

LIV 3  
file hepatitis C

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**COMPENSATION FOR HAEMOPHILIACS WITH HEPATITIS C (HCV)**

**Purpose of Submission**

1. This submission responds to PS(H)'s request, as set out in your minute of 12 January, for a submission on options for compensating haemophiliacs who contracted hepatitis C (HCV) before routine screening of blood products was introduced.

**Summary**

2. This submission:-

- looks at the options for a scheme for compensating haemophiliacs, with particular reference to (a) the existing scheme for compensating haemophiliacs infected with HIV and (b) the scheme introduced in the Irish republic for compensating people who have contracted HCV from blood or blood products;
- considers the possible reaction of the Haemophilia Society to the various options;
- notes that people infected through blood transfusion would have as good cause as haemophiliacs for access to a compensation scheme, and the effect of this on costs;
- warns of possible future claims, as yet unquantifiable, noting that the newly discovered hepatitis G virus (HGV) is ten times as prevalent as HCV;

13/25

## **RESTRICTED - POLICY**

- notes that the money for any scheme would have to be deducted from the money available for patient care.
- draws attention to existing policy on no-fault compensation schemes

3. Because the numbers of people involved are uncertain, as is the progress of the disease, all costings are inevitably broad brush - some more so than others. Whilst they give an idea of orders of magnitude, more work would be required to establish more precisely the amount of expenditure likely to be required overall and in any year.

### **Options**

4. This section of the submission

- looks briefly at the natural history of HCV infection, as this increases the range of options available;
- notes the numbers of haemophiliacs who might be able to claim;
- looks at schemes which would parallel the lump sum aspects of the existing HIV scheme;
- looks at a scheme similar to the continuing payments aspects of the existing HIV scheme;
- looks at a scheme similar to that recently introduced in the Irish republic.

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### The Natural History of HCV

5. The impact of HCV on individuals varies greatly from one to another and over a period of time. Although the full life history of the disease is still unclear, present indications are that:

- i) many people infected with HCV may enjoy a long period without any symptoms appearing;
- ii) a proportion of these (20% approximately) may eliminate the virus from the body completely and no longer be infectious. All others are likely to remain infectious and might transmit the virus through blood or much less easily through other body fluids;
- iii) 50% of sufferers may progress to chronic hepatitis with varying degrees of ill health. This can cause liver damage and mortality;
- iv) perhaps 20% of infected patients will develop cirrhosis, a progressive destruction of the liver, that may take 20 to 30 years;
- v) in addition a small proportion will develop primary liver cancer after a further time;
- vi) certain patient groups may have a worse prognosis and a more rapid disease progression, eg. immuno suppressed patients, those co-infected with HIV and/or hepatitis B, and alcohol abusers.

6. Interferon alpha is the only licensed drug for the treatment of chronic hepatitis C. This may be helpful to some patients but as yet its efficacy seems to be limited to about 20%. It is likely that other drugs and improved treatment regimes will be developed which will improve the management of the disease. But the way ahead is by no means clear at this stage.

### Numbers of Haemophiliacs Infected with HCV

7. There is general agreement that about 3,100 haemophiliacs are infected with HCV alone. A further 1,250 are infected with both HIV and HCV, but this submission assumes that no further compensation would be offered to this group. (MPs have quoted the case of 3 brothers, 2 of whom died of HIV and 1 of HCV and have sought compensation for the last of these, not double compensation for the first two. Except in

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Scotland, haemophiliacs with HIV had to renounce any further legal claims.) On the basis of the natural history of HCV set out above, therefore, over time

3,100 would be entitled (and entitled now) to payment on the basis of infection alone

1,550 will develop chronic hepatitis

620 will develop cirrhosis

By the end of 1993, approximately 28 HIV negative haemophiliacs had died from liver disease as well as 22 who were HIV positive.

### A Scheme Based on the Lump Sum Elements of the HIV Scheme

8. Lump sum payments agreed under the HIV scheme were:-

£20,000 each in 1989 (to haemophiliacs) and in 1992 (to those infected through blood transfusion)

the following additional payments in 1990/1992 (as above)

Single person infected	under 18	£21,500
	over 18	£23,500
Married person infected		£32,000
Married person with children		£60,500
Infected intimate adult spouse/partner		£23,500
Child who is married		£23,500
other child		£21,500

In addition those individuals involved in the HIV haemophilia litigation who were non-infected partners of infected haemophiliacs (but not those in a similar position who were not involved in the litigation) were awarded £2000 each to settle their claims and compensate them for the worry of possible infection.

9. The average payment under the HIV scheme was £60,000. Assuming a similar figure, the costs of HCV compensation would be

£180 million if paid to all infected

£90 million if limited to those with chronic hepatitis

£36 million if limited to those with cirrhosis (the John Marshall model)

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10. These figures exclude  
  
any extension of the scheme to infected spouses or children  
  
administration costs.
11. Under the HIV scheme, payments were made to the estates of people who had died. There would be an expectation that this would happen again. As noted above, not all those who have died have succumbed to liver disease. However, the relatives of those who had died from other causes might well seek to argue that infection with hepatitis C was a contributory factor.
12. It should also be noted that the different stages of disease are difficult to define precisely. Clinicians might be inclined to err on the side of overstating the severity of the disease if that would benefit the patient financially.
13. There are, of course, variants on this option. For example, £20,000 (say) could be paid on evidence of infection with higher sums if chronic disease was confirmed. So (with a further £40,000 payable) the cost would be £124 million.
14. The cost of any scheme would be heavily front loaded if based on infection, but spread over a period of many years if based on chronic disease, since the disease takes so long to develop..
15. A scheme of this kind would be:-
  - simple, but expensive and untargeted if based on infection alone
  - less simple (some would say impossible to operate), but somewhat better targeted, if it took account of the various stages of the disease.

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### A Scheme Based on the Discretionary Elements of the HIV Scheme

16. In addition to the lump sum payments, the Macfarlane Trust (for haemophiliacs) and the Eileen Trust (for people infected through blood transfusion) make payments to those suffering particular hardship. The trustees established scales of support for those in need so that as far as was possible there was equality of treatment to all those who applied. Currently these are as follows:-

#### Haemophiliacs infected with HIV and Widows Infected with HIV

Unconditional, paid on request	£70 a month, plus £500 a year winter payment
Receiving Unemployment Benefit, or certain other benefits	£132 a month
Receiving certain other benefits (e.g. Housing Benefit)	£151-£195 a month
Receiving Income Support	£169-£230 a month

#### Partner infected with HIV

Unconditional	£70 a month plus £500 a year winter payment
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#### Either of Above receiving Higher Rate DLA

Additional payment	£50 a month
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#### Widows and Dependants

Payments to all widows, other than those who are not disabled or incapacitated and have no children	£46-£137 a month
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Single payments are also made, especially to those who are sick and at the time of bereavement. All these payments are additional to any social security benefits to which recipients may be entitled. Those benefits are not abated in any way.

17. The Trusts are funded by occasional lump sum payments from the Department and have used a balance of interest and capital to make those payments. So far £15 million has been paid to the Macfarlane Trust and £500,000 to the Eileen Trust. A submission will be coming to PS(H) shortly proposing a further top up to the Macfarlane Trust.

18. The Macfarlane Trust's expenditure is running at around £2 million a year. Roughly £1.4 million goes on regular payments, £300,000 on winter payments, and £300,000 on single payments (averaging about £500 each).

19. Equity would suggest that payments to people infected with HCV should be on the same basis as payments to people infected with HIV. Payments at these levels would be most unlikely to be acceptable on their own, (many would get £70 a month) and would therefore be additional to any lump sum scheme. The alternative of paying higher rates without a lump sum would lead to levels of payment which would be a strong disincentive for many to seek work.



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20. Costing this idea is particularly difficult, as a detailed knowledge of the age profile and financial circumstances of potential recipients would be needed, along with more knowledge than we have about the likely progress of disease. A rule of thumb would suggest that a scheme for haemophiliacs infected with HCV would cost around £6 million a year, but the true figure is likely to be a bit higher, since the Haemophilia Society's report suggests that people infected with HCV claim to be tired and incapable of work at an earlier stage in their illness than those infected with HIV. A figure of £7 million a year might be a reasonable estimate. Total costs would depend on how long people lived, and how long they received various levels of benefit. People infected with hepatitis C are likely to survive on average considerably longer than those with HIV. An average of 20 years might be assumed, giving a cost (without taking account of inflation, but without discounting) of around £140 million. Assuming similar arrangements to those applied to the funding of the Macfarlane Trust, some of this cost would be met from the interest earned by the Trust, so it would not all fall to the public purse. An alternative approach might be to involve the insurance industry in the administration of a scheme. For example, the state could buy an insurance policy for every infected person that would offer benefits triggered by adverse outcomes as and when they occurred.

21. A scheme of this kind would enable needs to be targeted more precisely, but would have the disadvantages associated with means testing, as well as being expensive to administer. It would have to stay in place for many years, unless off-loaded to the insurance industry.

### A Scheme Based on the Irish scheme

22. Irish Ministers announced on 12 September 1995 a decision to extend the existing compensation scheme for people who have contracted HCV from the use of Anti D to include other individuals who became so infected from blood transfusion or blood products. The scheme is administered by a Tribunal, the members of which are appointed by the Minister for Health. Claimants are not required to provide evidence of negligence on the part of the blood service but that on the balance of probability the HCV in respect of which they have been diagnosed positive resulted from the use of blood or blood products. The awards of the Tribunal will be calculated by reference to the principles which govern the measure of damages in the law of tort. In calculating the award the Tribunal may take account of any statutory or non-statutory benefits to which the claimant had become entitled as a result of the HCV. The Tribunal may make single lump sum awards of compensation or provisional awards.

23. So far there have been no awards as the Tribunal has yet to be established, but there can be little doubt that, once the Irish scheme gets under way, comparisons will be made between what Irish haemophiliacs and others receive and what (if anything) is received by people in a similar position in the UK.

24. In the absence of hard information, it is very difficult to assess what sort of payments might arise under such a scheme. SOL advise that payments would be likely to vary greatly according to individual circumstances - for example, high earners with dependents would receive very substantially greater sums than people who were

## **RESTRICTED - POLICY**

unemployed. Those towards the lower end of the spectrum might receive around £30,000 for infection, or £50,000 for chronic disease. This suggests that paying the same as for HIV on the basis of infection alone would be generous. But the main point to note about this proposal is its unpredictability.

### **Possible Reaction of the Haemophilia Society**

25. It would be essential for any scheme to be acceptable to haemophiliacs generally, both in order to avoid the possibility of future litigation (as with the HIV scheme, people accepting compensation would have to agree to forego their right to seek money through the courts) and to avoid the prospect of Ministers being pressurised to increase their offer (for example, through comparisons being made with damages awarded in the courts for apparently more trivial problems).

26. The Haemophilia Society, inspired by what they see as a softening of the Department's position, are currently considering possible schemes. They are known to be having difficulty in seeking to balance what might be affordable (recognising that Ministers are unlikely to agree an expensive solution) and what would be acceptable to all their members, bearing in mind the risk of internal divisions among their membership. The Manor House Group, for example, are unlikely to be satisfied with anything short of the levels available through the HIV scheme.

27. Preliminary informal indications are that the Society will favour

- an across the board lump sum settlement of around £60,000 in recognition of the fact of infection

plus

- a system of regular payments to reflect need (but not based on diagnostic trigger points)

There have also been vague references to tribunals.

28. If this line is confirmed, it means that the Society will be pressing for the most expensive lump sum option plus ongoing payments. It also suggests that they are thinking about the Irish scheme, as is to be expected.

### **People Infected through Blood Transfusion**

29. PS(H) will have noted that neither the existing HIV scheme in this country, nor the HCV scheme in the Irish Republic is confined to haemophiliacs. In the view of officials, it would be impossible to confine any scheme to haemophiliacs - the pressure to extend it to people infected through blood transfusion would be irresistible. If anything their case is stronger because some were infected after tests were known to exist.

30. An exercise is currently under way to trace people who were infected with HCV through blood transfusion and who are still alive. This is expected to identify about



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3,000 people. At the very least, therefore, we should allow double the costs quoted above, i.e.:-

for payment on infection (the apparent preference of the Haemophilia Society)	£360 million
for payment for chronic hepatitis	£180 million
for payment for cirrhosis	£72 million
for a mixed scheme	£248 million
for an Irish type scheme	unpredictable - but at least as much as a mixed scheme
for a discretionary scheme (additional cost)	£280 million, but not all from the public purse

31. Besides the cost, administering a scheme for people infected through blood transfusion would be far more difficult than for haemophiliacs since:-

- it could not be assumed that blood transfusion was the source of infection (with haemophiliacs it would be reasonable to assume that blood products were the source)
- the scope for fraudulent claims would be far greater
- substantial issues would arise over how to treat deceased patients (half the people who receive blood die within a year; many of those traced by the lookback exercise are dead, and, in most cases, it will not be known whether they were infected with HCV, let alone whether this had any effect on the outcome).
- any discretionary scheme which paid out to those infected, whether or not they became ill would last for many decades since some babies will have been infected.

### Unquantifiable Future Claims

32. The opening of the door to future claims for no-fault compensation has previously been a matter of great concern to Ministers. There are a number of aspects to this.

33. First, HCV can be transmitted not only through blood and blood products but through any transplanted tissue.

34. Second, other viruses and infectious agents can be transmitted by blood or tissue. A new strain of hepatitis virus (HGV) has just been identified. It is far more prevalent than HCV; there is as yet no simple test for it; and, whilst its natural history is obscure, it has been shown to cause cirrhosis in some cases (the proportion is not yet known). Whilst it is very unlikely that there are haemophiliacs who have been infected with HGV but not with HCV, there could be as many as 10 times as many people infected with HGV through blood transfusion as have been infected with HCV through this route (i.e. in excess of 30,000 rather than in excess of 3,000) and infection is continuing as there is

## RESTRICTED - POLICY

currently no test to prevent this.

35. Third, potentially, the whole question of compensation for medical accidents is opened up. Haemophiliacs received the best possible treatment - treatment which prolonged their life. If they are to be compensated, who else should be? People who have been harmed by radiotherapy treatment? The patient who suffers from complications of surgery or anaesthesia carried out to a good standard? No treatment is entirely free of risk. Any moves to offer no fault compensation to haemophiliacs with HCV can be relied upon to stimulate further pressure from groups such as RAGE (Radiotherapy Action Group Exposure) amongst others for wider provision of no fault compensation.

36. More specifically, PS(H) will be aware that litigation is being taken against the Department and the Medical Research Counsel in respect of patients treated with human growth hormone (hGH). In this case, we are awaiting advice from lawyers on the question of negligence. When considering a possible compensation scheme for Haemophiliacs, it would seem inevitable that similar arrangements may need to be concluded for hGH patients. Some 2,000 patients were treated with growth hormone, 16 have died of CJD already and, on past experience, it is possibly that another 33 patients may yet contract the disease.

### Finance

37. The Treasury will not make additional money available to the Department. Any costs will therefore have to come from the resources already available for patient care.

38. The question of who should pay for people infected in Scotland, Wales and Northern Ireland would need further consideration. This Department bore and continues to bear the full cost of the original HIV scheme (apart from the initial £20,000 ex gratia payments which were paid for by the Treasury).

### Policy on No-Fault Compensation Schemes

39. Ministers regularly restate their broad opposition to no fault compensation. Secretary of State did so in evidence to the Health Committee last summer. PS(H)'s predecessor did so in response to adjournment debates on compensation for people harmed by radiotherapy treatment for cancers of the cervix and breast on 21 and 22 November 1995 respectively.

40. The most telling arguments put forward on those occasions were:

**Compensation in other spheres.** Proponents of no fault compensation have yet to explain why the system of compensation for victims of medical accidents should differ from the one for people harmed in any other way.

**Feelings of Victims of Negligence.** Victims rightly feel that the compensation system should address the additional issues raised by harm which but for the negligence of the clinician(s) involved would have been avoided. Many plaintiffs

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argue that what they want are an apology, an explanation and reassurance that what happened to them will not subsequently happen to somebody else. Failure to resist demands for no fault compensation could result in a system which deflects attention from plaintiffs most important concerns.

41. The Government's other principal reasons for opposing no fault compensation for cases involving the NHS are:

**Proof of causation and establishing quantum.** It could be just as difficult to establish that medical treatment had caused injury as it would be to prove that someone had been negligent. The level of quantum would still have to be established. Legal action would not necessarily be avoided. The process could still be lengthy.

**Unfairness.** Those disabled as a result of a medical accident would be compensated, whereas those disabled as a result of disease would not be.

**Cost.** Costs falling on the NHS could increase substantially. One independent estimate suggests that a no fault scheme could cost the NHS between £235m and £350m a year compared to the 1990/91 cost of negligence claims of around £60m. Even allowing for increases in the cost of negligence since then, this would inevitably reduce the amount available for direct patient care.

**Accountability.** The tort system holds all individuals accountable for their actions and arguably has a deterrent effect on malpractice. No fault compensation could remove an incentive to good practice and make some health care professionals less careful.

**Amounts payable.** In those countries which have no fault compensation schemes, the amounts payable are very small in comparison to payments for negligence.

42. In short, any compensation for HCV positive haemophiliacs would be a departure from the policy previously stated by the Secretary of State that payments should not be made when treatment given has been in accordance with the best knowledge and practice of the day.

43. PS(H) may like to know that these, and the issues surrounding compensation to haemophiliacs (apart from the Irish scheme which came later) were the subject of a lengthy submission from my predecessor in April last year. That was followed by a minute from the Permanent Secretary and a meeting with M(H). I would be happy to send the papers to PS(H) should he wish to see them.

### Clearance

44. This submission has been cleared with the Permanent Secretary, with Finance colleagues and with the other Health Departments.

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### Conclusions

45. ● A scheme, which would be contrary to general Government policy on no-fault compensation, could not be confined to haemophiliacs.
- The options considered here for compensation for infection with hepatitis C would cost in the order of £72 million to £360 million, with regular payments costing perhaps an additional £280 million over the years (though not all this latter cost would come from the public purse).
- Early indications are that only the most expensive scheme would be acceptable to the Haemophilia Society, but we shall know more when their own proposals are received.
- A scheme based on infection alone would be heavily front loaded.
- There would be incalculable repercussions for the future. The newly discovered hepatitis G virus alone could multiply the cost of compensating people infected through blood transfusion by 10 (giving a range of £400 million to £2,000 million for the lump sum options).
- The costs of this and future schemes would reduce the amount of money available for patient care.

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