secondarily-Infected Individuals.

The full text of the Settlement Agreement can be downloaded from the website www.hepc8690.com.

Eligible for financial compensation is any person who became infected with HCV during the period from January 1, 1986 to July 1, 1990, irrespective of the status of health. No compensation will be given to those who were infected outside this 1986 to 1990 window period.
Included in the scheme are also secondarily infected family members or persons (like spouses or former spouses, partners cohabiting for longer than two years, and their children) who became infected between 1986 and 1990. For survivors benefits will be paid.

The deadline for filing a claim is June 30, 2010. A surviving dependant of a HCV-infected person must file her/his claim within two years after the death of the HCV-infected person.

The settlement is Pan-Canadian in scope and will be administered for over 80 years. To fund the settlement agreement over one billion (Can$ 1,118,000,000), plus interest derived after April 1, 1998, will be provided.
It is hoped that payments will begin in January 2000.

Payment scheme:
The scheme applies to Canadian residents or former residents if they have received a transfusion or blood products in Canada („primarily HCV-infected persons"). Claimants having started legal action or proceedings must dismiss such action/proceedings before they can receive payment.

Together with the application form the claimant must submit the following:
a) medical, clinical or laboratory hospital records that the claimant has a congenital blood coagulation factor defect or deficiency and that the claimant received blood products during the „class period" from January 1, 1986, to and including July 1, 1990;
b) HCV antibody test report, HCV-PCR test report or similar test report;
c) a statutory declaration in which the claimant declares that he/she never used non-prescription intravenous drugs.
If requested by the Administrator of the Settlement Agreement, the claimant must also provide a consent authorizing the release to the Administrator of such medical, clinical, hospital records or other health information which the Adminstrator may need.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

The amount of the compensation payment and the timepoint of the individual payments is based on the „degree of illness“, payments increase with progression of the disease as following:

First payment	Can$ 10,000	if HCV antibody test is positive
Second payment	Can$ 20,000	if the HCV-PCR test is positive
Third payment *	Can$ 30,000	if the liver shows fibrous changes or the claimant has received Compensable HCV Drug Therapy (e.g. interferon) or meets the criteria for such therapy
Fourth payment	Can$ 65,000	if clinical proof of liver cirrhosis is established - proof can be established other than by means of liver biopsy, in which case the diagnostic findings establishing liver cirrhosis are defined and set forth in the Settlement Agreement
Fifth (final) payment	Can$ 100,000	if decompensation of the liver or hepatocellular cancer is diagnosed, or after liver transplantation

Compensation payments will not affect any social benefits or social assistance benefits which the claimant receives and are also income tax-free.

* The Can$ 30,000 payment may be waived in favor of „compensation for loss of income“ payments which may be received by the following persons if they became HCV-infected:

gainfully employed people	- the claimant must be „regularly unable to perform the substantial duties of his or her usual employment, occupation or profession no more than 20% of the usual work week“ - the paid amount is equal to 70% of the Annual Loss of Net Income and will be paid out each calendar year until the age of 65 years;
students under 18 years of age	- the student must attend (full-time attendance) an accredited educational institution in Canada;
persons who „normally performed the household duties“	- the person concerned must fulfil set criteria - the amount of the compensation payment will then be Can$ 12 per hour up to a maximum of Can$ 240 per week;

In addition to the above-mentioned compensation payments the following additional payments are made under the Settlement Agreement for HCV drug therapy and care:

(a) Compensation for HCV drug therapy:
Claimants who have received Compensable HCV Drug Therapy are entitled to the payment of Can$ 1,000 per each completed month of therapy.
This payment is made as compensation for the strains involved with HCV therapy.

(b) Compensation for non-covered treatment / medication:
An important feature of the Settlement Agreement is that claimants are entitled to be reimbursed for any costs incurred for the treatment and medication of HCV infection which are not covered by regular public or private health care plans or health insurance schemes existing in the Provinces / Territories. These costs are, however, only reimbursed, if the treatment was provided upon the recommendation of the treating physician.

This regulation extends also to outside Canada, in which case, however, reimbursement under the Settlement Agreement is only made to an amount of costs that would have been incurred if the treatment had been provided in Canada.

(c) <u>Compensation for costs of care</u>:
Provided that the claimant's treating physician has recommended the care, the claimant receives a compensation payment for the costs incurred for care. This payment is at maximum Can$ 50,000 in any calendar year. This regulation also applies for care provided outside of Canada, in which case the costs of care, if provided in Canada, will be reimbursed.
This compensation payment for costs of care does not include the above-mentioned compensation of the costs incurred for treatment or medication which are not covered by regular health care plans of Provinces / Territories.

(d) <u>Compensation for out-of-pocket expenses</u>:
To cover out-of-pocket expenses related with the claimant's seeking of medical advice or the treatment of HCV infection, as well as medical expenses incurred for establishing a claim, a compensation payment is made to also reimburse these out-of-pocket expenses, which include travel, hotels, meals, telephone etc.

<u>Compensation of HCV-infected claimants with concurrent HIV infection</u>:
A primarily HCV-infected claimant who is also HIV-infected and has received payments under the HIV Compensation Plan is paid Can$ 50,000 to satisfy all his claims pursuant to the HCV Settlement Agreement. But this payment does not affect the personal claim of a spouse, partner or child who is also HCV-infected.

<u>Compensation for deceased primarily HCV-infected persons</u>:
If a primarily HCV-infected persons with hemophilia is already deceased and if his <u>death occurred after January 1, 1999</u>, the surviving family or the deceased person's personal representative (e.g. an executor, administrator, trustee, tutor, guardian or curator) will receive all payments to which the deceased individual would have been entitled for the period up to his death. In the case that the surviving family receives the compensation, these payments will not affect the personal claims of secondarily HCV-infected spouses, partners or children.

If the individual is <u>deceased prior to January 1, 1999</u>, the surviving family or the deceased person's personal representative will receive the following compensation payments, which will not affect any personal claim of secondarily HCV-infected spouses, partners or children:

HCV-infected person with hemophilia	Can$	50,000
HCV-infected person with hemophilia leaving behind dependants & family members	Can$	120,000
HCV-infected person with hemophilia who was also HIV-infected	Can$	72,000

In all cases, an amount up to a maximum of Can$ 5,000 will be paid for uninsured <u>funeral expenses</u> incurred.

<u>Compensation payments to dependants and family members</u>:
Upon the death of a primarily HCV-infected person surviving dependants will be entitled to:

(a) „compensation for their loss of support" which is an amount of 70% of the deceased person's Annual Loss of Net Income each calendar year. The calculated net amount is reduced by an amount equal to 30% to allow for the deceased person's personal living expenses
or

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

(b) „compensation for the loss of services" in the home of the deaceased person at the rate of Can$ 12 per hour to a maximum of Can$ 240 per week.
„Compensation for loss of support" and „compensation for the loss of services" cannot be claimed for the same period.

For the „loss of guidance, care and companionship" the following payments are made to family members:

spouse	Can$	25,000
each child under the age of 21 years at the date of death of the HCV-infected person	Can$	15,000
each child 21 years or older at the date of death of the HCV-infected person	Can$	5,000
each parent	Can$	5,000
each sibling	Can$	5,000
each grandparent	Can$	500
each grandchild	Can$	500

If the deceased HCV-infected person was also HIV-infected and payments had been received under the HIV Compensation Scheme the above amounts may be reduced on a proportionate basis.

These payments will not affect the personal claims of secondarily infected family members.

Adjustment and re-assessment of compensation payments:
Individual payments made over longer periods will be regularly re-assessed by the Administrator of the Settlement Agreement.
And any restrictions (e.g. 70% net income payment, HIV co-infection payments) will be reviewed by the courts at regular intervals.

Financial assistance in Provinces/Territories:
Some Provinces have decided to grant compensation also to those people who became infected outside the 1986-1990 class period.
Ontario has provided Can$ 200 million of funding for this purpose, and the Province of Québec will pay out Can$ 10,000 to those who are not covered by the above-mentioned Settlement Agreement.

Support for HCV-infected people provided by the Hemophilia Society:
Legal counsel was given in the regions and at CHS chapters throughout the country to those who were planning to take legal action. The Society entrusted lawyers to prepare a class action suit against the Canadian Red Cross. Actions were coordinated by a committee that was made up of representative plaintiffs from the various Provinces. They discussed issues on a weekly basis and developed a national strategy.

Availability of treatment:
Besides supporting the campaigns for HCV compensation the Task Force for Hepatitis C has also addressed medical and social issues related to hepatitis C and carried out a survey to find out about interferon coverage in the various Provinces/ Territories. As each Province/Territory has its own Drug Plan, interferon is not globally free of cost. Some Provinces have medical insurance while others have special province-funded medical programs.
Patients who meet accepted criteria receive a 6-month alpha-interferon course free of costs. If everything else has shown no success liver transplantation might also be considered.
The now standard combination treatment of interferon and ribavirin is, however, not covered by the Health System for reasons of costs.

Litigation

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

In the Provinces of British Columbia, Ontario and Québec lawsuits through class action have been started. In these Provinces the settlement agreement had to be approved by the courts, which was done with some minor modifications relating to the following:
In principle, a claimant can opt out of the settlement agreement and sue the federal government, in which case the government could settle the action and then have the settlement fund pay the full amount. This way the government may „draw out" money of the fund. The Ontario judge who had to approve the settlement for the Province of Ontario barred this possibility to the end that, in case of a lawsuit, the plaintiff can collect only that amount of money that would have been paid if the plaintiff had stayed under the Settlement Agreement and had not opted out to take individual legal action. Any excess payment will have to be borne by the government and not by the Settlement fund.

(To explain class action processes and how the Settlement Agreement affects the individual a brochure has been developed, which can be downloaded in pdf-format from the website: www.hepc8690.com)

CROATIA

as of March 2, 2000

HCV infection: 88%
HBV infection: no data available

Patient population:
In Croatia, 88% of the patient population with hemophilia/VWD are HCV-infected.

Financial assistance:
Neither HIV-infected nor HCV-infected individuals receive any financial assistance or compensation payments.

Availability of treatment:
Interferon combination therapy with ribavirin is available. The costs of treatment are covered by the social insurance fund.

ESTONIA

as of April 17, 2000

HCV infection rate: 69%
HBV infection rate: 11%

There is no change since 1997 - there is no financial assistance for HCV-infected hemophiliacs in Estonia.

Availability of treatment:
Interferon is not used in general for the treatment of HCV-infected patients with hemophilia.
But if such treatment is indicated in an individual case the treatment costs will be borne by the health insurance.

FRANCE

as of March 2, 2000

HCV infection rate: 29% (80% estimated)
HBV infection rate: no data available

Patient population:

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

29% of the French patient population with hemophilia/VWD have been identified as being infected with HCV, but it is estimated that the HCV infection rate is much higher and comes up to 80%. Of these 50% have developed chronic hepatitis.
All patients who have been treated before 1987 are infected with HCV, and all patients treated before 1975-1980 had contact with HBV. Between 26-90% of the HCV-infected group are also co-infected with HIV.
Screening for hepatitis C was introduced in 1990, and the anti-HCV ELISA test became mandatory in March 1991.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

Financial assistance:
There is no financial assistance or compensation scheme for HCV-infected individuals, as was for HIV infection. As in total some 150,000-200,000 individuals have become HCV-infected from transfusions the government is reluctant to touch this matter, and because of the exorbitant sums involved the creation of a HCV compensation fund, similar to the HIV compensation fund, is surely not realizable.

Availability of treatment:
Interferon therapy and combination therapy with ribavirin is available and basically covered by the French health insurance.

HCV litigation:
In principle, patients may sue the blood transfusion center from which they received HCV-contaminated concentrate and can claim compensation from the center. Blood transfusion centers have meanwhile signed insurance contracts, which are however limited to a maximum sum of FFr 2.5 million per case and insurance year („plafond annuel"). However, there is presently a dispute ongoing whether the „plafond annuel" of FFr 2.5 million is per individual case or for all claimants at a blood transfusion center in an insurance year. Considered as a „case" is not only the index case who has been infected through contaminated blood or blood products, but also dependents who were infected by the index case person.

In a lawsuit against a blood transfusion center the plaintiff has to prove that he/she received blood or blood products from the center, though even only once, before the date of HCV seroconversion. A court has ruled that the blood transfusion center then has to prove that the transfused blood or its products were not contaminated, by following up and testing the blood donors. If such proof cannot be established the blood transfusion center is held liable and has to pay, via the insurers, for the damage incurred.

Court action may also be taken against the State for negligence of supervisory duties, but this is little successful.

Some HIV-infected patients, who are also HCV-infected, have taken legal action and received compensation before the courts. In October 1997, a court has granted a payment of FFr 2.5 million to two brothers who are HCV-infected and also HIV-infected. But this is not the rule, and payments vary from several thousand francs to several hundred thousand francs. Also, up to now all plaintiffs were co-infected with HCV and HIV, there was so far no legal case of singular HCV infection.

GERMANY

as of March 1, 2000

HCV infection rate: 83% estimated
HBV infection rate: no data available

Patient population:
It is estimated that 83% of patients with hemophilia/VWD are HCV-infected in Germany.

For the year 1999 it was reported from the National Hemophilia Registry in Munich that the total patient population counts >9,353 individuals with hemophilia/VWD, 6,353 individuals with hemophilia and >3,000 with VWD. It was also reported that altogether 1,153 individuals have been identified as being HCV-infected, which would come up to 12.3% of the entire patient population with hemophilia/VWD. However, this percentage may be rising as the National Hemophilia Registry is in the process of being established and only the data of about 7,000 patients have been entered into the database.

Time of infection:

In Germany, ALT testing of blood and plasma donations became mandatory in 1977 according to the

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

guidelines for plasmapheresis issued in and effective since 1977. Additionally, the German Drug Act became effective on January 1, 1978, requesting manufacturers to execute their duties on the basis of „current scientific knowledge and technology".

In the 1977 guidelines for plasmapheresis, which were based on the then current scientific knowledge and technology, it was prescribed that all plasma „brought into circulation" for the manufacturing of concentrates, had to be ALT-tested. But ALT testing of imported plasma was only begun in 1985.
In the United States ALT testing was recommended even later and as late as 1986. Up to 90% of the plasma that was used in Germany for the manufacturing blood coagulation concentrates was imported from the United States and came from „at risk" areas and paid donors. If this plasma had been ALT-tested since 1977 the risk of contamination of products would have been reduced to at least 30-40%.

Efforts of the Hemophilia Society to obtain financial assistance:
Since 1994 the German Hemophilia Society (DHG) has repeatedly approached the Minister of Health to also obtain compensation payments for HCV-infected individuals. Although these efforts were unsuccessful, the DHG is continuing to work for HCV compensation within the framework of a political solution.
In an approach towards the pharmaceutical industry, in August 1998, the DHG proposed negotiations to find a solution for HCV compensation. But the pharmaceutical industry was not willing to enter into negotiations. Only later, when the DHG announced that legal action and individual lawsuits against pharmaceutical manufacturers were being prepared, the pharmaceutical industry commenced negotiations with the DHG in February 1999. These have, however, shown no results up to this date as the pharmaceutical industry is arguing that ALT testing was a controversial issue and its value was scientifically not proven and remained internationally disputed. --

Overall, there exist two patient populations: those in the Western part of Germany who were always treated with concentrates and those in the Eastern part of Germany who had no access to Western concentrates prior to the reunification of Germany and were treated with cryoprecipitates manufactured in the former German Democratic Republic („DDR") and became infected with HCV through these products.
For the latter group of patients it has been stated, in 1998, in a legal counsel's opinion („Rechtsgutachten zur haftungsrechtlichen Situation der in der ehemaligen DDR mit HCV infizierten Hämophilen nach der deutschen Vereinigung") that those individuals with hemophilia/VWD who were infected with HCV in the former German Democratic Republic („DDR") have a statutory right to receive compensation, as well as to equal treatment if a compensation scheme were put into place.
For the other group, i.e. those individuals who were treated and infected in the Western part of Germany, litigation against manufacturers may be successful.
However, both patient groups have to be treated legally equally, a right which is founded in the German Statutes. As the situation is similar to HIV compensation it has, therefore, been proposed in the legal counsel's opinion to find a similar solution and to establish a HCV compensation fund.

Availability of treatment:
Interferon therapy and combination therapy with ribavirin is available and is also covered by the German health insurance system.

Litigation:
Early in 2000, several HCV-infected **patients have filed lawsuits against pharmaceutical companies before a court**.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

GREECE

as of February 28, 2000

HCV infection rate: 95% estimated
HBV infection rate: no data available

Patient population:
There exists no national hemophilia registry in Greece, but it is estimated that 95% of the patient population with hemophilia/VWD are infected with HCV.

Efforts of the Hemophilia Society to obtain HCV compensation:
There is no change since 1997, the issue of HCV compensation has not been discussed.

IRELAND

as of February 28, 2000

HCV infection rate: 18%
HBV infection rate: 2%

Patient population:
In Ireland, patients were tested for HCV in 1990. Today's statistics show that 18% of the the Irish patient population with hemophilia/VWD are HCV-infected.

Regarding HBV infection, 2% of individuals with hemophilia/VWD are HBsAg-positive.

Efforts of the Hemophilia Society to obtain HCV compensation:
In spring 1995, the Irish Haemophilia Society (IHS) began working towards obtaining compensation for its HCV-infected members.
The IHS was successful in negotiating a 2-component package for HCV-infected people with hemophilia, which included the following:
(1) a component related to the health care services provided and
(2) a compensation payment scheme (see below). --

The Irish Haemophilia Society was, in addition to its above efforts, requesting an Inquiry into the National Blood Transfusion Service Board and how patients with hemophilia became infected with HIV and HCV.
In October 1996, the Minister of Health proposed to establish a „Tribunal of Inquiry“ whose task is „to look into the circumstances of infection of people with haemophilia with HIV and hepatitis“ - especially during the period after 1985 when virus inactivation methods became available. In February 1999, the Irish Cabinet decided to establish the „Tribunal of Inquiry“. The discussions on the „Terms of Reference“ for this Tribunal lasted over two years. In the „Terms of Reference“ * it is set forth which issues shall be investigated by the Tribunal of Inquiry, these are the following:

- „To ascertain the source of infection of products manufactured or imported
- The role of the Blood Transfusion Service Board (BTSB), medical consultants and others in product selection
- The prevailing state of medical and scientific knowledge
- The implementation of a self-sufficiency policy by the BTSB
- Selection procedures with regard to manufacturers and fractionators
- Donor selection
- Donor testing
- Donor screening

- Plasma quarantine criteria
- Viral inactivation procedures
- Follow-up measures in respect of tracing, offering testing and minimising risk of infection
- Response to discovery that persons had been infected
- Role of the National Drugs Advisory Board
- Supervision of the NDAB and BTSB by the Department of Health.“

* cited from IHS newsletter, June 1999, p. 5

The hearings before the Tribunal have begun in May 2000. The IHS is issuing weekly „Tribunal News“ in which the proceedings of the individual case hearings are reproduced in the form of case histories. --

Financial assistance scheme:
In 1996, the 1970 Health Act was amended and became effective in September of the same year, resulting in an improvement of health care services. Within the framework of the 2-component package indirect financial assistance is provided to HCV-infected individuals through improved health care services and direct financial assistance is granted under the compensation payment scheme. There is no limitation to the duration of the compensation scheme.
Compensation is granted by the State of Ireland in the form of ex-gratia payments. By making payment on an ex gratia basis the State does not admit any fault or liability on the part of the National Blood Transfusion Service and, vice versa, claimants are not required to prove negligence on the part of the Blood Transfusion Service or any other party to receive the payment.

The Compensation Scheme is administered by the "Hepatitis C Compensation Tribunal", which was established by the Minister of Health in 1995 and consolidated on a statutory basis in 1997.
The Hepatitis C Tribunal receives applications for compensation payments, assesses the damage claimed and proposes the compensation payment ("award") to be made. The claimant can decide whether he/she would like to receive the payment in one single sum or by instalments. Payments are made directly by the Tribunal from a Fund that was especially installed and is operating for this purpose. (For the detailed payment scheme see the 1997 HIV / HCV Financial Assistance Report by the WFH Information Clearinghouse.)

For the assessment of the damage a patient has incurred the Tribunal relies on written medical reports and non-public hearings. By the end of 1998, some 118 cases had been heard before the Tribunal. The average compensation payment made in these cases amounted to:

£ 185,000

In the individual case the payments were ranging from £ 41,000 - 675,000. The latter sum was offered to an individual with hemophilia in 1997. --

In March 1997, the Minister of Health also established a "Consultative Council on Hepatitis C", which will be operating for a period of three years and on which the IHS is represented. The purpose of the Council is to monitor the changing needs of HCV-infected individuals, to follow up research results and safeguard that appropriate information is made available to HCV-infected patients.

Support for HCV-infected people provided by the Hemophilia Society:
IHS organizes hepatitis C weekends and has published brochures for patients, dealing with matters related to hepatitis C.

Availability of treatment:
Interferon therapy and combination therapy with ribavirin is available and provided free of charge under the amended Health Act.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

If clinically indicated, liver transplantation may be performed. In the event that liver transplantation cannot be done in Ireland the treating physician may recommend transplantation abroad.

ISRAEL

as of February 7, 2000

HCV infection rate: 50%
HBV infection rate: no data available

Patient population:
50 % of the patient population with hemophilia/VWD are HCV-infected.

Efforts of the Hemophilia Society to obtain financial assistence:
In Israel the situation has not changed since 1997. The Israeli Hemophilia Association has decided not to approach the government also for HCV compensation as the Association is seeing no chance for HCV compensation payments after compensation payments have been made to HIV-infected people.

ITALY

as of February 28, 2000

HCV infection rate: about 75%
HBV infection rate: about 2%

Patient population:
In Italy, about 75% of the patient population with hemophilia/VWD are HCV-infected.

Regarding HBV infection, 2% are HBsAg-positive according to information from the Centro Emofilia e Trombosi, Ospedale Maggiore, in Milano.

Financial assistance scheme
In July 1997, the basic law no. 210 of February 1992, under which HIV compensation payments have been made, was amended by a second law „Legge n. 238 del 25 luglio 1997: Modifiche ed integrazioni alla legge 25 febbraio 1992, no. 210, in materia di indennizzi ai sogetti danneggiati da vaccinazioni obbligatorie, transfusioni ed emoderivati", by which several injustices and inadequacies of Legge 210 were settled.
The benefits as stipulated in the amendment are now also guaranteed to spouses who became infected through their hemophilic partner and children who were infected through their mother during pregnancy. --

Patients with hemophilia/VWD who are infected with HBV or HCV receive the same payments as for HIV infection according to the below-given categories. Claims for HCV compensation payments must be submitted three years at the latest after the diagnosis of HCV infection has been established.

The amendment of Legge 210 entailed, in 1998, a raising of the initial life-pension payments to the following:

Categories	annual payment	bi-monthly payment	monthly payment	daily payment
1st category	Lit 14,280,060	Lit 2,380,010	Lit 1,190,005	Lit 39,120
2nd category	Lit 14,046,840	Lit 2,341,140	Lit 1,170,570	Lit 38,485
3rd category	Lit 13,815,120	Lit 2,302,520	Lit 1,151,260	Lit 37,850
4th category	Lit 13,582,440	Lit 2,263,740	Lit 1,131,870	Lit 37,210
5th category	Lit 13,349,160	Lit 2,224,860	Lit 1,112,430	Lit 36,575

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

6th category	Lit 13,115,880	Lit 2,185,980	Lit 1,092,990	Lit 35,935
7th category	Lit 12,883,140	Lit 2,147,190	Lit 1,073,595	Lit 35,295
8th category	Lit 12,649,860	Lit 2,108,310	Lit 1,054,155	Lit 34,655

Regarding the time-point for calculating payments the Constitutional Court ruled that payments are to be calculated from the date of infection and not from the date when the claim is submitted.

„Double infections", HCV and concurrent HIV infection, are settled as follows:
Verification of infection must be submitted for each infection separately, and the payment category is then also assigned separately for each infection. Of these two payments the higher payment is made in full while for the lower payment only 50% are paid out.

As a result of the amendment of Legge 210 many claims had to be reviewed and some are still pending, so that payments have been delayed and the payment scheme for „double infections" is not yet fully operating. It is hoped that payments for reviewed claims will be made in the first quarter of the year 2000.

Availability of treatment:
Interferon treatment is available. The costs of interferon treatment or combination treatment are fully borne by the Public Health Care System (Sistema Sanitario Nazionale).

Litigation
Some HCV-infected patient who are also HIV-infected have joined the litigation that was instituted as „collective patient action" by HIV-infected patients.

JAPAN

as of March 17, 2000

HCV infection rate: 41%
HBV infection rate: no data available

Patient population:
In Japan, HCV infection is predominant if compared with HBV infection.
Patient became infected with HCV some 25 years ago.

Financial assistance:
There is no financial assistance for HCV-infected patients with hemophilia.

It is universally admitted that the method of how to treat HCV-infected patients best must be sought. It is planned to enable the best possible treatment rather than to provide financial compensation.

Availability of treatment:
Interferon is available. The costs of interferon therapy are borne by the health insurance and the government.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

LATVIA

as of April 17, 2000

HCV infection rate:
HBV infection rate:

In 1997, there were no HCV infections in Latvia. But this situation has changed, and Latvia now reports that there are HCV infections.

Compensation or any other financial assistance is not provided.

Availability of treatment:
Interferon is now available in Latvia. There is, however, no combination treatment with ribavirin.
Interferon therapy is problematic because patients are not on prophylactic therapy with concentrate. It is reported that infectious disease specialists are refusing to treat HCV-infected patients suffering from severe hemophilia with interferon because of the risk of bleeding.

NETHERLANDS

as of March 8, 2000

HCV infection rate: 90% estimated
HBV infection rate: no data available

Patient population:
It is estimated that 90% of the patient population with hemophilia/VWD are HCV-infected. The exact percentage is not known as there is no national hemophilia registry in the Netherlands.
The percentage of HBV infection is also not known.

Financial assistance:
There is no financial assistance for individuals with hemophilia/VWD who are HCV-infected. The Netherlands Hemophilia Society consulted a lawyer whether sueing the government would have a chance of success, but he advised against such action. Legal action may only be successful in the case of new HCV infection from virus-inactivated concentrate, but not for the older HCV infections that occurred before 1990.

Availability of treatment:
Interferon is available for the treatment of HCV infection, but interferon therapy is still not paid by the health insurance. Combination therapy with ribavirin is only used in clinical trials and not freely available.

Litigation
There were 3-4 individual lawsuits, but all were unsuccessful.

NEW ZEALAND

as of January 27, 2000

HCV infection rate: 70% estimated overall - 90% in severe hemophilia
HBV infection rate: no data reported

Patient population:
In New Zealand, HCV infection is predominant, but hepatitis B is also very high. Patients with hemophilia/VWD are routinely tested for HCV.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

Since the 1970s altogether over 600 people have become HCV-infected through contaminated blood or blood products. 18 HCV-infected persons have meanwhile died since 1990.
Up to 90% of people with severe hemophilia have contracted hepatitis C.

The New Zealand Hepatitis C Support Group is of the opinion that a Full Prevalence Study is needed.

Time of infection:
Most HCV infections occurred before 1989. Since 1989 tests were available and many countries introduced the HCV antibody test, although some experts considered the earlier tests to be unreliable.
In New Zealand, the HCV antibody test was only introduced as late as July 1992, three years later. Moreover, unscreened blood products were continued to be used after this date. The introduction of superheat-treatment was delayed.

Financial assistance:
Under the Accident Compensation Act HIV infection had, in 1985, been recognized as an „accident due to medical misadventure". In 1992, the Accident Compensation Corporation (ACC) also recognized HCV infection as a "medical misadventure" so that compensation payments could be claimed under the 1982

Accident Compensation Act.
The deadline for filing claims was, however, at such a short notice that many HCV-infected patients missed it and could not file their claims. A major obstacle was also that many treating physicians had not informed their patients that they were HCV-infected.
This resulted in the fact that some people with HCV infection received payments and others not. Those who had missed the deadline could later file their claims under the new 1992 Accident Compensation Act, but received different payments. Moreover, the government later stopped all lump-sum payments (see below).

Payment scheme
There was no special fund set up. As for HIV infection all payments were directly made by the ACC. To receive a payment the claimant had to be over 16 years of age.

To become eligible for a lump-sum payment for HCV infection under the old 1982 ACC Act the diagnosis of HCV infection had to be established before July 1st, 1992, - this deadline was missed by many people because they were unaware of their HCV infection as their treating physician had not informed them.

Like for HIV infection HCV lump-sum payments were made under Sections 78 and 79 of the old 1982 ACC Act and were of the same amounts as for HIV infection (under Section 78 the maximum lump sum was NZ$ 17,000 and under Section 79 the maximum lump sum amounted to NZ$ 10,000).
Section 78 was applied for HCV infection, and as HCV infection is also progressive Section 79 becomes applicable in the case of chronic hepatitis.
To define the "loss or impairment of bodily function" in Section 78 of the ACC Act the Haemophilia Society pursued the policy that "two raised ALT levels not less than 28 days apart qualifies a person as having functional (liver) disability".

In 1992, the old 1982 ACC Act was amended into the 1992 Accident Compensation Act, which resulted in a definite change of emphasis and a more stringent handling of cases. Payments under the new 1992 ACC Act are based on whether or not there is a "physical injury" which is defined as "resulting from medical error or medical mishap". And a medical mishap is defined as a rare (less than 1%) and severe adverse consequence of treatment provided by a registered health professional, resulting in significant disability.

Overall, the following points make HCV compensation unfeasible under the new 1992 ACC Act:

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

1. HCV infection is unlikely to be a "medical error" as it does not meet the definition of failure of a registered health professional to observe standard care and skill.
2. It is also unlikely that HCV infection meets the criteria for "medical mishap" as it is neither "rare" (< 1%) nor "severe" (significant disability) - although HCV infection is, actually, severe and in most cases entails significant "disability" of liver function when the stage of chronic hepatitis is reached.

Moreover, lump-sum payments granted under the old 1982 ACC Act have been replaced, under the newly amended 1992 ACC Act, by an "independence allowance", which is calculated on the basis of a person's disability. The maximum amount comes up to NZ$ 40 per week (tax free). To receive this amount in full one has to have a 100% disability. A 10% disability entitles to only NZ$ 4 per week. (With regard to HCV infection a physical disability over 20% is, however, rather unusual.)
An independence allowance is only granted, if functional disability is present and has developed within one year after the date of diagnosis, otherwise the claim will be cancelled. Payment of an "independence allowance" may continue for lifetime, but is subject to periodic re-assessment, at least every five years.

HCV-infected people who had missed the 1992 deadline for filing their claims under the old 1982 ACC Act now to lodged their claims under the amended 1992 Act. **Claims were assessed differently** under the two versions of the ACC Act, **resulting in greatly varying compensation payments**.

Under the new 1992 ACC Act claims are not accepted later than 12 months after the date of diagnosis. This has turned out to be a considerable barrier for payments, as most HCV infections have occurred and been diagnosed by the treating physician long before.
The Haemophilia Society of New Zealand is demanding to correct this injustice by a general settlement with payments to all HCV-infected people with hemophilia or related bleeding disorders, irrespective of the date of the supposed infection. But such **a general settlement is still refused by the government**.

Efforts of the Haemophilia Society to reach a general settlement:
The Society answers queries related to HCV infection by e-mail: haemophilia@clear.net.nz

The Society is encouraging its HCV-infected members to talk on the radio, write letters to newspapers and magazines, contact the local MPs, go to candidates' meetings, and write to the Prime Minister - appropriate letters have been pre-formulated by the Society. In 1999, an 8-week Protest about Compensation was organized which ended before the Parliament and then spread into the regions. During a concerted campaign directed at MPs, political parties were asked in writing formal questions regarding a range of hemophilia care issues, including compensation for HCV infection. The Labour Party would like „to settle the outstanding issues in a timely fashion and without recourse to litigation", while the National Party points out that „compensation is available now through ACC".

To raise the necessary funding for litigation the Haemophilia Society created a "Fighting Fund", from which those taking legal action may receive financial aid. The Society has set up a Legal Services Committee which considers legal aid and coordinates applications for legal aid.

Availability of treatment:
Regarding interferon treatment, the Haemophilia Society launched a massive media campaign which led to the result that the Department of Health finally accepted to pay for interferon.

Litigation
But before any individual decisions could be taken the High Court had to rule on the question whether a person, who had already received a lump-sum payment for HIV infection as a "personal injury by accident" could file a claim for compensation of another separate such accident, i.e. HCV infection, which occurred at the same time as the original HIV infection accident.

A district court decided positively on this matter and ruled that two separate claims can be filed and a second lump-sum for HCV infection can be awarded to someone who has already received a lump-sum payment for HIV infection. However, the ACC appealed to the High Court against this decision and was successful:
The Auckland High Court ruled against payments to HCV-infected persons who have already received a lump-sum payment for HIV infection. -

Although HCV-infected patients have less chances under the amended 1992 ACC Act, the new Act holds possibilities for certain legal claims which were not possible under the old 1982 ACC Act.

To obtain satisfactory and equal lump-sum payments over 100 HCV-infected people have decided to take legal action. A consortium of legal firms and barristers is dealing with these HCV claims. The individual cases have different chances for success and have, therefore, been grouped - cases between 1990 and 1992 have the best legal basis, those between 1987 to 1990 have still good legal grounds, and those before 1987 are standing on moral grounds. Several „representative" claims for "exemplary damages" were filed in the High Court in a test case, sueing the government for negligence because blood was not screened for hepatitis C from 1990 - 1992 although several clinical groups had requested and advised to do so. The Society has stated that „the idea behind the court action is that the Government is being punished for a wrong doing rather than not paying out compensation".

So far no meeting has taken place between the lawyers representing the group of HCV-infected claimants and the lawyers acting for the government.

NORWAY

as of February 10, 2000

HCV infection rate: 44%
HBV infection rate: very low

Patient population:
In Norway, 44% of the patient population with hemophilia/VWD are infected with HCV.

Some patients became HCV-infected from one imported contaminated batch of FVIII concentrate when Norway was, due to difficulties with technical equipment, unable to manufacture sufficient quantities of concentrate. The other patients became infected through cryoprecipitates produced in Norway from voluntary blood donations in the late 1970s until the mid-1980s.
The majority of the 21 HIV-infected patients are also HCV-infected (14/21) - all of these patients have severe hemophilia A. (Some of the tests have been performed on plasma samples that have been stored since 1985).

Hepatitis B is very seldom in the hemophilia/VWD population in Norway, there have no new cases occurred since 1976.

Efforts of the Hemophilia Society to obtain financial assistance:
The Norwegian Hemophilia Society is striving for a compensation settlement with the government which is similar to the HIV compensation settlement, which was reached in the late 1980s/early 1990s and under which HIV-infected people had received in total NOK 500,000 and by which HIV-infected spouses and surviving family members were also covered.
In autumn of 1999 the Norwegian Parliament (Stortinget) decided to grant a compensation payment to all people who became HCV-infected through blood products.

Payment scheme:

However, there not yet full agreement on the exact amounts of payments to be made and the organization of the scheme. A compensation payment will only be made to those persons who are not entitled to other forms of compensation. Included in the HCV compensation scheme will only be primarily infected persons, payments to spouses and children are not planned.
A Health Authority body has recommended that a basic payment of the amount of NOK 100,000 be made to each individual who became HCV-infected through blood products, but it seems more likely that this payment will only amount to NOK 60,000.
Patients with severe liver damage resulting from hepatitis will, however, receive a higher amount.

The Norwegian Hemophilia Society is continuing its efforts to increase the amount of the basic payment.

Availability of treatment:
Interferon treatment and also combination treatment with ribavirin is available.
For coverage of such treatment by the Norwegian health system patients must make a special application for treatment. None has been denied so far.

POLAND

as of May 2, 2000

HCV infection rate: 60%
HBV infection rate: approx. 10%

Patient population:
There is no change in the HCV infection rate of 60%, as given in 1997, as further studies have not been done in the past ten years.
The percentage for HBV infection is approximately 10% and pertains to HBsAg-positive patients.

Financial assistance:
As for HIV infection, there is no compensation or financial assistance for HCV-infected persons with hemophilia in Poland.

Availability of treatment:
Interferon treatment and combination therapy are provided free of costs.

Litigation:
Lawsuits have not been filed.

SOUTH AFRICA

as of February 4, 2000

HCV infection rate: 27%
HBV infection rate: 38%

Patient population:
The infection rate figures reported from South Africa in 1999 are 27% for HCV, and 38% for HBV respectively.

Efforts of the Hemophilia Society to obtain financial assistance:
The South African Haemophilia Foundation (SAHF) is still struggling for adequate compensation from the government for people with HIV infection, so that SAHF has made no effort to press on the government also for HCV compensation.

Availability of treatment:
Interferon is available and used. Interferon treatment is paid either by the State or covered by insurance schemes.

Litigation
Lawsuits have not been filed.

SPAIN

as of March 17, 2000

HCV infection rate: 65%
HBV infection rate: not known

Patient population:
In Spain, 65% of the patient population with hemophilia/VWD are HCV-infected.

Financial assistance:
The Spanish Federation for Hemophilia has been negotiating with the Ministry of Health to obtain compensation for those who are HCV-infected since 1996.

On November 27, 1997, a law (Ley 50/1997) was passed which provided that, by Order, a special ministerial Commission should be created within the Ministry of Health whose task should be to carry out a survey and collect information on those individuals with hemophilia/VWD or other congenital blood coagulation disorders who have become HCV-infected resulting from treatment provided in facilities of the public health system. A later law of December 29, 1999 (Ley 55/1999) stipulates that the Commission should lay down the criteria for inclusion of HCV-infected individuals in the planned survey. The ministerial Commission was convened by Order of January 18, 2000, describing in detail the Commission's composition and expert membership.

The criteria for inclusion in the survey, as laid down by the Commission, are as follows:

- individulas with hemophilia/VWD or other congenital blood coagulation disorders
- HCV-PCR-positive test
- raised ALT levels at 3 different determinations within a period of 6 months.

The data will be collected from treatment centers and will be transferred to a central database that will be maintained by the Commission under the auspices of the Ministry of Health. **All HCV-infected individuals whose data will, after scrutiny, remain in the Commission's database will be entitled to receive HCV compensation from the government.**
The final results of this survey will be presented to the government by September 30, 2000. After this presentation the amount of the HCV compensation payment and the administrative details will be laid down.

Availability of treatment:
Interferon is available and used for HCV-infected patients. Interferon treatment is covered by the Social Security scheme which is under the responsibility of the Ministry of Health.

SWEDEN

as of February 4, 2000

HCV infection rate: 30 - 55%
HBV infection rate: 98%

Patient population:

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

There are no national Swedish figures for HCV or HBV infection as Sweden has no national Hemophilia Registry. The rates of infection reported in 1999 by the three hemophilia treatment centers are as follows:

	HCV	HBV
Göteborg	55%	98%
Malmö	46%	1%
Stockholm	30%	no data

Efforts of the Hemophilia Society to obtain financial assistance:
HCV infection and HBV infection or hepatitis are not recognized by the Pharmaceutical Benefits Scheme, which had been established to make HIV compensation payments.
The Swedish Hemophilia Society is, therefore, fighting to obtain HCV compensation from the Swedish government. A decision is pending and the Society is now **awaiting the ruling of the Court of Arbitration**.

Availability of treatment:
Interferon treatment, also combined with other medication or treatment, is available. The way of payment for such treatment is the same as for any other medication or treatment.
For HIV-infected patients with hemophilia/VWD who are concurrently HCV-infected interferon treatment is provided free of costs.

SWITZERLAND

as of May 22, 2000

HCV infection rate: 90%
HBV infection rate: no data available

Patient population:
In Switzerland, the prevalence of hepatitis C is 90%. No new HCV seroconversion has been observed since 1990.

Time of infection:
Before 1980 virus-inactivated concentrates were not available so that patients had to be treated with non-inactivated concentrates through which they became infected with HCV.

Financial assistance:
The Executive Committee of the Swiss Hemophilia Society (SHG) has in depth deliberated the matter of HCV compensation. As the majority of patients were infected with HCV before 1980 when virus-inactivated concentrates were not yet available in Switzerland it will be very difficult to provide proof of negligence - and this is the more difficult as hepatitis was a "calculated risk" in those times. For this reason the SHG Executive Committee believes that there is no chance of also obtaining financial assistance for HCV-infected persons with hemophilia and is, therefore, not considering any approach towards the government.

After the HIV disaster the Swiss Red Cross (SRK) has in part also assumed responsibility for the transmission of HCV through its blood products. The SRK has, therefore, offered assistance to needy individuals who can no longer work or who are in financial difficulties due to hepatitis C. To these individuals SRK makes a singular payment.

In cases of hardship limited financial support is also provided from the Solidarity Fund (Solidaritätsfonds) which is maintained by the Swiss Hemophilia Society and has been set up to provide „on-demand payments“ to people who are in a financial distress situation, especially to those who are suffering from a severe secondary disease like hepatitis C. However, from this Fund no regular payments can be made as such payments would exhaust the financial means of the Fund.

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

SHG was ventilating the idea of setting up a separate Hepatitis Fund and integrating it into the existing Solidarity Fund. But this idea was later discarded because the regular benefits from the health and invalidity insurances are, in general, high enough so that supplementary assistance is only needed in rare cases.

Support for HCV-infected people:
In May 1998, HCV-infected patients formed a new patient organization under the name of „Help C“ (Association pour la lutte contre l'hépatite C). A year later, in 1999, this group had already expanded into five regional groups. The purpose of this group is to provide to people who are infected with HCV counseling services and information regarding their medical, social and legal rights and create a platform for discussion. Help C has applied for SHG membership.

Availability of treatment:
Interferon therapy is available. The costs are borne by the Swiss Health Insurance Fund for a treatment period of 6 months. If it is considered medically necessary to extend the treatment protocol the treatment period may be prolonged to 12 months of free-of-cost treatment. Combination therapy with ribavirin is also available and is paid for by the health insurance since mid-April 2000.
In 1997, a treatment study was initiated to monitor the outcome of combination treatment with interferon and ribavirin, in which 40 patients with hemophilia and chronic hepatitis C were enrolled. Patients with concomitant HIV infection were not included in this study.

TURKEY

as of April 19, 2000

HCV infection rate: 83 %
HBV infection rate: 54 %

Patient population
The last survey by the Turkish Society was done in 1997 and the HCV infection rate reported then was 58%. The above infection rates were reported in 1998 for the hemophilia statistics survey carried out by the WFH Information Clearinghouse. These figures refer to members of the Turkish Hemophilia Society only.

Financial assistance scheme
There is no financial assistance for HCV-infected patients.

Availability of treatment
Interferon is available. However, interferon is only used for patients with chronic active hepatitis C who are covered by the social security scheme.
In Turkey, not all people have social security coverage, some have to pay for health-related costs by themselves. And if these patients do not have sufficient private monetary resources they may not be able to afford expensive medical treatment and drug therapies.

UNITED KINGDOM

as of January 26, 2000

HCV infection rate: 47%
HBV infection rate: no data available at the Clearinghouse

Patient population:

In the United Kingdom, 4,800 people with hemophilia are HCV-infected - 1,200 of these are also HIV-infected. In Scotland 200 - 300 patients are infected with HCV.
Most patients have severe hemophilia and had to infuse regularly, but there are also several patients with moderate or mild hemophilia who have been treated with concentrate only once or twice in their life.

Time of infection:
Nearly all HCV-infected patients became infected before 1986. In Scotland, patients may have been exposed to contaminated concentrates even for up to a year longer until 1987.

Efforts of the Haemophilia Society to obtain financial assistance:
The Haemophilia Society is campaigning for more than five years, since 1995, for financial assistance for those who are HCV-infected. The Society's main argument is that the situation is similar to HIV infection and, therefore, financial assistance in the form of an *ex gratia* lump-sum payment should be granted as it was done for HIV infection and a hardship fund should be set up. The Society is demanding equal treatment of those who are HCV-infected.

In late autumn of 1996, the then Conservative government had ruled out any financial assistance and denied the setting up of a hardship fund. But with the new Labour government the Society resumed the negotiations in May 1997 with the argument "that the Government has a moral responsibility for those people with haemophilia infected with hepatitis C". But despite intensive lobbying and a petition the government's attitude could not be reverted:
In July 1998 again, **the government refused any help to HCV-infected people**, remaining also unresponsive to the demand for a hardship fund.

In 1999, the campaign received a new impulse when a BBC investigation brought to light in Scotland that HCV-contaminated concentrates had even been used for a year longer, until 1987, than in England. As many as 50% of the 600 Scottish people with hemophilia may have become infected with HCV from blood products. The Scottish Minister of Health has announced a thorough inquiry into „how the haemophilia population of Scotland became infected with blood-borne viruses, in particular hepatitis C". The Society is now also negotiating with the Scottish Minister of Health, who has so far made no commitment to any financial assistance. It is hoped that, on the basis of the results of the inquiry, the Scottish Parliament may decide in favor of HCV financial assistance, which may then also have its effect on the hitherto non-responsive Parliament in London.
In England, a new approach towards the Prime Minister by a number of Labour MPs who requested a public inquiry into the HCV contamination was unsuccessful. The Prime Minister rejected the request for an inquiry and stated: "I am not convinced that a public inquiry would provide greater insight into the problem or pave the way for any further improvements in the safety controls which are now in place."

In 1999, after the Scottish HCV infections had come to light, the **U.K. Haemophilia Society** has again insisted on an investigation and **requested the Secretary of Health to conduct a full inquiry**.
To keep the topic high on the agenda and raise public and politicians' awareness the Society is encouraging its HCV-infected members to speak to the press and the other media and contact the MPs in their constituencies. To rally its forces the Society has implemented a HCV campaign supporters database.

In addition to direct financial assistance for those who are HCV-infected, the Haemophilia Society also demanded from the government that adequate funding be provided for the treatment of hepatitis C and for research into the disease. Early in 1996, the government granted L 1 million to fund research into the natural history of HCV infection, its prevalence, and the routes of viral transmission.
Early in 1996, the Society submitted its "Haemophilia and Hepatitis C Research Report" to the Department of Health. This report outlines the impact of HCV infection on the life of patients with hemophilia and recommends the setting up of HCV support services at hemophilia treatment centers.

Support for HCV-infected people provided by the Haemophilia Society:

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

The main site where information is given to HCV-infected people is the Society's home page: www.haemophilia.org.uk, from where regularly issued HCV Campaign Updates may be ordered and where a series of leaflets and fact sheets on current HCV-related issues is listed which have been published by the Society. A Hepatitis Telephone Support Network has also been installed by the Society, and Hepatitis Support & Information evenings have been organized.

Availability of treatment:
Interferon treatment is, in principle, available for all HCV-infected patients, if this is clinically indicated. The costs of interferon and/or ribavirin are borne by the Health Authorities. There are, however, reports of cases where the health authorities denied interferon treatment because of the costs, although the Department of Health has promised to cover the costs of such treatment.

HCV litigation
Recipients of *ex gratia* payments for HIV infection had to sign a disclaimer. This disclaimer also applies to hepatitis, so that all persons who received a payment because of HIV infection cannot file another claim for HCV compensation.
Some HCV-infected patients are not concurrently infected with HIV and have thus received no payment. They are planning to sue the National Blood Transfusion Service for medical negligence with regard to HCV. However, they have only a chance of being successful, if their HCV infection occurred after 1986. Several HCV-infected persons with hemophilia who were first treated with concentrate after 1977 have, nevertheless, taken legal action, alledging that the Blood Service was negligent because heat-treatment of concentrate had been introduced in England with delay as late as in 1985. In Scotland heat-treatment was introduced even later and not before the end of 1986.

UNITED STATES

as of March 6, 2000

HCV infection rate: 85%
HBV infection rate: no data available

Patient population:
In the United States, about 85 % of the patient population with hemophilia/VWD are infected with HCV.

In August 1997, the Blood Safety and Availability Committee of the Department of Health and Human Services (DHHS) initiated a look-back study and recommended the testing for hepatitis C of all individuals who received a blood transfusion or blood products prior to 1992. It is hoped that the look-back study will be completed by March 2001. The Committee also called upon the US blood industry to check its records for donors who tested positive for hepatitis C since 1992 and trace recipients of blood from these donors.

Time of infection:
Furthermore, CDC is encouraging hepatitis C testing of all individuals with blood coagulation factor deficiencies who were treated with blood products manufactured before 1987.

Financial assistance scheme
The National Hemophilia Foundation (NHF) is not seeking HCV compensation.
HCV-infected individuals who are also HIV-infected and receive the US$ 100,000 payment from the Ricky Ray Trust Fund cannot make further claims as it is stated in the Ricky Ray Act that recipients of the HIV compensation payment automatically renounce any further compensation claim.

Availability of treatment:

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

The costs of interferon therapy and combination therapy with ribavirin are covered by Medicaid. The Medicaid scheme generally covers the costs for all medications that are prescribed.
Until June 1998, alpha-interferon was the only treatment for hepatitis C approved by the FDA. In June 1998, combination therapy with ribavirin was approved by the FDA for those patients who did not respond to interferon alone.

Litigation
Class actions or individual lawsuits have not been filed as regards HCV infection or hepatitis C.

ANNEX: **Availability and cost coverage of treatment**

Country	Available treatment	Cost coverage	Comments
Australia	interferon (+ ribavirin)	Medicare scheme	In Victoria, at first interferon has to be tried alone - only if patients relapse under such monotherapy subsidized combination therapy with ribavirin is available;
Canada	interferon + ribavirin	Provincial / Territorial Drug Plans	Each Provinve and Territory has its own Drug Plan - costs for interferon are covered, combination therapy with ribavirin is not covered for reasons of costs;
Croatia	interferon + ribavirin	social insurance fund	
Estonia	(interferon)	(health insurance)	Interferon is not used in general - if indicated the costs are covered by the health insurance;
France	interferon + ribavirin	health insurance	
Germany	interferon + ribavirin	health insurance	
Ireland	interferon + ribavirin	Public Health Care system	Free of cost under the amended Health Act
Italy	interferon + ribavirin	Sistema Sanitario Nazionale (Public Health Care system)	
Japan	interferon	health insurance & government	
Latvia	interferon - no ribavirin		Infectious disease specialists refused to use interferon because of the risk of bleeding in severe hemophilia - there is no prophylaxis;
Netherlands	interferon ((+ ribavirin))	**no cost coverage**	Combination therapy is restricted to clinical trials and not freely available;
New Zealand	interferon	Dept. of Health	Cost coverage of interferon therapy was achieved only after massive media campaigns;

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany

Country	Available treatment	Cost coverage	Comments
Norway	interferon + ribavirin	health system	Cost coverage only after special application - but none has been denied so far;
Poland	interferon + ribavirin	national health care system	Interferon or combination therapy are provided free of costs;
South Africa	interferon	State or insurance schemes	
Spain	interferon	Social Security scheme	
Sweden	interferon + ribavirin	covered in the same way as any other medication	In HIV infection + concurrent HCV infection treatment is free of costs;
Switzerland	interferon + ribavirin	Health Insurance Fund	Treatment length is limited to 6 months - may be prolonged to 12 months if medically indicated;
Turkey	(interferon)	Social Security scheme - self-payment for those who are not covered by this scheme	Interferon therapy is used for chronic active hepatitis only;
United Kingdom	interferon + ribavirin	Health authorities	Treatment must be clinically indicated - in some cases cost coverage has been denied;
United States	interferon (+ ribavirin)	Medicaid	Combination therapy only if no response to interferon monotherapy;

© 2000 - World Federation of Hemophilia Information Clearinghouse, Munich Germany