RESTRICTED - POLICY

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From: **Mr Guinness CA OPU1-2**
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COMPENSATION FOR HAEMOPHILIACS WITH HEPATITIS C (HCV)

Introduction

1. Your minute of 28 February asked me to explore further the financial implications of John Marshall MP's suggestion that payments should be made, but restricted to people who develop cirrhosis. It quoted figures relating only to haemophiliacs but previous experience indicates that it would be impossible to hold the line there and this note therefore considers also the case of people infected through blood transfusion. PS(H) will recall that informal soundings suggest that Mr Marshall's proposal would be unlikely to be acceptable to the Haemophilia Society - any scheme has, of course, to be generally acceptable in order to be viable.

2. In order to be precise, we would need to know:-

- the amount of any payment (this note assumes £60,000 - the average payment under the HIV scheme - and takes no account of past or future inflation)
- the number of people who will be diagnosed as having developed cirrhosis
- when they were infected
- how long it will take each of them to develop cirrhosis
- how many have got cirrhosis now
- the number of people who were infected, developed cirrhosis, and have died

(whether from liver disease or not)

- how any scheme would be funded and administered (since the first affects the spread of the funding and the total cost - e.g. a Trust fund would require an up front payment but allow interest to be earned - and the second affects the administrative costs. As Mr Marshall's approach is based on spreading the cost, this note assumes that payments will be spread. Administrative costs are considered further below.)

3. Needless to say, much of this information is not available, but we can make a reasonable stab at producing an expenditure profile.

Haemophiliacs

4. We do have some information about haemophiliacs. We know how many there are, how many are severe, moderate or mild, and their age profile. We also have some information about deaths from liver disease from 1985 onwards. We also know that no haemophiliacs have been infected since 1985.

5. We have assumed that all severe haemophiliacs old enough to have been treated before 1985 will be HCV positive, as well as proportions (but we have to guess what proportions) of moderate and mild haemophiliacs. My earlier submission suggested that, of those not infected with HIV, some 1,550 haemophiliacs will develop chronic hepatitis, of whom 620 will develop cirrhosis. We have assumed that cirrhosis takes 20 years to develop. Obviously, in reality the length of time between infection and the development of cirrhosis is variable, but not enough is known about the disease to make more sophisticated estimates worthwhile. Given that it is 10 years or so since the last haemophiliac was infected, we have assumed that half of the 620 have already got cirrhosis, and that one tenth of the remainder will develop it for each of the next ten years. To those already eligible we have added 34 known to have died from liver disease (and not also HIV positive) between 1985 and 1994, plus a few who have died of liver cancer.

Blood Transfusion Recipients

6. We have had to make rather more heroic assumptions about blood transfusion recipients. We know that HCV got into the blood supply in the 1960s, and that its prevalence amongst donors increased (with a few blips, for example when certain categories of donors were excluded) until 1991 when testing of donations was introduced. Because there is a gap between infection and the test being able to detect the infection, some people continue to be infected, and a few - probably less than 5 a year - will go on to develop cirrhosis.

7. The number of transfusion recipients ever infected with hepatitis C in the UK is unknown. Estimates of the numbers who have been infected and lived long enough to develop cirrhosis vary by a factor of ten. On the basis of the figures we have for the incidence of hepatitis C in blood donors in 1991 when screening was first introduced in the UK and the current incidence in established and new donors, and some information

provided by St Mary's Hospital in London, we would suggest that an estimate of 40,000 blood transfusion recipients ever infected might be reasonable. This figure is around the middle of the range. (The figure may be compared with the 3,000 still alive we expect to trace through the lookback exercise, who have received blood from donors who were found after 1991 to have HCV infection.)

8. We know surprisingly little about recipients of blood, but about half die within a year of transfusion, and many others are elderly and will not live long enough to develop cirrhosis if it takes 20 years to develop. If we assume that 10% of the 40,000 live for 20 years after receiving blood, and that 20% of those develop cirrhosis that gives us 800 people with cirrhosis infected over about 25 years from the mid-sixties to 1991. Assuming (probably incorrectly in view of the varying prevalence of HCV infection in the donor population) that an equal number were infected each year, and again that cirrhosis takes precisely 20 years to develop, 10/25 will have developed cirrhosis already (of whom some will have died of it) and the remainder will develop it evenly each year until 2011. As I have already pointed out, there will be continuing small numbers indefinitely.

Diagnosis of Cirrhosis

9. A certain diagnosis of cirrhosis can only be made following a liver biopsy. Even then, a negative biopsy does not exclude cirrhosis since only part of the liver may be affected. It would not be justifiable to require people to undergo a biopsy in order to provide the evidence to claim a payment (though some will, of course, have had a biopsy for clinical reasons). It would be particularly unjustifiable in the case of haemophiliacs because of the risk of bleeding.

10. That leaves us with a dilemma. Terminal liver failure can be diagnosed without a biopsy, but by this stage patients probably have no more than 1 year to 18 months to live, and some will die within 2-3 months. In short, any compensation would be too late for the patients to enjoy, and some will die before it is awarded. Going down this route would postpone payments, compared with a scheme based on cirrhosis.

11. The alternative would be to pay on the basis of chronic liver disease. But this would apply to 50% rather than 20% of those infected (thus more than doubling the total cost) and, bearing in mind that it is 10 years since the last haemophiliac was infected and 5 years since there were any significant numbers of blood transfusion recipients infected, and that chronic disease develops far more quickly than cirrhosis, many more people would qualify now, compared with a scheme based on cirrhosis. In short, the aim of Mr Marshall's plan - to spread payments over a number of years - would largely <u>not</u> be achieved.

Administrative Arrangements

12. It would be reasonable to assume that any haemophiliacs who received blood products before 1985 and who were HCV positive had acquired their infection from blood products. It would have to be assumed that the development of cirrhosis was as a result of hepatitis C infection, although in some cases other causes such as alcoholism might be responsible. This would keep administrative costs down, though it would still be

necessary to establish that the claimant really had cirrhosis. As noted above, leaving aside attempts to obtain money by deception, the diagnosis of cirrhosis in the absence of biopsy evidence is difficult. Since the disease develops gradually, if payment of compensation depended on a diagnosis of cirrhosis, doctors might be inclined to err on the side of generosity. There would therefore need to be provision for independent medical assessment of the evidence, as well as the costs of processing claims.

13. Dealing with claims from people who believed they had been infected through blood transfusion would be considerably more complicated, since, as well as weeding out fraudulent claims (of which there would be more since the whole population could potentially "try it on" rather than just haemophiliacs), the cause of the cirrhosis and, if that was HCV infection, the likely source of infection would have to be identified, which could be difficult for people (or the dependents of the deceased) claiming infection from a donor who had not given blood after 1991.

14. In order to avoid the risk of legal challenge to the whole scheme, provision would need to be made for appeals. Under the scheme for compensating people infected with HIV through blood transfusion there is a panel to which dissatisfied claimants can apply. A scheme based on diagnosis of cirrhosis could lead to rather more dissatisfied customers. Even with an appeal mechanism, recourse to judicial review in some cases could not be ruled out.

Results

15. Putting all this together, and mindful of all the uncertainties, our best estimate, excluding administrative costs, for a scheme based on cirrhosis, is as follows:-

	Haemophiliacs £ million	Blood Transfusion Recipients £ million	Total £ million
Payable now	21	20	41
Payable each year until 2005	2	2	4
Payable each year from 2006 to 2011	0	2	2
Payable each year from 2012 onwards	0	*	*

* = less than £1 million.

A rough guess at administrative costs suggests costs of around £300,000 in dealing with the initial surge of claims, which would certainly require additional staff, £30,000 a year until 2005, and £20,000 a year from 2006 to 2011.

Hepatitis G

16. This note has looked only at hepatitis C. Hepatitis G (HGV) has just been identified. It is far more prevalent than hepatitis C and, though its natural history is obscure, it has been shown to cause cirrhosis in some cases.

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